

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

AB-2008-5

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<i>Argentina – Textiles and Apparel</i>	Appellate Body Report, <i>Argentina – Measures Affecting Imports of Footwear, Textiles, Apparel and Other Items</i> , WT/DS56/AB/R and Corr.1, adopted 22 April 1998, DSR 1998:III, 1003
<i>Australia – Salmon</i>	Appellate Body Report, <i>Australia – Measures Affecting Importation of Salmon</i> , WT/DS18/AB/R, adopted 6 November 1998, DSR 1998:VIII, 3327
<i>Brazil – Desiccated Coconut</i>	Appellate Body Report, <i>Brazil – Measures Affecting Desiccated Coconut</i> , WT/DS22/AB/R, adopted 20 March 1997, DSR 1997:I, 167
<i>Brazil – Retreaded Tyres</i>	Appellate Body Report, <i>Brazil – Measures Affecting Imports of Retreaded Tyres</i> , WT/DS332/AB/R, adopted 17 December 2007
<i>Canada – Aircraft</i>	Appellate Body Report, <i>Canada – Measures Affecting the Export of Civilian Aircraft</i> , WT/DS70/AB/R, adopted 20 August 1999, DSR 1999:III, 1377
<i>Canada – Aircraft (Article 21.5 – Brazil)</i>	Appellate Body Report, <i>Canada – Measures Affecting the Export of Civilian Aircraft – Recourse by Brazil to Article 21.5 of the DSU</i> , WT/DS70/AB/RW, adopted 4 August 2000, DSR 2000:IX, 4299
<i>Canada – Continued Suspension</i>	Panel Report, <i>Canada – Continued Suspension of Obligations in the EC – Hormones Dispute</i> , WT/DS321/R, circulated to WTO Members 31 March 2008
<i>Canada – Wheat Exports and Grain Imports</i>	Appellate Body Report, <i>Canada – Measures Relating to Exports of Wheat and Treatment of Imported Grain</i> , WT/DS276/AB/R, adopted 27 September 2004, DSR 2004:VI, 2739
<i>Chile – Price Band System (Article 21.5 – Argentina)</i>	Appellate Body Report, <i>Chile – Price Band System and Safeguard Measures Relating to Certain Agricultural Products – Recourse to Article 21.5 of the DSU by Argentina</i> , WT/DS207/AB/RW, adopted 22 May 2007
<i>EC – Approval and Marketing of Biotech Products</i>	Panel Report, <i>European Communities – Measures Affecting the Approval and Marketing of Biotech Products</i> , WT/DS291/R, WT/DS292/R, WT/DS293/R, Corr.1, and Add.1 to Add.9, adopted 21 November 2006, DSR 2006:III, 847
<i>EC – Asbestos</i>	Appellate Body Report, <i>European Communities – Measures Affecting Asbestos and Asbestos-Containing Products</i> , WT/DS135/AB/R, adopted 5 April 2001, DSR 2001:VII, 3243
<i>EC – Commercial Vessels</i>	Panel Report, <i>European Communities – Measures Affecting Trade in Commercial Vessels</i> , WT/DS301/R, adopted 20 June 2005, DSR 2005:XV, 7713
<i>EC – Hormones</i>	Appellate Body Report, <i>EC Measures Concerning Meat and Meat Products (Hormones)</i> , WT/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998, DSR 1998:I, 135

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<i>EC – Hormones</i>	Award of the Arbitrator, <i>EC Measures Concerning Meat and Meat Products (Hormones) – Arbitration under Article 21.3(c) of the DSU</i> , WT/DS26/15, WT/DS48/13, 29 May 1998, DSR 1998:V, 1833
<i>EC – Hormones (Canada)</i>	Panel Report, <i>EC Measures Concerning Meat and Meat Products (Hormones), Complaint by Canada</i> , WT/DS48/R/CAN, adopted 13 February 1998, as modified by Appellate Body Report, WT/DS26/AB/R, WT/DS48/AB/R, DSR 1998:II, 235
<i>EC – Hormones (Canada) (Article 22.6 – EC)</i>	Decision by the Arbitrators, <i>European Communities – Measures Concerning Meat and Meat Products (Hormones), Original Complaint by Canada – Recourse to Arbitration by the European Communities under Article 22.6 of the DSU</i> , WT/DS48/ARB, 12 July 1999, DSR 1999:III, 1135
<i>EC – Hormones (US)</i>	Panel Report, <i>EC Measures Concerning Meat and Meat Products (Hormones), Complaint by the United States</i> , WT/DS26/R/USA, adopted 13 February 1998, as modified by Appellate Body Report, WT/DS26/AB/R, WT/DS48/AB/R, DSR 1998:III, 699
<i>EC – Hormones (US) (Article 22.6 – EC)</i>	Decision by the Arbitrators, <i>European Communities – Measures Concerning Meat and Meat Products (Hormones), Original Complaint by the United States – Recourse to Arbitration by the European Communities under Article 22.6 of the DSU</i> , WT/DS26/ARB, 12 July 1999, DSR 1999:III, 1105
<i>EC – Sardines</i>	Panel Report, <i>European Communities – Trade Description of Sardines</i> , WT/DS231/R and Corr.1, adopted 23 October 2002, as modified by Appellate Body Report, WT/DS231/AB/R, DSR 2002:VIII, 3451
<i>India – Patents (US)</i>	Appellate Body Report, <i>India – Patent Protection for Pharmaceutical and Agricultural Chemical Products</i> , WT/DS50/AB/R, adopted 16 January 1998, DSR 1998:I, 9
<i>Japan – Agricultural Products II</i>	Appellate Body Report, <i>Japan – Measures Affecting Agricultural Products</i> , WT/DS76/AB/R, adopted 19 March 1999, DSR 1999:I, 277
<i>Japan – Apples</i>	Appellate Body Report, <i>Japan Measures Affecting the Importation of Apples</i> , WT/DS245/AB/R, adopted 10 December 2003, DSR 2003:IX, 4391
<i>Japan – Apples</i>	Panel Report, <i>Japan – Measures Affecting the Importation of Apples</i> , WT/DS245/R, adopted 10 December 2003, upheld by Appellate Body Report, WT/DS245/AB/R, DSR 2003:IX, 4481
<i>Mexico – Corn Syrup (Article 21.5 – US)</i>	Appellate Body Report, <i>Mexico – Anti-Dumping Investigation of High Fructose Corn Syrup (HFCS) from the United States – Recourse to Article 21.5 of the DSU by the United States</i> , WT/DS132/AB/RW, adopted 21 November 2001, DSR 2001:XIII, 6675
<i>Thailand – H-Beams</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, DSR 2001:VII, 2701
<i>US – 1916 Act</i>	Appellate Body Report, <i>United States – Anti-Dumping Act of 1916</i> , WT/DS136/AB/R, WT/DS162/AB/R, adopted 26 September 2000, DSR 2000:X, 4793

Short Title	Full Case Title and Citation
<i>US – Carbon Steel</i>	Appellate Body Report, <i>United States – Countervailing Duties on Certain Corrosion-Resistant Carbon Steel Flat Products from Germany</i> , WT/DS213/AB/R and Corr.1, adopted 19 December 2002, DSR 2002:IX, 3779
<i>US – Certain EC Products</i>	Panel Report, <i>United States – Import Measures on Certain Products from the European Communities</i> , WT/DS165/R and Add.1, adopted 10 January 2001, as modified by Appellate Body Report, WT/DS165/AB/R, DSR 2001:II, 413
<i>US – Continued Suspension</i>	Panel Report, <i>United States – Continued Suspension of Obligations in the EC – Hormones Dispute</i> , WT/DS320/R, circulated to WTO Members 31 March 2008
<i>US – FSC</i>	Panel Report, <i>United States – Tax Treatment for "Foreign Sales Corporations"</i> , WT/DS108/R, adopted 20 March 2000, as modified by Appellate Body Report, WT/DS108/AB/R, DSR 2000:IV, 1675
<i>US – FSC (Article 21.5 – EC)</i>	Appellate Body Report, <i>United States – Tax Treatment for "Foreign Sales Corporations" – Recourse to Article 21.5 of the DSU by the European Communities</i> , WT/DS108/AB/RW, adopted 29 January 2002, DSR 2002:I, 55
<i>US – Gambling</i>	Appellate Body Report, <i>United States – Measures Affecting the Cross-Border Supply of Gambling and Betting Services</i> , WT/DS285/AB/R, adopted 20 April 2005, DSR 2005:XII, 5663, and Corr.1
<i>US – Offset Act (Byrd Amendment)</i>	Appellate Body Report, <i>United States – Continued Dumping and Subsidy Offset Act of 2000</i> , WT/DS217/AB/R, WT/DS234/AB/R, adopted 27 January 2003, DSR 2003:I, 375
<i>US – Offset Act (Byrd Amendment)</i>	Panel Report, <i>United States – Continued Dumping and Subsidy Offset Act of 2000</i> , WT/DS217/R, WT/DS234/R, adopted 27 January 2003, as modified by Appellate Body Report, WT/DS217/AB/R, WT/DS234/AB/R, DSR 2003:II, 489
<i>US – Section 211 Appropriations Act</i>	Appellate Body Report, <i>United States – Section 211 Omnibus Appropriations Act of 1998</i> , WT/DS176/AB/R, adopted 1 February 2002, DSR 2002:II, 589
<i>US – Section 301 Trade Act</i>	Panel Report, <i>United States – Sections 301-310 of the Trade Act of 1974</i> , WT/DS152/R, adopted 27 January 2000, DSR 2000:II, 815
<i>US – Shrimp</i>	Appellate Body Report, <i>United States – Import Prohibition of Certain Shrimp and Shrimp Products</i> , WT/DS58/AB/R, adopted 6 November 1998, DSR 1998:VII, 2755
<i>US – Shrimp (Article 21.5 – Malaysia)</i>	Appellate Body Report, <i>United States – Import Prohibition of Certain Shrimp and Shrimp Products – Recourse to Article 21.5 of the DSU by Malaysia</i> , WT/DS58/AB/RW, adopted 21 November 2001, DSR 2001:XIII, 6481
<i>US – Softwood Lumber IV (Article 21.5 – Canada)</i>	Appellate Body Report, <i>United States – Final Countervailing Duty Determination with Respect to Certain Softwood Lumber from Canada – Recourse by Canada to Article 21.5 of the DSU</i> , WT/DS257/AB/RW, adopted 20 December 2005, DSR 2005:XXIII, 11357

Short Title	Full Case Title and Citation
<i>US – Softwood Lumber VI (Article 21.5 – Canada)</i>	Appellate Body Report, <i>United States – Investigation of the International Trade Commission in Softwood Lumber from Canada – Recourse to Article 21.5 of the DSU by Canada</i> , WT/DS277/AB/RW, adopted 9 May 2006, and Corr.1
<i>US – Underwear</i>	Panel Report, <i>United States – Restrictions on Imports of Cotton and Man-made Fibre Underwear</i> , WT/DS24/R, adopted 25 February 1997, as modified by Appellate Body Report, WT/DS24/AB/R, DSR 1997:I, 31
<i>US – Upland Cotton (Article 21.5 – Brazil)</i>	Appellate Body Report, <i>United States – Subsidies on Upland Cotton – Recourse to Article 21.5 of the DSU by Brazil</i> , WT/DS267/AB/RW, adopted 20 June 2008
<i>US – Wool Shirts and Blouses</i>	Appellate Body Report, <i>United States – Measure Affecting Imports of Woven Wool Shirts and Blouses from India</i> , WT/DS33/AB/R, adopted 23 May 1997, and Corr.1, DSR 1997:I, 323

LIST OF ABBREVIATIONS USED IN THIS REPORT

Abbreviation	Description
1999 Opinion	"Opinion of the SCVPH – Assessment of Potential Risks to Human Health from Hormone Residues in Bovine Meat and Meat Products" (30 April 1999) (Exhibits US-4 and CDA-2 submitted by the United States and Canada, respectively, to the Panel)
2000 Opinion	"Review of Specific Documents relating to the SCVPH Opinion of 30 April 99 on the Potential Risks to Human Health from Hormone Residues in Bovine Meat and Meat Products" (adopted on 3 May 2000) (Exhibits US-17 and CDA-4 submitted by the United States and Canada, respectively, to the Panel)
2002 Opinion	"Opinion of the SCVPH on Review of Previous SCVPH Opinions of 30 April 1999 and 3 May 2000 on the Potential Risks to Human Health from Hormone Residues in Bovine Meat and Meat Products" (adopted on 10 April 2002) (Exhibits US-1 and CDA-17 submitted by the United States and Canada, respectively, to the Panel)
ADI	Acceptable daily intake
Codex	Codex Alimentarius Commission
CVMP	Committee on Veterinary Medicinal Products of the European Union (a subcommittee of the European Medicines Agency (EMA))
DSB	Dispute Settlement Body
DSU	<i>Understanding on Rules and Procedures Governing the Settlement of Disputes</i>
FAO	Food and Agriculture Organization of the United Nations
FDA	Food and Drug Administration of the United States
GATT 1994	<i>General Agreement on Tariffs and Trade 1994</i>
IARC	International Agency for Research on Cancer
JECFA	Joint FAO/WHO Expert Committee on Food Additives
MGA	Melengestrol acetate
MRLs	Maximum residue limits
Panel Report, <i>Canada – Continued Suspension</i>	Panel Report, <i>Canada – Continued Suspension of Obligations in the EC – Hormones Dispute</i> , WT/DS321/R
Panel Report, <i>US – Continued Suspension</i>	Panel Report, <i>United States – Continued Suspension of Obligations in the EC – Hormones Dispute</i> , WT/DS320/R
<i>Rules of Conduct</i>	<i>Rules of Conduct for the Understanding on Rules and Procedures Governing the Settlement of Disputes</i> , WT/DSB/RC/1, adopted 3 December 1996
SCVPH	Scientific Committee on Veterinary Measures relating to Public Health of the European Commission
<i>SPS Agreement</i>	<i>Agreement on the Application of Sanitary and Phytosanitary Measures</i>
<i>TBT Agreement</i>	<i>Agreement on Technical Barriers to Trade</i>

Abbreviation	Description
<i>Vienna Convention</i>	<i>Vienna Convention on the Law of Treaties</i> , done at Vienna, 23 May 1969, 1155 UNTS 331; 8 International Legal Materials 679
WHO	World Health Organization of the United Nations
<i>WTO Agreement</i>	<i>Marrakesh Agreement Establishing the World Trade Organization</i>

WORLD TRADE ORGANIZATION
APPELLATE BODY

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

AB-2008-5

European Communities, *Appellant/Appellee*
United States, *Other Appellant/Appellee*
Canada, *Other Appellant/Appellee*

Present:

Australia, *Third Participant*
Brazil, *Third Participant*
China, *Third Participant*
India, *Third Participant*
Mexico, *Third Participant*
New Zealand, *Third Participant*
Norway, *Third Participant*
Separate Customs Territory of Taiwan, Penghu,
Kinmen and Matsu, *Third Participant*

Unterhalter, Presiding Member
Abi-Saab, Member
Bautista, Member

I. Introduction

1. The European Communities, the United States, and Canada each appeals certain issues of law and legal interpretations developed in the Panel Report, *United States – Continued Suspension of Obligations in the EC – Hormones Dispute*¹ (the "Panel Report, *US – Continued Suspension*"), and the Panel Report, *Canada – Continued Suspension of Obligations in the EC – Hormones Dispute*² (the "Panel Report, *Canada – Continued Suspension*").³ The Panels were established to consider complaints by the European Communities concerning the suspension of concessions or other obligations by the United States and by Canada against the European Communities because of the latter's alleged failure to comply with the recommendations and rulings of the Dispute Settlement Body (the "DSB") stemming from the *EC – Hormones* dispute.⁴ The European Communities asserts that the United States and Canada must cease the suspension of concessions because the European

¹WT/DS320/R, 21 March 2008.

²WT/DS321/R, 21 March 2008.

³In this Report, we refer to the United States first and then to Canada, in keeping with the chronology of the WT/DS numbers assigned to these disputes.

⁴The recommendations and rulings of the DSB resulted from the adoption on 13 February 1998, by the DSB, of the Appellate Body Report, WT/DS26/AB/R, WT/DS48/AB/R; the Panel Report, WT/DS26/R/USA; and the Panel Report, WT/DS48/R/CAN.

Communities adopted Directive 2003/74/EC⁵ and notified it to the DSB as a measure taken to comply with the DSB's recommendations and rulings in *EC – Hormones*.⁶

2. Before the panels in *EC – Hormones*⁷, the United States and Canada claimed that the ban imposed by the European Communities on meat from cattle treated with six hormones—oestradiol-17 β , progesterone, testosterone, trenbolone acetate, zeranol, and melengestrol acetate ("MGA")—was inconsistent with the *Agreement on the Application of Sanitary and Phytosanitary Measures* (the "*SPS Agreement*"), in particular, Articles 2, 3, and 5 thereof, the *Agreement on Technical Barriers to Trade* (the "*TBT Agreement*"), and the *General Agreement on Tariffs and Trade 1994* (the "GATT 1994").

3. The panel in *EC – Hormones* held that:

- by maintaining sanitary measures that are not based on a risk assessment, the European Communities had acted inconsistently with Article 5.1 of the *SPS Agreement*;
- by adopting arbitrary or unjustifiable distinctions in the levels of sanitary protection it considered appropriate in different situations which result in discrimination or a disguised restriction on international trade, the European Communities had acted inconsistently with Article 5.5 of the *SPS Agreement*; and
- by maintaining sanitary measures that are not based on existing international standards without justification under Article 3.3 of the *SPS Agreement*, the European Communities had acted inconsistently with Article 3.1 of that Agreement.⁸

4. The European Communities appealed the panel's findings under Articles 3.1, 3.3, 5.1, and 5.5 of the *SPS Agreement*. In addition, the European Communities claimed that the panels had erred in the selection and use of scientific experts, in allocating the burden of proof, and in applying the standard of review. The United States and Canada appealed the panel's decision not to make findings relating to Articles 2.2 and 5.6 of the *SPS Agreement*.

⁵Directive 2003/74/EC of the European Parliament and of the Council of 22 September 2003 amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists, *Official Journal of the European Union*, L Series, No. 262 (14 October 2003) 17 (Exhibits EC-1 and US-3 submitted by the European Communities and the United States, respectively, to the Panel).

⁶Panel Report, *US – Continued Suspension*, para. 1.1; Panel Report, *Canada – Continued Suspension*, para. 1.1.

⁷As the same individuals served on both panels, in this Report we will henceforth refer to the panels in the singular.

⁸Panel Report, *EC – Hormones (US)*, para. 9.1; Panel Report, *EC – Hormones (Canada)*, para. 9.1.

5. The Appellate Body upheld, albeit on the basis of modified reasoning, the panel's findings that the European Communities' import ban on meat and meat products treated with the six hormones at issue was inconsistent with Article 5.1 of the *SPS Agreement*, and, as a consequence, was also inconsistent with Article 3.3 of that Agreement. The Appellate Body found that the scientific studies submitted by the European Communities in that dispute were not "sufficiently specific to the case at hand"⁹, because they were "general studies which do indeed show the existence of a general risk of cancer; but they do not focus on and do not address the particular kind of risk here at stake".¹⁰ For this reason, the Appellate Body concluded that "no risk assessment that reasonably support[ed] or warrant[ed] the import prohibition embodied in the [European Communities'] Directives was furnished to the Panel"¹¹, and accordingly found that the European Communities' import ban, imposed under Directive 96/22/EC, was not "based on" a risk assessment within the meaning of Article 5.1. Moreover, the Appellate Body disagreed with the panel's interpretation of the relationship between Articles 3.1 and 3.3 of the *SPS Agreement*. The panel interpreted Article 3.3 to be an exception to the "general obligation" of Article 3.1, and found that the European Communities had not acted consistently with Article 3.1 and had not provided appropriate scientific justification for a higher level of SPS protection under Article 3.3. The Appellate Body concluded, however, that the right of Members to establish a higher level of sanitary protection under Article 3.3 is an autonomous right and not an exception to a "general obligation" under Article 3.1. Accordingly, the Appellate Body reversed the panel's conclusion that the import prohibition was inconsistent with Article 3.1. Nevertheless, as the Appellate Body found that the European Communities' import prohibition was inconsistent with Article 5.1, it also concluded that the import prohibition was inconsistent with Article 3.3. The Appellate Body, however, modified the panel's interpretation of "risk assessment" by holding that there was no requirement "to establish a minimum quantifiable magnitude of risk", and that the factors "not susceptible of quantitative analysis by the empirical or experimental laboratory methods commonly associated with the physical sciences" were not excluded from the scope of a risk assessment.¹² The Appellate Body also reversed the panel's findings that the European Communities had acted inconsistently with Article 5.5 of the *SPS Agreement*, which requires that a WTO Member avoid arbitrary or unjustifiable distinctions in the levels of sanitary protection that result in discrimination or a disguised restriction on international trade. Furthermore, the Appellate Body agreed with the panel that the precautionary principle would not override Articles 5.1 and 5.2 and that it had been incorporated in, *inter alia*, Article 5.7 of the *SPS Agreement*. With regard to the selection and use of experts by the panel, the Appellate Body concluded that the panel had acted consistently with the

⁹Appellate Body Report, *EC – Hormones*, para. 200.

¹⁰*Ibid.*

¹¹*Ibid.*, para. 208.

¹²*Ibid.*, para. 253(j).

requirements of the *Understanding on Rules and Procedures Governing the Settlement of Disputes* (the "DSU") and the *SPS Agreement*. The Appellate Body rejected the European Communities' claim that the panel had erred in the standard applied to the review of the evidence and thus found that the panel had complied with its obligation under Article 11 of the DSU. Finally, the Appellate Body concluded that the panel's exercise of judicial economy was proper in not making findings under Articles 2.2 and 5.6 of the *SPS Agreement*.

6. On 13 February 1998, the DSB adopted the panel and Appellate Body Reports in *EC – Hormones* and recommended that the European Communities bring its measures into conformity with the *SPS Agreement*. Following the adoption of the panel and Appellate Body reports by the DSB, the European Communities requested that the reasonable period of time for implementation be determined through arbitration in accordance with Article 21.3(c) of the DSU. The Arbitrator determined a reasonable period of time of 15 months, expiring on 13 May 1999.¹³

7. On 12 May 1999, the European Communities addressed a communication to the Chairman of the DSB, which stated:

[T]he Community has undertaken a complementary risk assessment in light of the relevant clarifications on risk assessment provided by the Appellate Body.

In light of such results of that risk assessment as are now available to it, the Community is not in a position to lift its existing import ban on 13 May.

The Community now intends to study in more depth these results in order to evaluate on this basis and in the light of any new relevant information what steps may be necessary in light of our WTO rights and obligations.¹⁴

8. As a result, the United States and Canada requested the DSB to authorize suspension of concessions and other obligations pursuant to Article 22.2 of the DSU. The European Communities objected to the levels of suspension of concessions proposed by the United States and Canada, and requested that such levels be determined through arbitration pursuant to Article 22.6 of the DSU.¹⁵ The Arbitrators concluded that the levels of nullification and impairment in relation to United States and Canadian meat exports were US\$116.8 million and Can\$11.3 million, respectively.¹⁶ On 26 July 1999, the United States and Canada obtained authorization from the DSB to suspend

¹³Award of the Arbitrator, *EC – Hormones*, para. 48.

¹⁴WT/DS26/18, WT/DS48/16.

¹⁵WT/DS26/20; WT/DS48/18.

¹⁶Decision by the Arbitrators, *EC – Hormones (US) (Article 22.6 – EC)*, para. 83; Decision by the Arbitrators, *EC – Hormones (Canada) (Article 22.6 – EC)*, para. 72.

concessions and other obligations in relation to the European Communities.

9. On 29 July 1999, the United States applied 100 per cent import duties on a range of imports from certain member States of the European Communities.¹⁷ On 1 August 1999, Canada applied 100 per cent *ad valorem* duties on a similar range of imports from the European Communities.¹⁸

10. After the adoption of the panel and Appellate Body Reports in the *EC – Hormones* dispute, the European Commission initiated 17 scientific studies to assess any risks to human health posed by the six hormones at issue.¹⁹ On 30 April 1999, the Scientific Committee on Veterinary Measures relating to Public Health (the "SCVPH") of the European Communities issued the Assessment of Potential Risks to Human Health from Hormone Residues in Bovine Meat and Meat Products²⁰ (the "1999 Opinion"). Subsequent to the adoption of the 1999 Opinion, additional scientific information was made available to the European Commission in the form of scientific studies conducted by: (i) the United Kingdom's Veterinary Products Committee sub-group on the 1999 Opinion (October 1999); (ii) the Committee for Veterinary Medicinal Products ("CVMP") of the European Union (a subcommittee of the European Medicines Agency (EMA)) (December 1999); and (iii) the Joint FAO/WHO Expert Committee on Food Additives ("JECFA") (February 2000). At the request of the European Commission, the SCVPH examined this scientific information and, on 3 May 2000, issued a review of its 1999 Opinion in which it declined to alter the conclusions contained therein²¹ (the "2000 Opinion"). On 10 April 2002, a second review of the 1999 Opinion was issued by the SCVPH²² (the "2002 Opinion") on the basis of more recent scientific data collected since the previous review. The

¹⁷Office of the United States Trade Representative, Implementation of WTO Recommendations Concerning *EC – Measures Concerning Meat and Meat Products (Hormones)*, United States Federal Register, Vol. 64, No. 143 (27 July 1999) 40638.

¹⁸European Union Surtax Order, *Canada Gazette Part II*, Vol. 133, No. 17 (18 August 1999).

¹⁹These scientific studies are contained in Exhibits EC-7 (US) through EC-42 (US) and Exhibits EC-4 (CDA) through EC-39 (CDA) submitted by the European Communities to the Panel.

²⁰"Opinion of the SCVPH – Assessment of Potential Risks to Human Health from Hormone Residues in Bovine Meat and Meat Products" (30 April 1999) (Exhibits US-4 and CDA-2 submitted by the United States and Canada, respectively, to the Panel). The main conclusions of the 1999 Opinion are set out in Panel Report, *US – Continued Suspension*, para. 7.391, and Panel Report, *Canada – Continued Suspension*, para. 7.388.

²¹"Review of Specific Documents relating to the SCVPH Opinion of 30 April 99 on the Potential Risks to Human Health from Hormone Residues in Bovine Meat and Meat Products" (adopted on 3 May 2000) (Exhibits US-17 and CDA-4 submitted by the United States and Canada, respectively, to the Panel). The main conclusions of the 2000 Opinion are set out in Panel Report, *US – Continued Suspension*, para. 7.392, and Panel Report, *Canada – Continued Suspension*, para. 7.389.

²²"Opinion of the SCVPH on Review of Previous SCVPH Opinions of 30 April 1999 and 3 May 2000 on the Potential Risks to Human Health from Hormone Residues in Bovine Meat and Meat Products" (adopted on 10 April 2002) (Exhibits US-1 and CDA-17 submitted by the United States and Canada, respectively, to the Panel). The 2002 Opinion confirmed the validity of the 1999 and 2000 Opinions and concluded that no amendments to those Opinions were justified. The main conclusions of the 2002 Opinion are set out in Panel Report, *US – Continued Suspension*, para. 7.393, and Panel Report, *Canada – Continued Suspension*, para. 7.390.

scientific data reviewed by the SCVPH included the final results of all 17 studies that had been commissioned by the European Commission.

11. In the light of the conclusions of the 1999, 2000, and 2002 Opinions, the European Communities adopted Directive 2003/74/EC on 22 September 2003²³, which amends Directive 96/22/EC in relation to the prohibition of the use of hormones in stockfarming. Directive 2003/74/EC maintains the permanent prohibition of the placing on the market of meat and meat products from animals treated with oestradiol-17 β for growth-promotion purposes originally contained in Directive 96/22/EC.²⁴ In relation to the five other hormones—testosterone, progesterone, trenbolone acetate, zeranol, and MGA—Directive 2003/74/EC continues to apply the prohibition contained in Directive 96/22/EC, but on a provisional basis.²⁵ Directive 2003/74/EC specifies that, even though the scientific information available showed the existence of risks associated with these substances, "the current state of knowledge does not make it possible to give a quantitative estimate of the risk to consumers".²⁶ Accordingly, the prohibition of these five hormones should apply "while the Community seeks more complete scientific information from any source, which could shed light and clarify the gaps in the present state of knowledge of these substances".²⁷

12. On 27 October 2003, the European Communities notified the DSB of the adoption, publication, and entry into force of Directive 2003/74/EC, as well as the 1999, 2000, and 2002 Opinions, which it considered to be risk assessments that sufficiently justified the permanent and provisional import prohibitions under the *SPS Agreement*.²⁸ The European Communities therefore claimed that it had fully implemented the DSB's recommendations and rulings in the original *EC – Hormones* disputes, and consequently considered that the suspensions of concessions by the United States and Canada were no longer justified. The United States and Canada refused to lift the measures taken pursuant to the DSB's authorization to suspend concessions or other obligations. The European Communities requested consultations with the United States and Canada

²³*Supra*, footnote 5.

²⁴Directive 2003/74/EC, *supra*, footnote 5, Recital 10 and Article 1 (amending Articles 2 and 3 of Directive 96/22/EC).

²⁵*Ibid.*

²⁶Directive 2003/74/EC, *supra*, footnote 5, Recital 7.

²⁷*Ibid.*, Recital 10.

²⁸WT/DS26/22, WT/DS48/20.

on 8 November 2004.²⁹ The Panel was established, at the request of the European Communities, on 17 February 2005.³⁰

13. Before the Panel, the European Communities put forward two "series of main claims", and a conditional "alternative" claim. In its first "series of main claims", the European Communities argued that, by maintaining their suspension of concessions and other obligations, the United States and Canada were seeking redress of a perceived violation of the *Marrakesh Agreement Establishing the World Trade Organization* (the "*WTO Agreement*") without having recourse to the rules and procedures of the DSU, in violation of Article 23.2(a) of the DSU read in conjunction with Articles 21.5 and 23.1.³¹ The European Communities argued that the United States and Canada should have initiated a compliance proceeding under Article 21.5 of the DSU following notification of the implementing measure to the DSB if they considered that this measure was not consistent with the covered agreements. Their failure to do so violated the specific prohibition to make unilateral determinations set out in Article 23.2(a) of the DSU. The European Communities therefore argued that the continued suspension of concessions or other obligations by the United States and Canada constituted a violation of Article 23.2(a) read in conjunction with Articles 21.5 and 23.1 of the DSU.

14. In its second "series of main claims", the European Communities argued that the United States and Canada, by failing to have recourse to, and abide by, the rules and procedures of the DSU, violated Article 23.1 read in conjunction with Articles 22.8 and 3.7 of the DSU. In particular, the European Communities argued that Article 22.8 of the DSU prohibits the continued application of the suspension of concessions when the measure found to be inconsistent is removed. In addition to the two series of main claims, the European Communities asserted that the continued suspension of concessions or other obligations by the United States and Canada violates Articles I and II of the GATT 1994.³² Finally, the European Communities made an "alternative" claim³³, conditional on "the

²⁹Panel Report, *US – Continued Suspension*, para. 1.1; Panel Report, *Canada – Continued Suspension*, para. 1.1.

³⁰Panel Report, *US – Continued Suspension*, para. 1.3; Panel Report, *Canada – Continued Suspension*, para. 1.3. Two separate Panels were established to examine the complaints against the United States and Canada, respectively; however, the Panels were composed of the same panelists. As the composition of both Panels was identical, in this Report we refer to the Panels collectively as the "Panel".

³¹Panel Report, *US – Continued Suspension*, para. 7.153; Panel Report, *Canada – Continued Suspension*, para. 7.140.

³²Panel Report, *US – Continued Suspension*, para. 3.1; Panel Report, *Canada – Continued Suspension*, para. 3.1.

³³Panel Report, *US – Continued Suspension*, para. 7.155; Panel Report, *Canada – Continued Suspension*, para. 7.142.

Panel find[ing] no violation of Article 23 of the DSU, ... that [the United States'/Canada's] measure[s] violate[] Article 22.8 of the DSU and Articles I and II of the GATT 1994."³⁴

15. The United States and Canada rejected the European Communities' claims, arguing that their measures suspending concessions or other obligations are consistent with Article 22.8 of the DSU. According to the United States and Canada, the suspension of concessions was authorized by the DSB and this authorization remains in effect.³⁵ They further argued that the European Communities has failed to comply with the DSB's recommendations and rulings stemming from *EC – Hormones*, because Directive 2003/74/EC is inconsistent with the *SPS Agreement*, in particular, Articles 3.3, 5.1, and 5.7.³⁶ The United States also alleged that the European Communities' implementing measure is inconsistent with Article 5.2 of the *SPS Agreement*.³⁷

16. The Panel Reports were circulated to Members of the World Trade Organization (the "WTO") on 31 March 2008. The Panel began its analysis with the European Communities' first series of main claims and found that the United States and Canada "violated Article 23.1 and 23.2(a) of the DSU by seeking redress of a violation of the *WTO Agreement* through a determination that the [European Communities'] implementing measure did not comply with the DSB recommendations and rulings in the *EC – Hormones* case without having recourse to dispute settlement in accordance with the rules and procedures of the DSU."³⁸ Turning to the European Communities' second series of main claims, the Panel explained that the European Communities' "second series of main claims" and its "conditional" claim under Article 22.8 of the DSU were both "based on the [European Communities'] view that it has complied with the recommendations and rulings of the DSB in the *EC – Hormones* case by adopting Directive 2003/74/EC and properly notifying it to the DSB".³⁹ "The difference", according to the Panel, "is that, under the conditional claim, the European Communities alleges actual compliance, and not that it should be presumed to have complied in good faith."⁴⁰ The Panel then observed that it "could not agree with the European Communities and base [its] findings of violation of Article 23.1 read in conjunction with Article 22.8 and 3.7 of the DSU on an irrebuttable

³⁴Panel Report, *US – Continued Suspension*, para. 3.2; Panel Report, *Canada – Continued Suspension*, para. 3.2.

³⁵Panel Report, *US – Continued Suspension*, para. 4.78; Panel Report, *Canada – Continued Suspension*, para. 4.78.

³⁶Panel Report, *US – Continued Suspension*, para. 7.180; Panel Report, *Canada – Continued Suspension*, paras. 7.398, 7.552, and 7.826.

³⁷Panel Report, *US – Continued Suspension*, para. 7.406.

³⁸Panel Report, *US – Continued Suspension*, para. 7.251; Panel Report, *Canada – Continued Suspension*, para. 7.244.

³⁹Panel Report, *US – Continued Suspension*, para. 7.156; Panel Report, *Canada – Continued Suspension*, para. 7.143. (emphasis omitted)

⁴⁰Panel Report, *US – Continued Suspension*, para. 7.156; Panel Report, *Canada – Continued Suspension*, para. 7.143.

presumption of good faith compliance".⁴¹ Consequently, the Panel said that it would have to determine whether it had jurisdiction to examine the consistency of the European Communities' implementing measure with the *SPS Agreement*. It concluded that it was "entitled to determine whether the European Communities has removed the measure found to be inconsistent with a covered agreement in order to establish whether Article 22.8 has been breached" by the United States and Canada.⁴² In particular, the Panel determined that it would review the compatibility of the European Communities' implementing measure with Articles 5.1, 5.7, and 3.3 of the *SPS Agreement*.⁴³ In the case against the United States, the Panel said it would additionally examine the compatibility with Article 5.2 of the *SPS Agreement*.⁴⁴

17. The Panel proceeded to examine the compatibility of the European Communities' implementing measure and made the following findings. As regards Article 5.2 in the case against the United States, the Panel found that "the European Communities took into account risk assessment techniques of the relevant international organizations and took into account the factors listed in Article 5.2 of the *SPS Agreement*."⁴⁵

18. In relation to Article 5.1 of the *SPS Agreement*, the Panel found:

[T]he Opinions do not constitute a risk assessment because the Opinions do not satisfy the definition of a risk assessment contained in Annex A(4) second sentence and because the scientific evidence referred to in the Opinions does not support the conclusions therein. Because the Opinions are not a risk assessment as appropriate to the circumstances, the measure cannot be based on a risk assessment within the meaning of Article 5.1.⁴⁶ (footnote omitted)

In light of the above, the Panel concludes that the [European Communities'] implementing measure on oestradiol-17 β is not compatible with Article 5.1 of the *SPS Agreement*.⁴⁷

19. In respect of Article 5.7 of the *SPS Agreement*, the Panel found:

[I]t has not been demonstrated that relevant scientific evidence was insufficient, within the meaning of Article 5.7 of the *SPS Agreement*,

⁴¹Panel Report, *US – Continued Suspension*, para. 7.359; Panel Report, *Canada – Continued Suspension*, para. 7.357.

⁴²Panel Report, *US – Continued Suspension*, para. 7.372; Panel Report, *Canada – Continued Suspension*, para. 7.369.

⁴³Panel Report, *US – Continued Suspension*, para. 7.411; Panel Report, *Canada – Continued Suspension*, para. 7.402.

⁴⁴Panel Report, *US – Continued Suspension*, para. 7.410.

⁴⁵*Ibid.*, para. 7.573.

⁴⁶Panel Report, *US – Continued Suspension*, para. 7.578; Panel Report, *Canada – Continued Suspension*, para. 7.548.

⁴⁷Panel Report, *US – Continued Suspension*, para. 7.579; Panel Report, *Canada – Continued Suspension*, para. 7.549.

in relation to any of the five hormones with respect to which the European Communities applies a provisional ban.⁴⁸

We therefore conclude that the [European Communities'] compliance measure does not meet the requirements of Article 5.7 of the *SPS Agreement* as far as the provisional ban on progesterone, testosterone, zeranol, trenbolone acetate and melengestrol acetate is concerned.⁴⁹

20. The Panel refrained from making findings on Article 3.3 of the *SPS Agreement*, explaining that, "[i]n light of our mandate and of our objectives in engaging in a review of the conformity of the [European Communities'] implementing measure with the *SPS Agreement*, we see no reason to reach a conclusion on Article 3.3 of the *SPS Agreement*, to the extent that this conclusion depends on a violation of Article 5."⁵⁰

21. Having concluded its analysis under the *SPS Agreement*, the Panel made the following findings in respect of the European Communities' second series of main claims:

[W]e conclude that it has not been established that the European Communities has removed the measure found to be inconsistent with a covered agreement.⁵¹

For these reasons and those developed above, we find that the European Communities did not demonstrate a breach of Article 22.8 of the DSU by [the United States and Canada].⁵²

The Panel recalls its understanding that violations of Articles 23.1 and 3.7 were only claimed in relation to the violation of Article 22.8 of the DSU. To the extent that Article 22.8 has not been breached, the European Communities has not established a violation of Articles 23.1 and 3.7 of the DSU. The Panel concludes that there is no violation of Articles 23.1 and 3.7 of the DSU by [the United States and Canada] as a result of a breach of Article 22.8.⁵³

⁴⁸Panel Report, *US – Continued Suspension*, para. 7.835; Panel Report, *Canada – Continued Suspension*, para. 7.821.

⁴⁹Panel Report, *US – Continued Suspension*, para. 7.836; Panel Report, *Canada – Continued Suspension*, para. 7.822.

⁵⁰Panel Report, *US – Continued Suspension*, para. 7.845; Panel Report, *Canada – Continued Suspension*, para. 7.830.

⁵¹Panel Report, *US – Continued Suspension*, para. 7.847; Panel Report, *Canada – Continued Suspension*, para. 7.832.

⁵²Panel Report, *US – Continued Suspension*, para. 7.850; Panel Report, *Canada – Continued Suspension*, para. 7.835.

⁵³Panel Report, *US – Continued Suspension*, para. 7.851; Panel Report, *Canada – Continued Suspension*, para. 7.836.

22. The Panel also rejected the European Communities' claims under Articles I:1 and II of the GATT 1994.⁵⁴ Finally, the Panel addressed the European Communities' alternative claim of violation of Article 22.8 of the DSU:

We recall that the European Communities also raised a *conditional* claim of violation of Article 22.8 of the DSU *per se*. The European Communities specified in its first written submission that this claim was "made in the alternative and only on the condition that the Panel does not establish any violation under Articles 23.1, 23.2(a), 3.7, 22.8 and 21.5 of the DSU".

We note that we have established a violation of Article 23.1 and 23.2(a). We also recall that we have already addressed the alleged violation of Article 22.8 of the DSU as part of our review of the [European Communities'] claim of violation of Article 23.1 read together with Article 22.8 and Article 3.7 of the DSU. Under those circumstances, it is not necessary for the Panel to address the conditional claim of violation [of] 22.8 of the DSU *per se* in the alternative.⁵⁵ (original emphasis; footnote omitted)

23. On the basis of the above, the Panel concluded that the United States and Canada had made the following "procedural violations":

(a) by seeking, through the measure at issue—that is the suspension of concessions or other obligations subsequent to the notification of the [European Communities'] implementing measure (Directive 2003/74/EC)—the redress of a violation of obligations under a covered agreement without having recourse to, and abiding by, the rules and procedures of the DSU, [the United States and Canada have] breached Article 23.1 of the DSU;

(b) by making a determination within the meaning of Article 23.2(a) of the DSU to the effect that a violation had occurred without having recourse to dispute settlement in accordance with the rules and procedures of the DSU, [the United States and Canada have] breached Article 23.2(a) of the DSU.⁵⁶

24. As regards the European Communities' claims concerning Article 23.1 of the DSU, read together with Articles 22.8 and 3.7, the Panel concluded:

(a) to the extent that the measure found to be inconsistent with the *SPS Agreement* in the *EC – Hormones* dispute [(WT/DS26, WT/DS48)] has not been removed by the European Communities,

⁵⁴Panel Report, *US – Continued Suspension*, para. 7.853; Panel Report, *Canada – Continued Suspension*, para. 7.838.

⁵⁵Panel Report, *US – Continued Suspension*, paras. 7.854 and 7.855; Panel Report, *Canada – Continued Suspension*, paras. 7.839 and 7.840.

⁵⁶Panel Report, *US – Continued Suspension*, para. 7.856; Panel Report, *Canada – Continued Suspension*, para. 7.841.

[the United States and Canada have] not breached Article 22.8 of the DSU;

(b) to the extent that Article 22.8 has not been breached, the European Communities has not established a violation of Articles 23.1 and 3.7 of the DSU *as a result of a breach of Article 22.8*.⁵⁷ (original emphasis)

25. In the light of its conclusions, the Panel recommended that the DSB request the United States and Canada to bring their measures into conformity with their obligations under the DSU.⁵⁸ The Panel made the following additional remarks and suggestion pursuant to Article 19.1 of the DSU regarding the implementation of its findings and conclusions:

Whereas it is for the Members to decide on the appropriate steps needed to bring measures found in breach of their WTO obligations into conformity, the Panel deems it important to recall its conclusion in [paragraph 7.251 in *US – Continued Suspension* and paragraph 7.244 in *Canada – Continued Suspension*] as the parties have apparently diverging opinions as to how this report should be implemented by the respondent. As already mentioned, while the Panel performed functions similar to that of an Article 21.5 panel, this was done only in order to determine whether Article 22.8 of the DSU had been breached. This Panel was not called upon, nor does it have jurisdiction, to determine the compatibility of Directive 2003/74/EC with the covered agreements. In that context, the Panel suggests that, in order to implement its findings under Article 23 and in order to ensure the prompt settlement of this dispute, [the United States and Canada] should have recourse to the rules and procedures of the DSU without delay.⁵⁹

26. On 29 May 2008, the European Communities notified the DSB, pursuant to Article 16.4 of the DSU, of its intention to appeal certain issues of law covered in the Panel Reports in *US – Continued Suspension* and *Canada – Continued Suspension* and certain legal interpretations developed by the Panel and filed a single Notice of Appeal⁶⁰, pursuant to Rule 20 of the *Working Procedures for Appellate Review*⁶¹ (the "*Working Procedures*").

27. In a letter dated 30 May 2008, the Division noted that, in the interests of "fairness and orderly procedure", as referred to in Rule 16(1) of the *Working Procedures*, and in agreement with the participants, the appellate proceedings in respect of the European Communities' appeal from the Panel

⁵⁷Panel Report, *US – Continued Suspension*, para. 7.857; Panel Report, *Canada – Continued Suspension*, para. 7.842.

⁵⁸Panel Report, *US – Continued Suspension*, para. 8.2; Panel Report, *Canada – Continued Suspension*, para. 8.2.

⁵⁹Panel Report, *US – Continued Suspension*, para. 8.3; Panel Report, *Canada – Continued Suspension*, para. 8.3.

⁶⁰WT/DS320/12, WT/DS321/12 (attached as Annex I to this Report).

⁶¹WT/AB/WP/5, 4 January 2005.

Reports in *US – Continued Suspension* and *Canada – Continued Suspension* would be consolidated due to the substantial overlap in the content of the disputes. A single Division would hear and decide the appeals, and a single oral hearing would be held by the Division.⁶² The participants were further informed that Appellate Body Member, Mr. Georges Abi-Saab, had been selected, on the basis of rotation, to serve on the Division hearing these appeals, and that, in accordance with Rule 15 of the *Working Procedures*, the Appellate Body had notified the Chairman of the DSB of its decision to authorize Mr. Abi-Saab to complete the disposition of the appeals even though his second term as Appellate Body Member was due to expire before the completion of the appellate proceedings.

28. On 5 June 2008, the European Communities filed an appellant's submission.⁶³ On 10 June 2008, the United States and Canada each notified the DSB, pursuant to Article 16.4 of the DSU, of its intention to appeal certain issues of law covered in the respective Panel Report and certain legal interpretations developed by the Panel and filed a Notice of Other Appeal⁶⁴, pursuant to Rule 23(1) and (2) of the *Working Procedures*. On 13 June 2008, the United States and Canada each filed an other appellant's submission.⁶⁵ On 26 June 2008, Canada, the European Communities, and the United States each filed an appellee's submission⁶⁶, and Australia, Brazil, New Zealand, and Norway each filed a third participant's submission.⁶⁷ On the same day, China, India, Mexico, and the Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu each notified the Appellate Body Secretariat of its intention to appear at the oral hearing as a third participant.⁶⁸

29. After consultation with the Appellate Body Secretariat, Canada, the European Communities, and the United States each agreed that it would not be possible for the Appellate Body to circulate its Reports in these appeals within the 90-day time-limit referred to in Article 17.5 of the DSU.⁶⁹ Canada, the European Communities, and the United States agreed that additional time was needed because of the preliminary procedural issue arising in these proceedings, the size of the Panel record, the number and complexity of the issues appealed, and the fact that there was another appellate

⁶²At the oral hearing, the United States and Canada confirmed their preference for two separate Appellate Body reports. We have issued separate reports (WT/DS320/AB/R and WT/DS321/AB/R), which are identical except for the Findings and Conclusions section.

⁶³Pursuant to Rule 21 of the *Working Procedures*.

⁶⁴WT/DS320/13 (attached as Annex II to this Report); WT/DS321/13 (attached as Annex III to this Report).

⁶⁵Pursuant to Rule 23(3) of the *Working Procedures*.

⁶⁶Pursuant to Rules 22 and 23(4) of the *Working Procedures*. After consultation with the participants, the Division hearing this appeal allocated additional time for filing the appellees' submissions and the third participants' submissions and notifications, pursuant to Rules 16, 22, 23, 24, and 26 of the *Working Procedures*.

⁶⁷Pursuant to Rule 24(1) of the *Working Procedures*.

⁶⁸Pursuant to Rule 24(2) of the *Working Procedures*.

⁶⁹Letter from the European Commission to the Director of the Appellate Body Secretariat dated 11 July 2008; Letter from Canada to the Director of the Appellate Body Secretariat dated 15 July 2008; Letter from the United States to the Director of the Appellate Body Secretariat dated 17 July 2008.

proceeding running simultaneously. Accordingly, Canada, the European Communities, and the United States each confirmed that it would deem the Appellate Body Reports in these proceedings, issued no later than 16 October 2008, to be Appellate Body reports circulated pursuant to Article 17.5 of the DSU.⁷⁰

30. On 27 June 2008, the European Communities sent a letter to the Appellate Body Secretariat noting that the United States and Canada had filed their appellee's submissions after the 5:00 p.m. time-limit set out by the Division in the Working Schedule drawn up for these appeals. The European Communities referred to Rule 18(1) of the *Working Procedures* and requested that the Division "inform the parties of the treatment that should be accorded to these documents".⁷¹ The United States and Canada responded in separate letters and requested the Division to reject the European Communities' request.⁷² At the oral hearing, the Division gave a ruling on the European Communities' request regarding the late filing of the appellee's submission by the United States and Canada. The Division emphasized the importance of all participants adhering strictly to the time-limits set out in the Working Schedule, given the time constraints imposed upon both the participants and the Appellate Body Members in these proceedings. It also noted that the failure to strictly observe such time-limits can have an impact upon the fairness and the orderly conduct of the proceedings. However, having thoroughly examined the matter, and in the light of the particular time-limits concerned and potential prejudice that might be involved, the Division decided nevertheless to consider the appellees' submissions filed by the United States and Canada.

31. Canada, the European Communities, and the United States requested, on 3 June 2008, that the Division authorize public observation of the oral hearing. They argued that public observation of the oral hearing was not precluded by the DSU, the *Working Procedures*, or the *Rules of Conduct for the*

⁷⁰On 22 July 2008, the Appellate Body notified the Chairman of the DSB that the expected date of circulation of its Report was 16 October 2008 (WT/DS320/14, WT/DS321/14).

⁷¹Letter from the European Commission to the Director of the Appellate Body Secretariat dated 27 June 2008.

⁷²Letter from Canada to the Director of the Appellate Body Secretariat dated 30 June 2008; Letter from the United States to the Director of the Appellate Body Secretariat dated 1 July 2008. Canada noted that the European Communities' appellee's submission sent via email was also slightly delayed. The United States noted that the European Communities announced in an email message that it had delivered printed copies of its appellee's submission to the Appellate Body Secretariat and to the other participants and third participants before 5 p.m.; however, the United States received the electronic copy of the European Communities' appellee's submission after 5 p.m., whereas the Working Schedule states that "[t]welve printed copies, as well as an electronic copy, of each written submission should be filed by 5 p.m., Geneva, Switzerland time, on the due date indicated in this Working Schedule". (original underlining) In the event the Appellate Body were to rule on the European Communities' request regarding the United States' appellee's submission, the United States requested the Appellate Body also to inform the European Communities of the treatment to be accorded to its submission in the light of Rule 18 of the *Working Procedures*.

*Understanding on Rules and Procedures Governing the Settlement of Disputes*⁷³ (the "*Rules of Conduct*"). The participants proposed various logistical arrangements that would allow public observation, while respecting the confidentiality of any third participants that did not wish to disclose their oral statements or responses to questions.⁷⁴ On 4 June 2008, the Division invited the third participants to comment in writing on the participants' request to open the hearing to public observation. In particular, the Division asked for the third participants' views on the permissibility of opening the hearing for public observation under the DSU and the *Working Procedures*, and, if they so wished, on the specific logistical arrangements proposed in the requests. Comments were received, on 12 June 2008, from Australia, Brazil, China, India, Mexico, New Zealand, Norway, and the Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu. Australia, New Zealand, Norway, and the Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu supported the participants' request to open the hearing to public observation. Brazil, China, India, and Mexico requested the Appellate Body to deny the participants' request. According to these third participants, the oral hearing forms part of the proceedings of the Appellate Body and, therefore, is subject to the requirement of Article 17.10 of the DSU that "[t]he proceedings of the Appellate Body shall be confidential". On 16 June 2008, the Division invited Canada, the European Communities, and the United States to comment on the submissions made by the third participants. Third participants who wished to submit comments on the submissions made by the other third participants were also invited to do so. Additional comments from Canada, the European Communities, and the United States were received on 23 June 2008. On 7 July 2008, the Division held an oral hearing with the participants and third participants, exclusively dedicated to exploring the issues raised by the request of the participants to authorize public observation. The participants and third participants made oral statements and responded to questions from the Division. At the end of the oral hearing, the participants and third participants were invited to submit, by close of business, 8 July 2008, additional comments relating specifically to the technical modalities proposed by the participants for public observation. Comments were received from Brazil, China, India, and Mexico, as well as Canada, the European Communities, and the United States.

32. On 10 July 2008, the Division issued a Procedural Ruling in which it authorized the public observation of the oral hearing and adopted additional procedures for that purpose in accordance with Rule 16(1) of the *Working Procedures*. The Procedural Ruling is attached as Annex 4 of this Report. Public observation took place via simultaneous closed-circuit television broadcast to a separate room.

⁷³The *Rules of Conduct*, as adopted by the DSB on 3 December 1996 (WT/DSB/RC/1), are incorporated into the *Working Procedures* (WT/AB/WP/5), as Annex II thereto. (See WT/DSB/RC/2, WT/AB/WP/W/2)

⁷⁴The participants expressed a preference for simultaneous closed-circuit broadcast to a separate room.

Notice of the opening of the hearing to public observation and registration instructions were provided on the WTO website. A total of 80 individuals registered to observe the oral hearing.

33. The oral hearing took place on 28-29 July 2008. Pursuant to the additional procedures adopted by the Division, Canada, the European Communities, and the United States were authorized to disclose their oral statements and responses to questions. Australia, New Zealand, Norway, and the Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu were also authorized to disclose their statements and responses to questions. The oral statements and responses to questions of the other third participants were not subject to observation by the public.

II. Arguments of the Participants and the Third Participants

A. Claims of the European Communities – Appellant

1. Procedural Issue – Public Observation of the Oral Hearing

34. The European Communities requested the Appellate Body to allow public observation of the oral hearing in these proceedings. The European Communities recognizes that Article 17.10 of the DSU provides that "[t]he proceedings of the Appellate Body shall be confidential". Nevertheless, for the European Communities, "it is by no means obvious that the term 'proceedings' covers the oral hearing of the Appellate Body."⁷⁵ The European Communities submits that "an interpretation of the ordinary meaning of that term in its context and in light of the DSU's object and purpose will demonstrate that '[t]he proceedings of the Appellate Body' rather refers to the Appellate Body's internal work, and does not include its oral hearing, and that Article 17.10 in any event does not prohibit an open oral hearing."⁷⁶

35. The European Communities acknowledges that Article 14.1 of the DSU refers to the "deliberations" of the panel as being confidential. However, the European Communities argues that the choice of the different words "deliberations" and "proceedings" may be explained by the fact that the idea of creating an Appellate Body emerged relatively late in the negotiations on the DSU, and the fact that the DSU regulates the appellate review in much more rudimentary terms than the panel procedure. Therefore, the European Communities finds no basis for understanding the choice of the different words "deliberations" and "proceedings" as reflecting an intention to draw a difference for the question at issue, and to rule out public observation of Appellate Body oral hearings. The European Communities also refers to the French and Spanish versions of Article 17.10 that use the terms "*travaux*" and "*actuaciones*", respectively. The European Communities states that these are

⁷⁵European Communities' request for an open hearing, para. 9.

⁷⁶*Ibid.*

"very broad terms that could cover every work which the Appellate Body performs", but that such a literal reading "would give rise to absurd results".⁷⁷ Thus, these terms have to be given a "more plausible meaning"⁷⁸ and are best understood as capturing the internal work of the Appellate Body.

36. According to the European Communities, interpreting "proceedings" more broadly than "the internal work of the Appellate Body" leads to problematic results. First, the oral hearing would be confidential with "the absurd result ... that the parties themselves could not attend the hearing in their own dispute".⁷⁹ Secondly, it would preclude the Appellate Body from referring to the arguments of the participants in the Appellate Body report. Thirdly, the Notices of Appeal could not be circulated to WTO Members and made public.

37. The European Communities asserts that, if the Appellate Body was "empowered"⁸⁰ by Article 17.9 of the DSU to draw up its *Working Procedures* and thereby to create the "oral hearing", even though an oral hearing is not foreseen in the DSU, it is also entitled to hold an oral hearing that is open for public observation. The European Communities submits that allowing public observation of the oral hearing "gives effect to the choice which the DSU offers to the parties"⁸¹ under Article 18.2 of the DSU, which provides that "[n]othing in [the DSU] shall preclude a party to a dispute from disclosing statements of its own positions". Moreover, the European Communities states that, in accordance with Article 3.7 of the DSU, the objective of the WTO dispute settlement mechanism is "to secure a positive solution to a dispute". It follows that if the parties to a dispute jointly consider that an open hearing is an important part of their desired way to find a positive solution of their dispute, then it is in line with the object and purpose of the DSU to accommodate that request.

38. The European Communities maintains that confidentiality under the DSU is correctly understood as protecting the interests of WTO Members where they consider that they need that protection, and not as an obligation imposed, even where WTO Members do not desire confidentiality. The European Communities adds that "[t]he other function of confidentiality is to protect the integrity of the (quasi-)judicial process, but in contrast to secret deliberations, this function does not require closed hearings."⁸² On the contrary, the European Communities argues that open hearings are even better and more natural for the judicial process, as the tradition of open oral hearings in national and international judiciaries around the world demonstrates.

⁷⁷European Communities' request for an open hearing, para. 15.

⁷⁸*Ibid.*

⁷⁹*Ibid.*, para. 19.

⁸⁰*Ibid.*, para. 25.

⁸¹*Ibid.*, para. 26. (emphasis omitted)

⁸²*Ibid.*, para. 31.

39. Finally, the European Communities submits that the Appellate Body should follow the example of the Panel in these proceedings and of other panels which have allowed public observation of their meetings with the parties. The European Communities additionally refers to various international courts and tribunals that allow the public to observe their hearings.

40. The European Communities rejects the arguments made by the third participants that oppose the request to open the hearing on the basis of their interpretation of the scope of the term "proceedings". The European Communities states that none of these third participants "has commented on the many inconsistencies that would arise out of such a reading ..., not least the fact that the confidentiality requirement obviously does not apply to certain other aspects of the 'proceedings' in a broad sense (such as the notice of appeal, the disclosure of statements in the report etc. ...)."⁸³ The European Communities also rejects the relevance of the interpretation of the term "proceedings" in *Canada – Aircraft*, because that case involved a different issue, namely, whether additional procedures were necessary for the protection of business confidential information. As regards Article 18.2 of the DSU, the European Communities considers that this provision "trumps any confidentiality requirements that may exist elsewhere in the agreement"⁸⁴, rather than vice-versa, as suggested by some third participants. Moreover, the European Communities disagrees with the argument that the Appellate Body's decision in this case will prejudice the outcome of the DSU review negotiations.

41. For these reasons, the European Communities requests the Appellate Body to allow public observation of the hearing in these proceedings. The European Communities states that its preferred format is to allow public observation of the Appellate Body's oral hearing "by way of real-time closed-circuit audio and video broadcast to a separate room".⁸⁵

2. Articles 23.2(a) and 21.5 of the DSU

42. Although it agrees with the Panel's finding that the United States and Canada have acted inconsistently with Articles 23.2(a) and 23.1 of the DSU, the European Communities asserts that the Panel erred by failing to find that Article 23.2(a), read together with Articles 21.5 and 23.1, required the United States and Canada to initiate Article 21.5 proceedings if they considered that Directive 2003/74/EC did not comply with the DSB's recommendations and rulings in *EC – Hormones*.

⁸³European Communities' comments on third participants' comments, para. 4.

⁸⁴*Ibid.*, para. 10.

⁸⁵European Communities' request for an open hearing, para. 45.

43. According to the European Communities, when a WTO Member considers that the implementing measure taken by another WTO Member is not consistent with the covered agreements, and proceeds to enforce what it considers to be its rights under the DSU, that Member is obliged first to have recourse to a compliance procedure under Article 21.5 of the DSU. The European Communities asserts that "a WTO Member is not entitled, in these circumstances, to seek the redress of an alleged violation through the suspension of obligations without first having recourse to a compliance procedure."⁸⁶

44. In the view of the European Communities, the Panel confused the question of whether recourse to Article 21.5 is obligatory and the question of what procedures are available under Article 21.5. The European Communities disagrees with the Panel's interpretation of the phrase "except through recourse to dispute settlement in accordance with the rules and procedures of this Understanding" in Article 23.2(a) as "encompassing any of the means of dispute settlement provided in the DSU, including consultation, conciliation, good offices and mediation".⁸⁷ According to the European Communities, "[i]t is not in dispute"⁸⁸ that the United States and Canada disagree with the European Communities as to the consistency of Directive 2003/74/EC with the *SPS Agreement*. Consequently, the present dispute "clearly" falls within the scope of Article 21.5 because it concerns a "disagreement as to the existence or consistency with a covered agreement of measures taken to comply with the recommendations and rulings"⁸⁹ of the DSB in *EC – Hormones*. The European Communities emphasizes that consultation, conciliation, good offices, and mediation under the DSU have no effect unless the results are accepted by the parties. In this dispute, the European Communities argues, "it is manifest that no procedure requiring the agreement between the parties was available"⁹⁰, because the European Communities exhausted all available options, including arbitration under Article 25 of the DSU, in its attempt to come to an agreement with the responding parties. The European Communities submits that the phrase "shall be decided through recourse to these dispute settlement procedures, including wherever possible resort to the original panel" in Article 21.5 implies an obligation to have recourse to compliance panel proceedings and that, in the absence of an amicable solution, there must be a final and binding ruling by an adjudicative body. The European Communities concludes from this that "Article 21.5 of the DSU is the applicable provision because the WTO members clearly privileged that provision in case of disagreement between the parties on implementation".⁹¹ Thus, the European Communities maintains that the Panel

⁸⁶European Communities' appellant's submission, para. 57.

⁸⁷*Ibid.*, para. 48 (referring to Panel Report, *US – Continued Suspension*, para. 7.247; and Panel Report, *Canada – Continued Suspension*, para. 7.240).

⁸⁸European Communities' appellant's submission, para. 59.

⁸⁹*Ibid.*, para. 49.

⁹⁰*Ibid.*, para. 54.

⁹¹*Ibid.*, para. 61.

erred in failing to draw the necessary conclusion that an Article 21.5 panel proceeding was the only applicable procedure available under the DSU and that such a panel procedure was "the only way for the United States and Canada to proceed".⁹²

45. The European Communities argues furthermore that the Panel erred in finding that compliance panel proceedings may be initiated by the European Communities as the original responding party in *EC – Hormones*. On the contrary, the European Communities submits, it is inherent in the wording, context, and object and purpose of the provision that the original complaining parties, that is, the United States and Canada, are required to have recourse to Article 21.5.⁹³ The European Communities maintains that references in Articles 3.12, 4.4, 4.7, and 6 of the DSU to "complaining party" and "complainant" confirm that the WTO dispute settlement system is based on the notion of "adversarial proceedings" and "is not applicable to requests for an abstract confirmation of the *consistency* of a measure"⁹⁴ by the defending party. Thus, where a complaining party alleges that an implementing measure is not consistent with the covered agreements, the "implementing Member cannot have recourse to Article 21.5 of the DSU in order to confirm the WTO-consistency of its compliance measure."⁹⁵ The European Communities asserts that this understanding is confirmed by the very notion of the DSU as a "dispute" settlement system and by the basic logic reflected in Article 3.3 of the DSU and Article XXIII:2 of the GATT 1994, which assumes a situation where a WTO Member considers that its rights are being impaired by another Member's measure and therefore challenges that measure, and "does not address the situation where a Member is complaining against its own measure".⁹⁶

46. The European Communities additionally contends that "[i]t would be manifestly impossible for the European Communities to fulfil the very basic requirements of Article 6" as regards the content of the request for the establishment of a panel, because "it would not be in a position to identify the provisions of the *SPS Agreement* that are violated."⁹⁷ Moreover, the European Communities maintains that compliance panel proceedings initiated by the European Communities would not lead to recommendations addressed to the retaliatory measures taken by the United States and Canada, because these measures are not the measure taken to comply with respect to which a disagreement exists within the meaning of Article 21.5. The European Communities also points out that an original complainant may refuse to participate in compliance panel proceedings initiated by the original respondent, as in fact occurred in *EC – Bananas III (Article 21.5 – EC)*. The European

⁹²European Communities' appellant's submission, para. 55.

⁹³See *ibid.*, para. 75.

⁹⁴*Ibid.*, para. 78. (original emphasis)

⁹⁵*Ibid.*, para. 78.

⁹⁶*Ibid.*, para. 85.

⁹⁷*Ibid.*, para. 88.

Communities considers that the "subsequent practice"⁹⁸ that has developed in the WTO dispute settlement system confirms its understanding that Article 21.5 is only available to complaining parties in the original dispute. The European Communities points out that, since the establishment of the WTO, 30 out of 31 proceedings pursuant to Article 21.5 were initiated by the original complaining party, and the panel report in the one remaining proceeding, initiated by the original responding party, was never adopted. This demonstrates that such a procedure is not an option for the original responding party.

47. On this basis, the European Communities requests the Appellate Body to reverse the Panel's findings that the scope of the phrase "recourse to these dispute settlement procedures" in Article 23.2(a) is not limited to Article 21.5 panel proceedings initiated, in this case, by the United States and Canada as the original complaining parties, and that the European Communities, as the original respondent, may initiate Article 21.5 proceedings.

3. Article 22.8 of the DSU

48. The European Communities alleges that the Panel erred in finding that the European Communities' second series of main claims were premised on: (i) a violation by the United States and Canada of their obligations under Article 22.8 of the DSU; and (ii) the actual conformity with the *SPS Agreement* of the implementing measure taken by the European Communities.⁹⁹ In its second series of main claims before the Panel, the European Communities argued that the United States and Canada have acted inconsistently with Article 23.1 of the DSU, read together with Articles 22.8 and 3.7, by maintaining the suspension of concessions despite the removal of the "measure found to be inconsistent" within the meaning of Article 22.8—that is, Directive 96/22/EC.¹⁰⁰

49. The European Communities explains that it never argued that the claim under Article 23.1 of the DSU was dependent on a violation of Article 22.8 by the United States and Canada and never argued that this claim would be premised on the conformity of the implementing measure with the *SPS Agreement*. Rather, the violation the European Communities claimed was the unilateral determination made by the United States and Canada according to which "the measure taken to comply" with the recommendations and rulings of the DSB, that is, Directive 2003/74/EC, is not, in their view, consistent with the *SPS Agreement*. The European Communities adds that such a determination is a violation of Article 23.1 of the DSU read in the light of Article 22.8 of the DSU,

⁹⁸European Communities' appellant's submission, para. 91.

⁹⁹*Ibid.*, paras. 99 and 100 (referring to Panel Report, *US – Continued Suspension*, para. 7.272; and Panel Report, *Canada – Continued Suspension*, para. 7.288).

¹⁰⁰Panel Report, *US – Continued Suspension*, para. 7.252; Panel Report, *Canada – Continued Suspension*, para. 7.245.

not a claim of violation of Article 22.8 in itself, and is not premised on the conformity of the implementing measure with the *SPS Agreement*. The European Communities additionally notes that only in the alternative, and only on the condition that the Panel did not establish any violation under Articles 23.1, 23.2(a), 3.7, 22.8 and 21.5 of the DSU, did the European Communities make an alternative claim under Article 22.8 of the DSU.¹⁰¹

50. The European Communities asserts that the Panel "fail[ed] to provide any serious legal argumentation"¹⁰² as to why, under Article 22.8, what is to be achieved is not the removal of the measure, but actual compliance with the DSB's recommendations and rulings. The European Communities takes issue with the Panel's finding that the replacement of Directive 96/22/EC by Directive 2003/74/EC did not constitute the removal of the inconsistent measure within the meaning of Article 22.8, because Directive 2003/74/EC, like its predecessor, imposes an import ban on meat treated with hormones. According to the European Communities, this finding contradicts the Panel's earlier finding that "it is not the ban on meat treated with growth promotion hormones as such that was found illegal in the *EC – Hormones* case, but the justification for this ban which was found insufficient."¹⁰³ Moreover, the European Communities underscores the Panel's finding that Directive 2003/74/EC "shows all the signs of an implementing measure having gone through all the formal process required for its adoption and showing, on its face, all the signs of a measure adopted in good faith."¹⁰⁴ The European Communities contends that, because the Panel concluded that Directive 96/22/EC—the measure found to be inconsistent with a covered agreement—has been removed, it follows from the wording of Article 22.8 that the application of the suspension of concessions was no longer authorized after the adoption and the subsequent notification of Directive 2003/74/EC to the DSB. The European Communities also emphasizes that Articles 3.7 and 22.8 both recognize that the suspension of concessions or other obligations is a temporary measure of last resort.¹⁰⁵

51. The European Communities emphasizes that Article 22.8 refers to whether the "measure found to be inconsistent with a covered agreement" has been removed. The European Communities asserts that, in this particular case, the measure found to be inconsistent within the meaning of Article 22.8 was the measure that was subject to the original dispute in *EC – Hormones* and that was

¹⁰¹European Communities' appellant's submission, para. 97.

¹⁰²*Ibid.*, para. 105.

¹⁰³*Ibid.*, para. 106 (quoting Panel Report, *US – Continued Suspension*, para. 7.207; and Panel Report, *Canada – Continued Suspension*, para. 7.199). (emphasis omitted)

¹⁰⁴*Ibid.*, para. 108 (quoting Panel Report, *US – Continued Suspension*, para. 7.238; and Panel Report, *Canada – Continued Suspension*, para. 7.231). (emphasis omitted)

¹⁰⁵*Ibid.*, paras. 115 and 116. The European Communities also refers to its own conduct in *US – FSC*, where it suspended the application of retaliatory measures and initiated an Article 21.5 proceeding because it considered the United States' implementing measure to be inconsistent with the relevant covered agreements. (*Ibid.*, para. 156)

identified by the Appellate Body as the measure found to be inconsistent with the *SPS Agreement* in 1998. That measure was Directive 96/22/EC. Thus, once the European Communities adopted Directive 2003/74/EC, which was based on a new risk assessment that explicitly aimed at addressing the shortcomings found in *EC – Hormones* with respect to Directive 96/22/EC, the suspension of concessions or other obligations could no longer be applied. Once the original measure was removed, the suspension of concessions would continue without its main objective—implementation of the DSB's recommendations and rulings—because the implementing measure had already been taken. The objective to induce compliance could only "revive after it has been properly established before a compliance procedure under Article 21.5 of the DSU that the implementing measure has been insufficient to remedy a WTO violation."¹⁰⁶

52. The European Communities contends that "Articles 21 and 22 of the DSU [were] ... drafted around a basic dichotomy between 'the measure found to be inconsistent' and the 'measures taken to comply'."¹⁰⁷ Therefore, "whether the measure taken [by the European Communities] to comply is compliant with the recommendations and rulings of the DSB"¹⁰⁸ is a matter to be determined by a panel acting under Article 21.5 of the DSU. Unlike Article 21.5, Article 22.8 refers to whether the measure has been removed and does not refer to whether the measure taken to comply is consistent with the DSB's recommendations and rulings. The European Communities adds that interpreting Article 22.8 as referring to "actual compliance", as the Panel did, would allow the original complaining Member to make a unilateral determination of the substantive merits of the measure taken to comply without recourse to Article 21.5 of the DSU.

53. The European Communities considers that the Panel "fundamentally erred" in the manner in which it identified the "measure found to be inconsistent with a covered agreement" in order to determine whether it "has been removed"¹⁰⁹ within the meaning of Article 22.8 of the DSU. The European Communities states that, even though the Panel initially considered that Directive 96/22/EC, that is, the SPS measure subject to the original proceedings in *EC – Hormones*, was removed, the Panel later held the view that considering Directive 96/22/EC as the measure found

¹⁰⁶European Communities' appellant's submission, para. 141.

¹⁰⁷*Ibid.*, paras. 136 and 137 (referring to the Appellate Body's statement in paragraph 36 of its Report in *Canada – Aircraft (Article 21.5 – Brazil)* that "a measure which has been 'taken to comply ...' ... will *not* be the same measure as the measure which was the subject of the original dispute, so that, in principle, there would be two separate and distinct measures" (original emphasis; footnote omitted)).

¹⁰⁸*Ibid.*, para. 142.

¹⁰⁹*Ibid.*, para. 145.

to be inconsistent with a covered agreement within the meaning of Article 22.8 is "unsatisfactory, as Directive 96/22/EC was replaced by Directive 2003/74/EC which also imposes an import ban".¹¹⁰

54. For these reasons, the European Communities requests the Appellate Body to reverse the Panel's finding that the European Communities' claims under Articles 23.1, 22.8, and 3.7 of the DSU were premised on a violation of Article 22.8 and on the actual compliance of Directive 2003/74/EC with the *SPS Agreement*. It also requests the Appellate Body to complete the analysis and find that the United States and Canada have breached Article 23.1 of the DSU by continuing the suspension of concessions despite the adoption and subsequent notification to the DSB of Directive 2003/74/EC.

4. The Panel's Terms of Reference

55. The European Communities maintains that its alternative claim of a "direct"¹¹¹ violation of Article 22.8, on the basis of its actual compliance with the *SPS Agreement*, was "strictly"¹¹² predicated on the condition that the Panel found no violations pursuant to the European Communities' two series of main claims. The European Communities asserts that the Panel should not have ignored the "hierarchy"¹¹³ and "conditional order of the legal claims" because it "form[ed] part of [its] mandate".¹¹⁴ The European Communities reiterates that its second series of main claims, alleging that the United States and Canada have violated Article 23.1, read together with Articles 22.8 and 3.7, did not depend on the presumed or actual compliance of Directive 2003/74/EC with the DSB's recommendations and rulings, but were premised on the fact that the measure found to be inconsistent with a covered agreement, within the meaning of Article 22.8, had been removed. Therefore, whether Directive 2003/74/EC complies with the *SPS Agreement* was only relevant for the European Communities' conditional "alternative" claim, which the Panel should have examined only if the condition that the Panel found no violation under the European Communities' two series of main claims had been met. On this basis, the European Communities argues that the Panel ignored the clear indication by the European Communities as to the hierarchy and conditional order of its claims and exceeded its mandate by reviewing the compatibility of Directive 2003/74/EC with the *SPS Agreement*, even though the Panel had already found that the United States and Canada had breached Articles 23.1 and 23.2(a) of the DSU.

¹¹⁰European Communities' appellant's submission, para. 146 (quoting Panel Report, *US – Continued Suspension*, paras. 7.283 and 7.284; and Panel Report, *Canada – Continued Suspension*, paras 7.299 and 7.300).

¹¹¹*Ibid.*, para. 160 (quoting Panel Report, *US – Continued Suspension*, para. 7.164; and Panel Report, *Canada – Continued Suspension*, para. 7.151).

¹¹²*Ibid.*, para. 165.

¹¹³*Ibid.*, para. 162.

¹¹⁴*Ibid.*, para. 167.

56. The European Communities alleges that, as shown by the panel report in *EC – Sardines*, when a panel has clear indications by the complaining party as to the order of its legal claims, it is "bound by the sequencing order of the legal claims"¹¹⁵ if such an order does not affect the proper interpretation of the relevant provisions of the covered agreements. In this dispute, the order of claims raised by the European Communities did not affect the proper interpretation of the relevant provisions of the DSU and the *SPS Agreement*, and the Panel erred in failing to follow this order.

57. The European Communities emphasizes that its "main point in these proceedings was to establish that the proper place to review compliance was before an Article 21.5 panel at the request of the United States or Canada on the basis of explicit claims setting out their objections to the new measures."¹¹⁶ It adds that, had the Panel followed the order and conditions of the claims made by the European Communities, it would not have acted as a compliance panel in blatant disregard of its terms of reference and the very specific requirements under Article 21.5 of the DSU as informed, *inter alia*, by Article 6 of the DSU. The European Communities notes, in this regard, what it considers to be contradictory statements by the Panel with respect to whether or not the Panel was "substitut[ing]" itself for, or "perform[ing]"¹¹⁷ the role of, an Article 21.5 panel.

58. Therefore, the European Communities asserts that the Panel "acted ... in blatant disregard of [its] terms of reference and the ... requirements under Article 21.5 of the DSU"¹¹⁸ and erroneously assumed the function of an Article 21.5 panel, in contravention with Articles 7 and 21.5 of the DSU.

5. The Panel's Suggestion for Implementation

59. The European Communities requests the Appellate Body to "modify"¹¹⁹ the Panel's suggestion that the United States and Canada "should have recourse to the rules and procedures of the DSU without delay".¹²⁰ According to the European Communities, as a result of the Panel's findings that the United States and Canada have breached Articles 23.2(a) and 23.1 of the DSU, there is "no doubt"¹²¹ that the continued suspension of concessions is inconsistent with the DSU, even if a compliance proceeding were initiated without delay. Consequently, the European Communities considers that "the United States and Canada should remove their suspension of WTO obligations and

¹¹⁵European Communities' appellant's submission, para. 168 (referring to Panel Report, *EC – Sardines*, paras. 7.14-7.19).

¹¹⁶*Ibid.*, para. 170.

¹¹⁷*Ibid.*, paras. 172 and 173 (referring to Panel Report, *US – Continued Suspension*, paras. 7.276 and 8.3; and Panel Report, *Canada – Continued Suspension*, paras. 7.292 and 8.3). (emphasis omitted)

¹¹⁸*Ibid.*, para. 171.

¹¹⁹*Ibid.*, para. 456.

¹²⁰*Ibid.*, para. 478 (quoting Panel Report, *US – Continued Suspension*, para. 8.3; and Panel Report, *Canada – Continued Suspension*, para. 8.3).

¹²¹*Ibid.*, para. 468.

have recourse to the rules and procedures of the DSU without delay if they continue to take issue with the European Communities' implementation of the recommendations"¹²² stemming from *EC – Hormones*.

60. The European Communities adds that the phrase "through recourse to dispute settlement" in Article 23.2(a) requires an outcome of the recourse in the form of binding decisions or an agreement between the parties. Thus, the European Communities argues, the inconsistency resulting from the continued suspension of concessions will not disappear if the United States and Canada merely request consultations or initiate mediation procedures. Instead, the United States and Canada must "complete"¹²³ Article 21.5 proceedings against the European Communities. The European Communities further submits that it "would be deprived of the protection of Article 23 of the DSU, if [it] can secure the withdrawal of the sanctions only by winning in the compliance dispute brought by the United States and Canada, as suggested by the Panel."¹²⁴ In the European Communities' view, Article 23 would be "turned on its head"¹²⁵ if a WTO Member were allowed to make first a unilateral determination—by keeping the suspension of concessions in place—that an implementing measure of another Member is WTO-inconsistent, and only later obtain multilateral findings in proceedings initiated by the implementing Member that provide a valid basis for the determination.

61. The European Communities states that the circumstances of this dispute require "clarity" and a suggestion by the Appellate Body would be "very useful"¹²⁶, explaining that the Panel's suggestion is "too vague to be of much assistance".¹²⁷ Thus, the European Communities requests the Appellate Body to "improve"¹²⁸ the Panel's suggestion so as to make it clear that the United States and Canada must cease applying the suspension of concessions, and must seek resolution of any remaining disagreement concerning the consistency with the *SPS Agreement* of Directive 2003/74/EC by having recourse to Article 21.5 panel proceedings or any other proceeding to which the parties may agree.

6. The Panel's Selection of Experts

62. The European Communities takes issue with the Panel's selection of two experts—Dr. Jacques Boisseau and Dr. Alan Boobis—who contributed to the reports by JECFA regarding the use of the hormones at issue in this dispute. The European Communities claims that "any 'reliance'

¹²²European Communities' appellant's submission, para. 454.

¹²³*Ibid.*, para. 461.

¹²⁴*Ibid.*, para. 475.

¹²⁵*Ibid.*, para. 476. (emphasis omitted)

¹²⁶*Ibid.*, para. 477.

¹²⁷*Ibid.*, para. 479.

¹²⁸*Ibid.*, para. 480.

the Panel[] [has] placed on what these two experts from JECFA said is a violation of the relevant rules on conflict of interest, of its rights of due process and of the requirement for the Panel[] to perform an 'objective assessment' of the matter before [it]"¹²⁹, as required under Article 11 of the DSU.

63. Recalling the Appellate Body's finding in *Thailand – H-Beams* that the "requirement of due process is fundamental to ensuring a fair and orderly conduct of dispute settlement proceedings"¹³⁰, the European Communities posits that due process "informs the entire Dispute Settlement Understanding".¹³¹ In the view of the European Communities, "the consultation of experts by the Panel[] for the purposes of scientific and technical advice including their selection must respect general principles of law, and in particular the principle of due process."¹³² The European Communities adds that "[i]t is inherent in the principle of due process that the parties to a dispute are given a fair hearing including that the experts a court, tribunal or panel hears or consults are *independent and impartial*."¹³³

64. The European Communities contends that "the relevant legal test"¹³⁴ for evaluating whether an expert is independent and impartial is found in Section VI.2 of the *Rules of Conduct*, which requires that experts "disclose any information that could reasonably be expected to be known to them at the time [they are requested to serve as experts] which ... is likely to affect or give rise to justifiable doubts as to their independence or impartiality." The European Communities asserts that this standard is "quite simple and low" and "does not require certainty or high probability".¹³⁵ The European Communities asserts that "the Panel[] never actually addressed the relevant legal question"¹³⁶ of whether this standard served to disqualify these experts.

65. The European Communities alleges that the Panel disregarded its "most important objection"¹³⁷ that Drs. Boisseau and Boobis, who participated in the drafting of JECFA reports, could not be independent and impartial because they were asked to evaluate the risk assessments that were "very critical of the JECFA reports".¹³⁸ The European Communities observes that as "co-authors" of the JECFA reports, these experts "cannot be considered to be independent and impartial in these

¹²⁹European Communities' appellant's submission, para. 202.

¹³⁰*Ibid.*, para. 184 (quoting Appellate Body Report, *Thailand – H-Beams*, para. 88).

¹³¹*Ibid.*, para. 184.

¹³²*Ibid.*, para. 188.

¹³³*Ibid.* (original emphasis)

¹³⁴*Ibid.*, para. 195.

¹³⁵*Ibid.*

¹³⁶*Ibid.*, para. 196.

¹³⁷*Ibid.*, para. 203.

¹³⁸*Ibid.*, para. 196.

circumstances, because this would amount to asking them to review and criticise reports that are their own doing".¹³⁹

66. In addition, the European Communities claims that the Panel's decision to select these experts was "based on a very narrow definition of a perceived conflict of interest because it required an actual or almost certain conflict, not a perceived, likelihood or a justifiable doubts test".¹⁴⁰ According to the European Communities, a perceived conflict of interest arises in this dispute due to the fact that Dr. Boisseau took "a position in favour of the safety of these hormones" and Dr. Boobis "has been receiving funding from the pharmaceutical industry in his research and counselling".¹⁴¹

67. The European Communities alleges several further errors committed by the Panel. It faults the Panel for "relying overwhelmingly"¹⁴² on the opinions of Drs. Boisseau and Boobis on practically all scientific aspects of the matters; for failing to ensure that Drs. Boisseau and Boobis complied with the self-disclosure requirement before their selection; and for failing to "actually examine[] whether all of the experts had a potential conflict of interest and whether [Drs. Boisseau and Boobis] fulfilled the conditions to be truly independent and impartial".¹⁴³ Finally, the European Communities argues that, "even if one were to take the view that the Panel[] could accept the non-independent experts provided that they would constantly bear in mind the potential conflicts [of interest and the lack of independence] when weighing the expert opinions, it is clear that the Panel[] refused to do so, considering the issue of the experts finally resolved when dismissing the European Communities' objections."¹⁴⁴ Indeed, these experts "dominate[d] the entire scientific examination by the Panel[] both from the point of view of how often they [were] referred to and whether the Panel[] ever question[ed] their opinions and whether their opinions go beyond science and stray into the area of the risk regulator."¹⁴⁵

68. On this basis, the European Communities submits that the Panel failed to respect the principle of due process; failed to ensure compliance with the requirements on self-disclosure under the *Rules of Conduct*; erred in accepting as experts persons whose independence and impartiality was not

¹³⁹European Communities' appellant's submission, para. 205. The European Communities seeks to draw analogy from a judgment by the European Court of Human Rights, which found that a person was denied a fair trial because the expert appointed by the relevant tribunal had drafted the report triggering the trial against that person. (*Ibid.*, para. 206 (referring to European Court of Human Rights, Judgment of 6 May 1985, *Case of Bönisch v. Austria*, Application no. 8658/79 (Exhibit EC-131 submitted by the European Communities to the Appellate Body)))

¹⁴⁰European Communities' appellant's submission, para. 203.

¹⁴¹*Ibid.*

¹⁴²*Ibid.*, para. 212.

¹⁴³*Ibid.*, para. 192.

¹⁴⁴*Ibid.*, para. 211. (footnote omitted)

¹⁴⁵*Ibid.*, para. 208.

assured; and acted inconsistently with its obligations under Article 11 of the DSU. The European Communities therefore requests the Appellate Body to "reverse all the findings of the Panel[] which depend on the advice they received from" Drs. Boisseau and Boobis.¹⁴⁶

7. Article 5.1 of the SPS Agreement

69. The European Communities argues that the Panel erred in finding that the permanent ban on meat and meat products from cattle treated with oestradiol-17 β applied pursuant to Directive 2003/74/EC was not based on a risk assessment within the meaning of Article 5.1 and Annex A, paragraph 4, of the *SPS Agreement*. The European Communities requests the Appellate Body to reverse this finding for the following reasons.

70. The European Communities submits that the Panel erred in its interpretation and application of Article 5.1 and Annex A, paragraph 4, of the *SPS Agreement* as informed by Article 5.2 of that Agreement. The European Communities asserts that the Panel "[a]dopted an extremely narrow and consequently erroneous"¹⁴⁷ interpretation of "risk assessment" when it excluded from the scope of its analysis under Article 5.1 arguments and evidence concerning the misuse and abuse and difficulties of control in the administration of hormones to cattle for growth-promotion purposes. The European Communities refers to the Panel's statement that Article 5.2 of the *SPS Agreement* "instructs Members on how to conduct a risk assessment"¹⁴⁸, and argues that the Panel erroneously rendered Article 5.2 "entirely procedural".¹⁴⁹ In the European Communities' view, Article 5.2 "does not prescribe a given method or procedure to be followed in conducting a risk assessment", but provides "substantive factors"¹⁵⁰ to be taken into account in a risk assessment and offers guidance on the substantive content of a "risk assessment" within the meaning of Article 5.1. Consequently, the Panel made a "fundamental legal error" by "considerably narrowing down the scope"¹⁵¹ of a risk assessment within the meaning of Article 5.1. In doing so, the Panel wrongly excluded "risk management" aspects from the coverage of Article 5.1, and thereby adopted the same restrictive interpretation of "risk assessment" in Article 5.1 that was overturned by the Appellate Body in *EC – Hormones*.¹⁵²

71. The European Communities relies on the Appellate Body's finding in *EC – Hormones* that risk assessors "may examine and evaluate ... risks arising from potential abuse in the administration of

¹⁴⁶European Communities' appellant's submission, para. 212.

¹⁴⁷*Ibid.*, para. 308.

¹⁴⁸*Ibid.*, para. 316 (quoting Panel Report, *US – Continued Suspension*, para. 7.440). (emphasis omitted)

¹⁴⁹*Ibid.*, para. 320. (original emphasis)

¹⁵⁰*Ibid.*, para. 316. (original emphasis)

¹⁵¹*Ibid.*, para. 320.

¹⁵²*Ibid.*, para. 322 (referring to Appellate Body Report, *EC – Hormones*, para. 187).

controlled substances and from control problems".¹⁵³ The European Communities maintains that the SCVPH Opinions explicitly addressed evidence concerning the abusive use and difficulties of control in the administration of hormones for growth-promotion purposes, and yet the Panel "simply ignore[d] the evidence".¹⁵⁴ The Panel failed to take account of the fact that the abusive use and difficulties of control were important factors in the risk assessment underlying the SCVPH Opinions, adding considerably to the risk identified. Instead, the Panel instructed the scientific experts to examine only that part of the evidence concerning the residues in meat from these hormones administrated "in accordance with good veterinary practice".¹⁵⁵ The European Communities adds that the fact that Codex Alimentarius Commission ("Codex") standards do not usually address the possibility of misuse and abuse throws the Panel's approach into question, because the notion of risk assessment under Article 5.1 of the *SPS Agreement* is clearly wider than that under Codex.

72. The European Communities also asserts that the Panel erred in finding that the European Communities has acted inconsistently with Article 5.1 by failing to evaluate specifically the risks arising from residues of oestradiol-17 β in meat from cattle treated with this substance for growth-promoting purposes. The European Communities highlights the conclusion in the risk assessment underlying Directive 2003/74/EC that new evidence concerning the genotoxicity¹⁵⁶ of oestradiol suggests that oestradiol-17 β "acts as a complete carcinogen by exerting tumour initiating and promoting effects".¹⁵⁷ This conclusion demonstrates that the risk assessment focused on and addressed specifically the particular kind of risks at stake—the carcinogenic and genotoxic potential of the residues of oestradiol-17 β found in meat treated with this hormone.

73. The European Communities maintains further that the Panel erred in requiring the quantification of the risks to human health arising from the consumption of meat containing residues of oestradiol-17 β . The European Communities asserts that, by referring to "potential occurrence"¹⁵⁸ of adverse effects when posing questions to the experts, the Panel "imposed a quantitative method of

¹⁵³European Communities' appellant's submission, para. 324 (referring to Appellate Body Report, *EC – Hormones*, paras. 206 and 207).

¹⁵⁴*Ibid.*, para. 329.

¹⁵⁵*Ibid.*, para. 274 (referring to Question 13 posed by the Panel to the scientific experts, Panel Reports, Annex D, p. D-22; Panel Report, *US – Continued Suspension*, paras. 6.102, 6.164, and 6.165; and Panel Report, *Canada – Continued Suspension*, paras. 6.94, 6.154, and 6.155).

¹⁵⁶Genotoxicity is the ability to cause damage to genetic material (DNA). Such damage may be mutagenic and/or carcinogenic. (See Panel Report, *US – Continued Suspension*, footnote 370 to para. 7.77; and Panel Report, *Canada – Continued Suspension*, footnote 362 to para. 7.75 (referring to replies of Dr. Boobis and Dr. Guttenplan to Question 2 posed by the Panel to the scientific experts, Panel Reports, Annex D, paras. 41 and 58, respectively) See also transcript of the Panel's joint meeting with the scientific experts on 27-28 September 2006, Panel Reports, Annex G, paras. 85-90)

¹⁵⁷European Communities' appellant's submission, para. 337 (referring to 1999 Opinion, p. 73).

¹⁵⁸*Ibid.*, para. 346.

risk assessment on the European Communities borrowed from Codex Alimentarius and JECFA".¹⁵⁹ However, the Panel's rejection of a "purely qualitative analysis of risk"¹⁶⁰ and the imposition of such a quantitative requirement find no basis in the *SPS Agreement* and contradict the Appellate Body's finding in *EC – Hormones* that a risk assessment under the *SPS Agreement* does not require the establishment of a minimum magnitude of risk. In addition, the experts acknowledged that quantification of risk is not necessary for substances that have genotoxic potential, such as oestradiol-17 β . For this reason, the European Communities suggests that a qualitative analysis of risk must be *a fortiori* sufficient to meet the requirements of Article 5.1 and Annex A, paragraph 4, of the *SPS Agreement*.

74. The European Communities argues that the Panel erred in allocating the burden of proof under Article 5.1 of the *SPS Agreement*. The fact that the European Communities is the complaining party in this dispute "does not change the basic standard on the burden of proof under the *SPS Agreement*".¹⁶¹ Accordingly, it was incumbent upon the United States and Canada to rebut the *prima facie* case of consistency made by the European Communities in relation to Directive 2003/74/EC. The European Communities submits that, because of the particularity of the case, this obligation to rebut the *prima facie* case made by the European Communities amounts to the same standard as making a *prima facie* case in a dispute where the United States and Canada proceed with a normal panel procedure against an SPS measure taken by the European Communities. The Panel nevertheless found that the United States and Canada had "sufficiently refuted the [European Communities'] allegation of compliance in [their] first written submission[s] through positive evidence of breach of the *SPS Agreement*"¹⁶² without articulating the rationale for this conclusion. Therefore, the Panel erred in law in shifting the burden of proof to the European Communities without first examining, provision by provision under the *SPS Agreement*, whether the arguments of the United States and Canada had sufficient merit to shift the burden of proof back to the European Communities.

75. The European Communities further argues that the Panel failed to conduct an objective assessment of the facts of the case, as required by Article 11 of the DSU. While the European Communities agrees with the Appellate Body's interpretation of the standard of review applicable under the *SPS Agreement*, it also notes that, when reviewing governmental measures in highly complex or technical matters, domestic courts and international tribunals usually follow a "reasonableness" approach to the fact-finding of competent authorities. The European Communities

¹⁵⁹European Communities' appellant's submission, para. 308. See also *ibid.*, para. 296.

¹⁶⁰*Ibid.*, para. 353 (referring to Panel Report, *US – Continued Suspension*, para. 7.530; and Panel Report, *Canada – Continued Suspension*, para. 7.502).

¹⁶¹*Ibid.*, para. 287.

¹⁶²*Ibid.*, para. 288 (quoting Panel Report, *US – Continued Suspension*, para. 7.385; and Panel Report, *Canada – Continued Suspension*, para. 7.382).

recalls that, according to the Appellate Body's interpretation of Article 5.1, Members are entitled to rely on "divergent opinion[s] coming from qualified and respected sources"¹⁶³ in their risk assessments when adopting SPS measures. For this reason, a panel reviewing a Member's SPS measure under Article 5.1 should seek to determine whether there is any reasonable scientific basis for such measures and respect the "important and autonomous right"¹⁶⁴ of Members to set their level of SPS protection. A panel should not substitute its scientific judgement for that of the Member taking the measure and should not "second guess"¹⁶⁵ Members, particularly in situations where available science is providing alternative and competing explanations. Thus, in this dispute, the Panel should have asked whether there were divergent opinions in the scientific community, and, if the European Communities based itself on a divergent opinion, if those opinions are qualified and respected.

76. Instead of determining "whether there was any reputable support within the relevant scientific community for the determination made by the European Communities in the light of its chosen level of protection"¹⁶⁶, the Panel stated that it was in a situation "similar"¹⁶⁷ to that of a risk assessor and sought to determine what the correct scientific conclusions were relating to the hormones at issue. In doing so, the Panel "drifted into a *de novo* review"¹⁶⁸ of the European Communities' risk assessment and decided "to become the jury on the correct science ... by picking and choosing between the conflicting and contradictory opinions of the experts in an arbitrary manner".¹⁶⁹ The Panel imposed its choices on the European Communities between the different "scientifically plausible alternatives", either by basing itself on the views expressed by a majority of the experts, or by selecting the "most specific" or "best supported" views.¹⁷⁰ As a result, the Panel failed to take into account diverging views reflecting a "genuine and legitimate scientific controversy"¹⁷¹ among the experts over the safety of residues of hormones in meat. The Panel also ignored that some of the experts reported the same concerns as expressed in the SCVPH Opinions, "praised"¹⁷² the analysis in those Opinions, or highlighted that the Opinions followed a different, but equally plausible, scientific approach.

77. The European Communities alleges the following specific errors in connection with its claim

¹⁶³European Communities' appellant's submission, para. 226 (quoting Appellate Body Report, *EC – Hormones*, para. 194). (emphasis omitted)

¹⁶⁴*Ibid.*, para. 222 (referring to Appellate Body Report, *EC – Hormones*, para. 172). (emphasis omitted)

¹⁶⁵*Ibid.*, para. 222.

¹⁶⁶*Ibid.*, para. 240.

¹⁶⁷*Ibid.*, para. 237 (quoting Panel Report, *US – Continued Suspension*, para. 7.418; and Panel Report, *Canada – Continued Suspension*, para. 7.409).

¹⁶⁸*Ibid.*, para. 237.

¹⁶⁹*Ibid.*, para. 239. (emphasis omitted)

¹⁷⁰*Ibid.*, para. 240.

¹⁷¹*Ibid.*, para. 248.

¹⁷²*Ibid.*, para. 247.

that the Panel failed to make an objective assessment of the facts. First, the European Communities alleges that the Panel acted inconsistently with Article 11 of the DSU when it failed to take into account evidence related to the assessment of risks to human health arising from exposure to residues of hormones from multiple endogenous and exogenous sources. The European Communities maintains that the Panel Reports explain this issue "very briefly"¹⁷³, even though it was raised several times in the European Communities' written submissions and comments, and was discussed extensively during the meeting of the Panel with the experts. The European Communities observes that "there is no mention at all [of the risks of multiple exposures] in the Panel[']s findings."¹⁷⁴

78. Secondly, the European Communities maintains that the Panel "failed to consider or distorted"¹⁷⁵ scientific evidence demonstrating that no safe threshold levels exist for the consumption by humans of oestradiol-17 β due to its actual or potential genotoxicity. The European Communities emphasizes that a majority of the experts advising the Panel agreed that there was sufficient scientific evidence in support of the European Communities' conclusion that oestradiol-17 β is actually or potentially genotoxic. However, the Panel "side-stepped" such crucial evidence and "mischaracteri[zed]" the evidence when finding that the European Communities had "not provided analysis of the potential for these [genotoxic] effects to arise from the consumption of meat and meat products which contain residues of oestradiol-17 β ".¹⁷⁶ The European Communities observes that to have conclusive evidence on whether or not a threshold can be applied "might require scientific testing on humans", which would be "totally unethical" and require a Member "to do the impossible".¹⁷⁷ The European Communities considers the conclusion that no threshold levels may be established in relation to oestradiol-17 β to be "just as valid"¹⁷⁸ scientifically as the opposing position held by the United States, Canada, and JECFA. Therefore, the Panel acted inconsistently with Article 11 of the DSU by ignoring "the totality of the evidence"¹⁷⁹ and by failing to recognize the significance of the "'genuine' and 'legitimate' scientific controversy"¹⁸⁰ relating to the question of whether risks to human health arising from the consumption of residues of oestradiol-17 β could be addressed through the establishment of threshold levels.

¹⁷³European Communities' appellant's submission, para. 249 (referring to Panel Report, *US – Continued Suspension*, paras. 7.502 and 7.503; and Panel Report, *Canada – Continued Suspension*, paras. 7.474 and 7.475).

¹⁷⁴*Ibid.*, para. 249.

¹⁷⁵*Ibid.*, para. 250.

¹⁷⁶*Ibid.*, para. 251 (quoting Panel Report, *US – Continued Suspension*, para. 7.537; and Panel Report, *Canada – Continued Suspension*, para. 7.509).

¹⁷⁷*Ibid.*, para. 258.

¹⁷⁸*Ibid.*

¹⁷⁹*Ibid.*

¹⁸⁰*Ibid.*

79. The European Communities argues furthermore that the Panel reached the "manifestly unfounded"¹⁸¹ finding that the European Communities had not evaluated the specific risks to humans arising from the consumption of meat containing residues of oestradiol-17 β as a result of the cattle being treated with this hormone for growth-promotion purposes. In reaching this finding, the Panel incorrectly imposed a "specificity" or "direct causality"¹⁸² requirement pursuant to which the European Communities had to demonstrate *actual* adverse effects, rather than the *possibility* of adverse effects, contrary to the Appellate Body's findings in *EC – Hormones* and *Japan – Apples*.¹⁸³ In the European Communities' view, the Appellate Body's findings in these disputes did not prevent a Member from meeting the standard in Article 5.1 by demonstrating that the identified adverse effects may "*possibl[y]* arise from the residues in meat" and that "there is no need to demonstrate real causality" as the Panel in this dispute required.¹⁸⁴ Moreover, the European Communities notes that no country has conducted the kind of specificity test required by the Panel, and the European Communities cannot be found in violation of the *SPS Agreement* for failing to meet such a test. In addition, the Panel ignored the fact that three of the experts advising the Panel confirmed that the potential for adverse effects had been demonstrated by the European Communities. On this basis, the European Communities submits that the Panel ignored and "grossly misinterpreted" part of the relevant evidence in reaching this finding and failed to explain how its conclusions "have a reasonable relationship to the totality of the evidence".¹⁸⁵ As a result, the Panel exceeded the bounds of its discretion as the trier of facts in its assessment of the evidence, in violation of Article 11 of the DSU.

80. The European Communities submits that the Panel failed to interpret and apply correctly Article 5.1 of the *SPS Agreement* and failed to conduct an objective assessment of the matter as required by Article 11 of the DSU. Therefore, the European Communities requests the Appellate Body to reverse the Panel's findings under Article 5.1 of the *SPS Agreement*.

8. Article 5.7 of the *SPS Agreement*

81. The European Communities argues that the Panel erred in finding that the relevant scientific evidence on the five hormones was not "insufficient" within the meaning of Article 5.7 of the *SPS Agreement* and that, consequently, the provisional ban on the importation and marketing of meat

¹⁸¹European Communities' appellant's submission, para. 270.

¹⁸²*Ibid.*, para. 262.

¹⁸³*Ibid.*, para. 261 (referring to Panel Report, *US – Continued Suspension*, paras. 7.511 and 7.512; and Panel Report, *Canada – Continued Suspension*, paras. 7.483 and 7.484, in turn referring to Appellate Body Report, *EC – Hormones*, para. 200; and Appellate Body Report, *Japan – Apples*, para. 202 and footnote 372 thereto).

¹⁸⁴*Ibid.*, para. 261. (original emphasis)

¹⁸⁵*Ibid.*, para. 270.

from cattle treated with these five hormones does not meet the requirements of Article 5.7. The European Communities requests the Appellate Body to reverse this finding for the following reasons.

82. First, the European Communities argues that the Panel erred in its interpretation of Article 5.7 because it expressly rejected the relevance of the level of protection set by a Member for evaluating whether the scientific evidence is "insufficient" within the meaning of Article 5.7. The European Communities takes issue with the Panel's "sweeping statement"¹⁸⁶ that the "presumption of consistency of measures conforming to international standards", provided in Article 3.2 of the *SPS Agreement*, "implies that these standards ..., particularly those referred to in this case, are based on risk assessments that meet the requirements of the *SPS Agreement*."¹⁸⁷ According to the European Communities, the presumption of consistency that applies to measures conforming to international standards under Article 3.2 does not necessarily lead to the conclusion that the scientific evidence underlying the international standards is sufficient to conduct a risk assessment within the meaning of Article 5.1. This is because the international standard may not be based on a risk assessment at all, may be based on a risk assessment that is not informed by all factors listed in Articles 5.1 and 5.2, or the relevant evidence behind the international standard may be insufficient, or outdated, or no longer the mainstream scientific opinion.

83. The European Communities asserts that an international standard already "implies or encapsulates"¹⁸⁸ a certain level of protection. However, Article 3.3 of the *SPS Agreement* allows Members to adopt SPS measures that result in a higher level of protection than the one underlying an international standard. Consequently, the intended level of protection must be relevant for determining whether the scientific evidence is "insufficient" within the meaning of Article 5.7, and a Member that sets a higher level of protection may find the relevant scientific evidence underlying an international standard to be insufficient. The European Communities thus maintains that the Panel's approach entirely disconnected the sufficiency of the scientific evidence from the level of protection set by the European Communities, and this approach is contrary to the explicit wording of Article 3.3 and the views expressed by the experts it had selected. Referring to the distinction drawn by the Appellate Body in *Japan – Apples* between "scientific uncertainty" and "insufficiency of scientific evidence"¹⁸⁹, the European Communities notes that this distinction does not exclude that the insufficiency of the scientific evidence may be due to scientific uncertainty created by the existence of divergent minority opinions.

¹⁸⁶European Communities' appellant's submission, para. 388.

¹⁸⁷*Ibid.*, para. 387 (quoting Panel Report, *US – Continued Suspension*, para. 7.644; and Panel Report, *Canada – Continued Suspension*, para. 7.622).

¹⁸⁸*Ibid.*, para. 397.

¹⁸⁹*Ibid.*, paras. 377 and 378 (referring to Appellate Body Report, *Japan – Apples*, para. 184).

84. Secondly, the European Communities argues that the Panel erred in imposing on the European Communities the initial burden of demonstrating that Directive 2003/74/EC meets the requirements of Article 5.7 in relation to the provisional ban on the five hormones at issue. By imposing the burden of proof on the European Communities, the Panel "seem[ed]"¹⁹⁰ to have erroneously considered Article 5.7 as an exception to the rules laid down in Article 5.1, even though Article 5.7 confers to WTO Members a "qualified right"¹⁹¹ to take provisional measures under certain conditions. The European Communities maintains that Article 5.7 has "its own legal regime that is distinct from Article 5.1".¹⁹² This is because Article 2.2 of the *SPS Agreement* explicitly exempts measures taken under Article 5.7 from its scope of application, and Article 5.1, which is a specific application of the obligations in Article 2.2, cannot be applicable under the circumstances where Article 2.2 is not applicable. The European Communities recalls the Appellate Body's finding in *Japan – Apples* that a link exists between Articles 5.7 and 5.1 in that "relevant scientific evidence" will be "insufficient" within the meaning of Article 5.7 if the body of available scientific evidence does not allow the performance of an adequate assessment of risks as required under Article 5.1.¹⁹³ On this basis, the European Communities argues that "there is a continuum of 'relevant scientific evidence' that is divided between the respective scopes of application of Articles 5.1 and 5.7."¹⁹⁴ Therefore, a Member that is "sufficiently diligent ... must be able"¹⁹⁵ to take an SPS measure under either Article 5.1 or Article 5.7, and the sufficiency of the scientific evidence "is determinative on whether or not the measure concerned falls under Article 5.1 or 5.7".¹⁹⁶ Thus, the European Communities argues that, because it has a right to impose provisional measures when it considers that relevant scientific evidence is insufficient, the United States and Canada should bear the burden of demonstrating that this condition for applying provisional measures under Article 5.7 has not been fulfilled. Instead, the Panel erroneously shifted this burden to the European Communities when it limited its review exclusively to the "insufficiencies"¹⁹⁷ identified by the European Communities in its submissions. By requiring the European Communities to identify the issue for which relevant scientific evidence is insufficient, the Panel allocated to the European Communities the burden "to prove the negative".¹⁹⁸

¹⁹⁰European Communities' appellant's submission, para. 362.

¹⁹¹*Ibid.*, para. 368.

¹⁹²*Ibid.*, para. 367.

¹⁹³*Ibid.*, para. 371 (quoting Appellate Body Report, *Japan – Apples*, para. 179).

¹⁹⁴*Ibid.*, para. 374.

¹⁹⁵European Communities' statement at the oral hearing.

¹⁹⁶European Communities' appellant's submission, para. 374.

¹⁹⁷*Ibid.*, para. 380 (quoting Panel Report, *US – Continued Suspension*, para. 7.653; and Panel Report, *Canada – Continued Suspension*, para. 7.630).

¹⁹⁸*Ibid.*, para. 291.

85. Thirdly, the European Communities argues that the Panel erred in finding that, where international standards for a substance exist, a "critical mass" of new scientific evidence that calls into question the fundamental precepts of previous knowledge is required to render the relevant scientific evidence "insufficient" within the meaning of Article 5.7. The European Communities asserts that the "critical mass" standard developed by the Panel "imposed a high quantitative and qualitative threshold"¹⁹⁹ with respect to the new scientific evidence that is required to render prior scientific evidence insufficient. The European Communities submits that the quality of the scientific evidence is more important than the quantity. For this reason, even a single study made by qualified and respectable scientists, even when in the minority, could be considered *a priori* sufficient to question the sufficiency of the previous scientific evidence if its merits are particularly relevant for the circumstances of the risk assessment. According to the European Communities, the Panel's mistake stemmed from the erroneous premise of its analysis that the existence of an international standard presupposes that the scientific evidence has been sufficient to conduct a risk assessment. This error led the Panel to assume wrongly that a "critical mass" of new evidence is required to question the sufficiency of the scientific evidence and consequently to disregard "serious concerns"²⁰⁰ expressed by the experts in relation to the "fundamental scientific controversy"²⁰¹ concerning the risks to human health posed by the five hormones. The European Communities observes that the relevant question is not only whether relevant scientific evidence can "become" insufficient, but also whether it "is" insufficient in the first place.²⁰² Furthermore, the European Communities argues that the Panel's application of the "critical mass" standard excludes *a priori* the possibility of a WTO Member basing its risk assessment on a "respectable minority view".²⁰³ This effectively "preclude[d] [the] application"²⁰⁴ of the precautionary principle in the interpretation of Articles 5.1 and 5.7, contrary to the Appellate Body's finding that "the precautionary principle indeed finds reflection in Article 5.7 of the *SPS Agreement*."²⁰⁵ The European Communities explains that the Panel's "critical mass" standard implies that the scientific evidence passes immediately from a state of insufficiency to a state of complete knowledge, because there will be no "transitional period"²⁰⁶ in which Article 5.7 could apply.

86. The European Communities alleges that, in applying the "critical mass" standard to the evidence before it, the Panel "systematically downplay[ed]"²⁰⁷ and ignored "highly relevant scientific

¹⁹⁹European Communities' appellant's submission, para. 412.

²⁰⁰*Ibid.*, para. 421.

²⁰¹*Ibid.*, para. 426.

²⁰²*Ibid.*, para. 419.

²⁰³*Ibid.*, para. 409.

²⁰⁴*Ibid.*, para. 427.

²⁰⁵Appellate Body Report, *EC – Hormones*, para. 124.

²⁰⁶European Communities' statement at the oral hearing.

²⁰⁷European Communities' appellant's submission, para. 427.

evidence"²⁰⁸ which "support[ed] the position of the European Communities ... that in fact the scientific evidence was indeed insufficient"²⁰⁹ to perform a risk assessment. The European Communities challenges the Panel's analysis of the evidence on the following issues with respect to all five hormones: (i) effects of hormones on certain population groups; (ii) dose response; (iii) long latency periods for cancer and confounding factors; and (iv) adverse effects on human growth and reproduction.²¹⁰ In addition, the European Communities raises specific concerns relating to the Panel's application of the "critical mass" standard when it evaluated the sufficiency of the information individually for each of the five hormones.

87. As regards the Panel's finding that the scientific evidence on the effects of the five hormones on certain population groups was not "insufficient" within the meaning of Article 5.7, the European Communities argues that the Panel ignored Dr. Sippell's testimony that the development of more sensitive detection methods has identified lower endogenous hormonal levels in pre-pubertal children than previously thought, calling into question the range of physiological levels of sex hormones believed to exist in humans. According to the European Communities, the Panel downplayed the significance of this development by referring to Dr. Boobis' statement that such new detection methods were "not yet validated".²¹¹ In the area of dose response, the European Communities submits that the Panel Reports contain "no serious analysis"²¹² of this issue, and that the only basis articulated by the Panel in support of its conclusion was its prior finding that the ultra-sensitive detection methods had not yet been validated. The European Communities also suggests that the Panel ignored Dr. Cogliano's testimony confirming that the relevant scientific evidence was insufficient to conduct a risk assessment for all of the five hormones, because "you cannot estimate that dose-response curve with any kind of certainty."²¹³

88. In respect of the long latency period of cancer and the existence of confounding factors, the European Communities argues that the Panel's "critical mass" standard "essentially require[d] the European Communities to do the impossible"²¹⁴, because long latency periods for cancer and the existence of confounding factors do not permit the establishment of a causal link between the

²⁰⁸European Communities' appellant's submission, para. 447.

²⁰⁹*Ibid.*, para. 427.

²¹⁰In its appellant's submission, the European Communities also refers to the Panel's analysis concerning bioavailability. (European Communities' appellant's submission, paras. 179 and 432) However, at the oral hearing, the European Communities stated that this issue was not implicated in its appeal of the Panel's findings under Article 5.7.

²¹¹European Communities' appellant's submission, para. 430 (quoting Panel Report, *US – Continued Suspension*, para. 7.670; and Panel Report, *Canada – Continued Suspension*, para. 7.647).

²¹²*Ibid.*, para. 431.

²¹³*Ibid.*, para. 444 (quoting transcript of the Panel's joint meeting with the scientific experts on 27-28 September 2006, Panel Reports, Annex G, para. 871).

²¹⁴*Ibid.*, para. 433.

prevalence of cancer and the consumption of residues of the five hormones in meat. In order to establish such causal link, it would be necessary to conduct tests on humans by isolating them from the rest of the population "for years if not decades", which constitutes "an unrealistic requirement".²¹⁵

89. As for the evidence of adverse effects of the five hormones on human growth and reproduction, the European Communities argues that the Panel "systematically downplay[ed]"²¹⁶ the opinions of Drs. Sippell and Guttenplan in reaching its finding that the relevant scientific evidence was not "insufficient" within the meaning of Article 5.7. For the European Communities, "[t]he fact that the new evidence relates *inter alia* to children, the most vulnerable and sensitive part of the population, is a major concern for the European Communities" and this concern is "reinforced by the opinions expressed by Dr. Sippell and Dr. Guttenplan".²¹⁷ The European Communities additionally maintains that the Panel "arbitrarily"²¹⁸ gave a different status to the statements of different experts advising the Panel. For example, whereas Dr. Guttenplan's expression of concerns regarding potential developmental effects of hormones on children was characterized by the Panel as an expression of "doubts"²¹⁹, the opinion of Dr. Boobis that new evidence obtained by the European Communities did not indicate additional concern regarding risks of the five hormones was "manifestly given the status of scientific evidence".²²⁰

90. Turning to the Panel's assessment of each of the five hormones individually, the European Communities argues that the Panel ignored evidence demonstrating that progesterone and testosterone are carcinogenic to humans. Such evidence consisted of International Agency for Research on Cancer ("IARC") studies that concluded that progesterone is "possibly carcinogenic to humans"²²¹ and that testosterone is a "probable carcinogenic to humans".²²² The European Communities further submits that the Panel confused Articles 5.1 and 5.7 when it concluded that the IARC studies addressed the carcinogenicity of progesterone and testosterone in general, but did not specifically address the carcinogenic potential to humans of consuming residues of these hormones in meat. According to the European Communities, it is precisely because scientific evidence is lacking on this specific question that the European Communities decided to impose provisional restrictions on the basis of available pertinent information.

²¹⁵European Communities' appellant's submission, para. 434.

²¹⁶*Ibid.*, para. 435.

²¹⁷*Ibid.*, para. 436.

²¹⁸*Ibid.*

²¹⁹*Ibid.* (quoting Panel Report, *US – Continued Suspension*, para. 7.719; and Panel Report, *Canada – Continued Suspension*, para. 7.696).

²²⁰*Ibid.*, para. 436.

²²¹*Ibid.*, para. 437 (referring to Panel Report, *US – Continued Suspension*, para. 7.737; and Panel Report, *Canada – Continued Suspension*, para. 7.714, in turn referring to IARC written replies to Question 25 posed by the Panel, Panel Reports, Annex E-3, p. 129). (emphasis omitted)

²²²*Ibid.*, para. 438.

91. With respect to the Panel's finding that the relevant scientific evidence on trenbolone acetate was not "insufficient" within the meaning of Article 5.7, the European Communities argues that the Panel drew its conclusions exclusively on the basis of Dr. Boobis' opinion. The European Communities draws attention to Dr. Guttenplan's opinion that the scientific evidence showed that trenbolone acetate was "significantly estrogenic" and that it did not appear that "accurate ADIs [(acceptable daily intakes)] can be established at this point" for this substance.²²³ The Panel "attempt[ed] to downplay"²²⁴ this opinion of Dr. Guttenplan by referring to his statement that, although accurate acceptable daily intakes ("ADIs") cannot be established, a risk assessment can still be carried out. In the European Communities' view, the Panel failed to ascertain whether Dr. Guttenplan merely meant that the four steps of the JECFA risk assessment can be formally conducted or whether a risk assessment within the meaning of Article 5.1 of the *SPS Agreement* can be conducted, and that it was the latter that was relevant to the Panel's analysis.

92. As regards the Panel's finding that the relevant scientific evidence was not "insufficient" in relation to the carcinogenicity of zeranol, the European Communities argues that the Panel failed to take into account Dr. Guttenplan's testimony that "additional tests of zeranol should be carried out".²²⁵ The European Communities argues further that the Panel downplayed Dr. Sippell's concerns regarding the effects of zeranol in human breast cancer cells by relying, instead, on Dr. Boobis' opinion.

93. Moreover, the European Communities argues that the Panel concluded "in a sweeping manner"²²⁶ that the evidence on MGA was "sufficient" to conduct a risk assessment, because a process towards adopting an international standard for this hormone is underway in Codex. The European Communities also charges the Panel with downplaying the new studies the European Communities has conducted since 1999, even though the Panel recognized that the evaluation carried out by JECFA was based on studies that date back to the 1960s and 1970s. Furthermore, the European Communities criticizes the Panel for disregarding the opinion of Dr. De Brabander in relation to trenbolone acetate, zeranol, and MGA, which called into question residue levels estimated by JECFA and raised concerns regarding the potential effects of these hormones and their metabolites on the environment.

94. Finally, the European Communities asserts that the Panel failed to make an objective

²²³European Communities' appellant's submission, para. 439 (quoting Panel Report, *US – Continued Suspension*, para. 7.779; and Panel Report, *Canada – Continued Suspension*, para. 7.761).

²²⁴*Ibid.*, para. 440.

²²⁵*Ibid.*, para. 441 (quoting Panel Report, *US – Continued Suspension*, para. 7.797; and Panel Report, *Canada – Continued Suspension*, para. 7.781).

²²⁶*Ibid.*, para. 442.

assessment of the facts in reaching its findings under Article 5.7 of the *SPS Agreement*, in violation of Article 11 of the DSU. The European Communities underscores Dr. Cogliano's statement that "the data are not sufficient" to conduct a "low-dose prediction of risk at levels you might find in hormone-treated meat"²²⁷, and observes that this statement was not reflected in the Panel Reports. The European Communities argues that the Panel decided to accept only those expert opinions that it considered "acceptable", and in so doing the Panel "arbitrarily chose between different scientific opinions" instead of establishing whether the European Communities had "followed a scientifically plausible alternative" when adopting Directive 2003/74/EC and the Panel thus "failed to recognise the legal significance of a genuine scientific controversy".²²⁸ Consequently, the Panel found that the SCVPH Opinions "came to the wrong scientific conclusions"²²⁹, and thus conducted a *de novo* review of the facts, contrary to the requirements in Article 11 of the DSU to make an objective assessment of the facts, as reflected in the European Communities' risk assessment.

95. The European Communities submits that the Panel failed to interpret and apply correctly Article 5.7 of the *SPS Agreement* and failed to conduct an objective assessment of the matter as required by Article 11 of the DSU. Therefore, the European Communities requests the Appellate Body to reverse the Panel's findings under Article 5.7 of the *SPS Agreement*.

B. *Arguments of the United States – Appellee*

1. Procedural Issue – Public Observation of the Oral Hearing

96. The United States requests that the Appellate Body allow public observation of the oral hearing in these proceedings. The United States refers to the experience with open hearings at the panel stage and states that this development has been of great benefit to the WTO and the multilateral trading system. The United States explains that "[t]he ability of the public at large—e.g., representatives of civil society, such as NGOs, journalists, academics, and individual citizens—to observe dispute settlement hearings has helped foster greater confidence in the WTO dispute settlement system and the manner in which it operates."²³⁰ The United States also considers that the practice of having open panel meetings with the parties has served to strengthen the "legitimacy and credibility"²³¹ of the system and that this increased confidence in the dispute settlement process can translate into a greater acceptance of the outcome of the dispute settlement proceeding, with potential benefits in respect of implementation. In addition, the United States points out that the practice of

²²⁷European Communities' appellant's submission, para. 279 (quoting transcript of the Panel's joint meeting with the scientific experts on 27-28 September 2006, Panel Reports, Annex G, para. 871).

²²⁸*Ibid.*, para. 281.

²²⁹*Ibid.*, para. 282.

²³⁰United States' request for an open hearing, para. 5.

²³¹*Ibid.*

opening panel meetings with the parties has also been of great benefit to the governments of many WTO Members because "a significant number of delegates from WTO Members that were not parties to the dispute have taken advantage of the opportunity to attend an open panel meeting in order to follow a dispute more closely than they otherwise could."²³² The United States further notes that "opening meetings allows the WTO to compare more favourably to other international fora"²³³ and refers to the practice of many international tribunals. The United States observes that this dispute involves questions of human health and scientific judgements and therefore "provides a particularly strong example of public interest in WTO dispute settlement".²³⁴

97. In the United States' view, there is nothing in the DSU, the *Working Procedures* or the *Rules of Conduct* that addresses the issue of open hearings "directly".²³⁵ The United States does not consider that Article 17.10 precludes open appellate hearings. The United States argues that because there is no mention of an Appellate Body oral hearing in the DSU, "Article 17.10 cannot be directed at the question of whether such a hearing should be open or closed."²³⁶ The United States observes, in this regard, that third parties that were not third participants in both appeals in *US – Shrimp (Thailand)* and *US – Customs Bond Directive* were allowed to attend the consolidated oral hearing that was held for those appeals. The United States adds that "[s]omething similar appears to have occurred"²³⁷ in the *US – 1916 Act* appellate proceedings. The United States submits, furthermore, that "there is nothing in the DSU that authorizes a third party to observe any Appellate Body hearing" and that, "[i]f Article 17.10 required that the hearing be confidential, then the Appellate Body could not have permitted third parties to observe the hearing."²³⁸

98. According to the United States, Article 17.10 has not been interpreted as "literally requiring the confidentiality of Appellate Body hearings" because Appellate Body reports "routinely describe events at a hearing or even include quotations from the statements or answers to questions".²³⁹ Moreover, the United States notes that an Appellate Body report routinely discloses the arguments of the participants and third participants in their written submissions, and Notices of Appeal and of Other Appeal are always circulated as public WT/DS documents.

99. The United States also emphasizes that Article 17.10 must be read and applied in conjunction with Article 18.2 of the DSU. For the United States, the phrase "[n]othing in this Understanding" in

²³²United States' request for an open hearing, para. 6.

²³³*Ibid.*, para. 7.

²³⁴*Ibid.*, para. 13.

²³⁵*Ibid.*, para. 15.

²³⁶*Ibid.*, para. 17.

²³⁷*Ibid.*, para. 19.

²³⁸*Ibid.*, para. 20.

²³⁹*Ibid.*, para. 21.

Article 18.2 must be read to mean "that not even Article 17.10 could interfere with a party's right to disclose its own positions to the public, including statements made in the course of an Appellate Body hearing".²⁴⁰ The United States adds that if the statements and answers to questions can be made public by the participants, there is no reason why the parties cannot agree to have such statements and answers made public at the time they are uttered.

100. The United States alleges that it is not aware of anything in the negotiating history of the DSU that would suggest that parties could not agree to open an Appellate Body hearing to public observation. Nor does the United States consider that the *Working Procedures* require an oral hearing that is closed to the public. Furthermore, it does not see anything in the *Rules of Conduct* that would be an impediment to opening the hearing, because where parties agree to make their statements in the presence of the public, "there is no confidential information to be protected and no confidentiality of the proceedings to be maintained."²⁴¹ The United States clarifies that by authorizing the request of the participants, the Appellate Body "would not be prejudging"²⁴² the DSU review negotiations.

101. In response to the comments of the third participants, the United States refers to the Recommendations by the Preparatory Committee for the WTO.²⁴³ The United States asserts that the Recommendations indicate that the Preparatory Committee viewed Article 17.10 as focused on the deliberations of the Appellate Body and any confidential information submitted by the participants to an appeal. The United States also argues that the third participants that oppose the request to open the hearing fail to reconcile their understanding of the term "proceedings" with the fact that statements made at the oral hearing and responses to questions are routinely quoted and described in Appellate Body reports. Moreover, the United States points out that Article 18.2 refers to "statements of its own positions", which include responses to questions posed at the oral hearing, and does not impose a limitation on when the disclosure may occur. Finally, the United States rejects the argument that the Appellate Body may not consider the request to open the hearing because transparency is being discussed in the DSU review negotiations.

102. The United States therefore requests that the Appellate Body allow public observation of the oral hearing and discusses several modalities that could be used to accommodate any third participants wishing to maintain the confidentiality of their submissions. The United States, however,

²⁴⁰United States' request for an open hearing, para. 24. (emphasis omitted)

²⁴¹*Ibid.*, para. 26.

²⁴²*Ibid.*, para. 28.

²⁴³United States' comments on third participants' comments, paras. 5 and 6 (referring to Establishment of the Appellate Body: Recommendations by the Preparatory Committee for the WTO approved by the Dispute Settlement Body on 10 February 1995 (WT/DSB/1), para. 9).

indicates a preference for allowing public observation by means of closed-circuit simultaneous broadcast.

2. Articles 23.2(a) and 21.5 of the DSU

103. The United States submits that the Panel properly found that the phrase "recourse to dispute settlement" within the meaning of Article 23.2(a) of the DSU is not limited to an Article 21.5 panel proceeding and that Article 23.2(a) did not require the United States to initiate a compliance panel proceeding for purposes of examining the compatibility of Directive 2003/74/EC with the *SPS Agreement*.

104. The United States considers that the Panel's interpretation of the phrase "recourse to dispute settlement in accordance with [the DSU]" in Article 23.2(a) as encompassing all procedures under the DSU, rather than relating exclusively to an Article 21.5 panel proceeding, was "sensible and well supported"²⁴⁴ by the text of the DSU. The United States observes that Article 21.5 refers to "these dispute settlement procedures" without specifying any particular subset of the procedures provided in the DSU, and thus does not exclude any aspect of the DSU procedures.²⁴⁵ Moreover, in the United States' view, a complaining party always retains the option to initiate an ordinary panel proceeding to avoid the limitations on the scope of measures and claims that may be brought in an Article 21.5 proceeding. Therefore, the United States argues, Article 21.5 provides no contextual support for the European Communities' assertion that the phrase "rules and procedures of [the DSU]" in Article 23.2(a) refers exclusively to a panel operating under the jurisdictional limitations and accelerated timeframes provided for in Article 21.5. The United States contends that, unless the European Communities is suggesting that it would refuse to participate in any proceeding other than a compliance panel proceeding initiated by the United States to examine the consistency of Directive 2003/74/EC with the *SPS Agreement*, there is no reason to assume that an Article 21.5 proceeding is the only means by which the United States and the European Communities could reach a resolution of this dispute.

105. The United States disagrees with the European Communities' interpretation of the term "shall be decided" in Article 21.5 as indicating that "final" resolution results only from a panel proceeding. If that were the case, this dispute would have been finally resolved in 1998 with the adoption of the DSB's recommendations and rulings in *EC – Hormones*. The United States argues that the term "shall be decided" should not be read in such a restrictive way, because the goal of the DSU is to secure a positive resolution, and a mutually acceptable solution is preferable for achieving this goal. The

²⁴⁴United States' appellee's submission, para. 126.

²⁴⁵See *ibid.*, para. 127.

United States also disagrees with the European Communities' contention that the term "shall be decided" in Article 21.5 requires a decision by an adjudicative body. Rather, the use of the passive tense leaves open the question by whom a disagreement under Article 21.5 should be decided, and may include the parties, a regular panel, an arbitrator, or a mediator or other facilitator.

106. The United States submits that the European Communities' "frustrated experience as an original responding party"²⁴⁶ initiating an Article 21.5 proceeding in *EC – Bananas III (Article 21.5 – EC)* does not lead to the conclusion that such an approach is disallowed by the DSU. The United States argues that the European Communities "cannot have it both ways": insisting, in *EC – Bananas III (Article 21.5 – EC)*, upon the right to initiate an Article 21.5 proceeding when it "thought that avenue would be to its advantage", and now arguing that an original respondent is foreclosed from initiating an Article 21.5 proceeding.²⁴⁷ Moreover, the United States rejects the European Communities' claim that the fact that the panel report in *EC – Bananas III (Article 21.5 – EC)* was not adopted signifies certain "subsequent practice"²⁴⁸, noting that it was the European Communities itself that did not seek adoption of that report.²⁴⁹

107. For these reasons, the United States requests the Appellate Body to reject the European Communities' claim that Article 23.2(a) of the DSU required the United States to initiate an Article 21.5 panel proceeding for purposes of examining the WTO-consistency of Directive 2003/74/EC. The United States nevertheless observes that the Appellate Body need not address the European Communities' claims in this regard if it reverses the Panel's findings that the United States has acted inconsistently with Articles 23.1 and 23.2(a) of the DSU, as requested by the United States in its other appeal.²⁵⁰

3. Article 22.8 of the DSU

108. The United States maintains that the Panel correctly interpreted Article 22.8 of the DSU in finding that it requires not just the *pro forma* removal of the measure found to be inconsistent, but the achievement of actual compliance with the DSB's recommendations and rulings, before the application of the suspension of concessions must be terminated.

109. The United States alleges that, in replacing Directive 96/22/EC with Directive 2003/74/EC,

²⁴⁶United States' appellee's submission, para. 134.

²⁴⁷*Ibid.*

²⁴⁸*Ibid.*, para. 115 (quoting Article 31(3)(b) of the *Vienna Convention on the Law of Treaties* (the "*Vienna Convention*").

²⁴⁹*Ibid.*, para. 135.

²⁵⁰*Ibid.*, para. 125 (referring to United States' other appellant's submission, sections II and III). See also *infra*, paras. 188-194.

the European Communities simply switched the legal instruments underlying the import ban and, in so doing, failed to remove the inconsistent measure within the meaning of Article 22.8. The United States contends that the phrase "until such time as the measure found to be inconsistent with a covered agreement has been removed" in Article 22.8 requires the elimination of the WTO-inconsistency, that is, actual compliance. The United States notes that the ordinary meaning of "removed" is "lifted, taken away".²⁵¹ The United States explains that it is difficult to see how a WTO-inconsistent measure can be said to be taken away if an equivalent measure is put in its place. The United States further argues that the context provided by other provisions of the DSU—namely, Articles 21.1, 21.5, 22.1, and 22.2—confirm that it is actual compliance that is required by Article 22.8. These provisions indicate that the drafters of the DSU "contemplated that suspension of concessions and 'full implementation' were alternatives to one another".²⁵² The United States adds that interpreting Article 22.8 as requiring actual compliance is also supported by the purpose of the suspension of concessions, which is to induce compliance.

110. The United States rejects the European Communities' contention that Articles 21 and 22 of the DSU establish a "basic dichotomy" between "the measure found to be inconsistent" and the "measures taken to comply", arguing that the European Communities draws an "artificial distinction" between the "removal of a measure" and "existence or consistency" of a measure taken to comply.²⁵³ The United States draws attention to Article 3.7 of the DSU as reflecting the object and purpose of the DSU. Article 3.7 provides that "the first objective of the dispute settlement mechanism is usually to secure the withdrawal of the measures concerned", which the United States understands as referring "not to ... a mere repeal of a measure that is replaced by another, but ... instead to an actual elimination of the measure that brings about compliance".²⁵⁴ According to the United States, the removal of an inconsistent measure, accompanied by the taking of a measure that undermines such removal, results in the absence of a measure taken to comply.

111. Moreover, the United States disagrees with the European Communities' contention that Article 22.8 requires the suspension of concessions to be terminated "in the presence of an implementation [measure]" that has not yet been found to be WTO-inconsistent through Article 21.5

²⁵¹United States' appellee's submission, para. 102 (quoting *The New Shorter Oxford English Dictionary*, 4th edn, L. Brown (ed.) (Clarendon Press, 1993), Vol. 2, p. 2543).

²⁵²*Ibid.*, para. 103. (emphasis omitted)

²⁵³*Ibid.*, para. 104 (quoting European Communities' appellant's submission, paras. 136-142).

²⁵⁴*Ibid.*, para. 106. (emphasis omitted)

proceedings.²⁵⁵ The United States submits that this contention is not supported by Article 22.8, which does not state that the suspension of concessions shall only be applied "until the measure found to be inconsistent is *claimed* to have been removed".²⁵⁶ The United States also rejects the European Communities' argument that the Panel, in finding that Directive 96/22/EC was replaced by Directive 2003/74/EC, failed to consider that Directive 96/22/EC ceased to exist upon the adoption of Directive 2003/74/EC, and that the latter contains changes to the justification for the import restrictions imposed by the former. According to the United States, the Panel's approach was consistent with the Appellate Body's treatment in *EC – Hormones* of Directive 96/22/EC as a substitute for the previous Directives that had "ceased to exist" when they were replaced by Directive 96/22/EC, despite changes made by that Directive to the import restrictions imposed by the previous Directives.²⁵⁷

112. Furthermore, the United States alleges that the European Communities' logic, according to which an original complainant must terminate its suspension of concessions and initiate an Article 21.5 proceeding when an original respondent claims compliance, will lead to "a strange and absurd result".²⁵⁸ If the Article 21.5 panel concludes that compliance has not been achieved, there is neither a renewed reasonable period of time nor another opportunity to request authorization for the suspension of concessions.

113. On this basis, the United States requests the Appellate Body to reject the European Communities' appeal of the Panel's findings that Article 22.8 of the DSU requires the achievement of actual compliance with the DSB's recommendations and rulings before the application of the suspension of concessions must be terminated.

4. The Panel's Terms of Reference

114. The United States disagrees with the European Communities' claim that the Panel exceeded its terms of reference by assuming the powers of an Article 21.5 panel.

115. The United States observes that, pursuant to Article 7.1 of the DSU, a panel's standard terms of reference cover the matter referred to in the request for the establishment of a panel. The United

²⁵⁵United States' appellee's submission, para. 114 (referring to European Communities' appellant's submission, para. 98). As regards the European Communities' argument that it had suspended retaliatory action during the Article 21.5 proceedings in *US – FSC*, the United States contends that the European Communities continues to suspend concessions in *US – Offset Act (Byrd Amendment)* without initiating an Article 21.5 proceeding, even though the United States has notified the DSB of the repeal of the Continued Dumping and Subsidy Offset Act of 2000. (*Ibid.*)

²⁵⁶*Ibid.*, para. 115. (original emphasis)

²⁵⁷*Ibid.*, para. 111.

²⁵⁸*Ibid.*, para. 117.

States notes that, in its panel request, the European Communities specifically asked the Panel to consider its complaint with a view to finding that the United States had acted inconsistently with Article 22.8 of the DSU. Article 22.8 thus fell within the Panel's terms of reference, and the Panel was free to develop its own legal reasoning when addressing the claims raised by the European Communities under Article 22.8.

116. For the United States, the Panel's finding that the European Communities' claims under Article 22.8 were premised on the actual compliance of Directive 2003/74/EC with the *SPS Agreement* was based on a correct interpretation of Article 22.8 and was supported by the text, context, and object and purpose of the DSU. Furthermore, the United States rejects the European Communities' reference to the panel report in *EC – Sardines* as "inapposite", noting that, unlike in this dispute, following the order of analysis requested by the complainant in that dispute did not lead to an error of law.²⁵⁹

117. Accordingly, the United States requests the Appellate Body to reject the European Communities' assertion that the Panel exceeded its terms of reference under Articles 7 and 21.5 of the DSU by examining the compatibility of Directive 2003/74/EC with the *SPS Agreement*. The United States maintains that the Panel in fact limited its terms of reference improperly on the basis of the manner in which the European Communities presented its claims.²⁶⁰

5. The Panel's Suggestion for Implementation

118. The United States asserts that the Appellate Body should decline the European Communities' request to improve the Panel's suggestion for implementation. The United States disagrees with the European Communities' contention that "the Panel's suggestions require that the United States remove the suspension of concessions, and initiate and conclude an Article 21.5 compliance panel proceeding."²⁶¹ The United States underscores that, on the contrary, the Panel declined to suggest that the United States discontinue its suspension of concessions despite its finding that the United States has committed procedural violations under Articles 23.2(a) and 23.1 of the DSU. The United States considers that a suggestion on implementation is "inappropriate"²⁶², because it is for a WTO Member to decide on the steps needed to bring itself into conformity. In addition, the United States argues that the Appellate Body should reject the European Communities' request to improve the Panel's suggestion, because improvement of panels' suggestions is not within the Appellate Body's mandate,

²⁵⁹United States' appellee's submission, para. 122 (referring to European Communities' appellant's submission, para. 68, in turn referring to Panel Report, *EC – Sardines*, paras. 7.17 and 7.18).

²⁶⁰See also *infra*, para. 196.

²⁶¹United States' appellee's submission, para. 136. (footnote omitted)

²⁶²*Ibid.*, para. 139.

which is circumscribed by Articles 17.6 and 17.13 of the DSU. The United States observes that, in any event, the Appellate Body would not need to address this issue if it were to reverse the Panel's findings of procedural violations under Articles 23.1 and 23.2(a), as requested by the United States in its other appeal.

6. The Panel's Selection of Experts

119. The United States argues that the European Communities is "[r]ecycling yet another of its failed challenges from its appeal in *EC – Hormones*"²⁶³ by objecting to the expert selection process in its appeal. The United States explains that, in *EC – Hormones*, the Appellate Body found no fault with the panel because it had consulted with the parties regarding the selection of experts. The United States describes the steps taken by the Panel in this case to consult with the parties on expert selection, and concludes that 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. Moreover, the United States asserts that the Panel "obtain[ed] self-disclosure information from all of the experts, including from Dr. Boisseau".²⁶⁴

120. Noting the assertion by the European Communities that the relevant legal test was "likelihood or justifiable doubts" as to an expert's independence or impartiality, the United States argues that "[t]he fact of the matter is that the Panel and the parties were provided with full disclosure of the experts' professional affiliations and financial interests" and "[t]he record demonstrates that the Panel took the [European Communities'] concerns into account in concluding that the two experts in question were not disqualified from serving."²⁶⁵

121. The United States alleges that the European Communities provides no support for the claims regarding due process rights, arguing that the European Communities cited nothing more "than the most general statement" by the Appellate Body in *Thailand – H-Beams* and a judgment by the European Court of Human Rights that the European Communities "recycled from its challenge to the panel's expert selection process in *EC – Hormones*".²⁶⁶ In the United States' view, neither of those citations supports the European Communities' claim. Finally, to the extent the European Communities alleges a breach of Article 11 of the DSU, the United States argues that the Panel acted within the proper bounds of its discretion as fact-finder.

122. Consequently, the United States requests the Appellate Body to reject the European

²⁶³United States' appellee's submission, para. 83.

²⁶⁴*Ibid.*, para. 86. (footnote omitted)

²⁶⁵*Ibid.*, paras. 87 and 88.

²⁶⁶*Ibid.*, para. 89.

Communities' claim that the Panel acted inconsistently with the principle of due process, the requirements in the *Rules of Conduct*, and its duties under Article 11 of the DSU, in selecting Drs. Boisseau and Boobis, and to reject the request to reverse the Panel's findings that relied on the advice of these two experts.

7. Article 5.1 of the SPS Agreement

123. The United States argues that the Panel was correct in finding that the European Communities' permanent ban on meat and meat products from cattle treated with oestradiol-17 β for growth-promoting purposes was not based on a risk assessment within the meaning of Article 5.1 of the *SPS Agreement*. The United States requests the Appellate Body to dismiss the European Communities' appeal for the following reasons.

124. The United States rejects the European Communities' argument that the Panel erred by excluding, on an *a priori* basis, the European Communities' evidence regarding misuse and abuse in the administration of oestradiol-17 β . The United States considers that the "core"²⁶⁷ of the European Communities' argument is that, because misuse and abuse in the administration of oestradiol-17 β might occur one day, the European Communities is justified in banning oestradiol-17 β entirely. Contrary to the European Communities' argument, the Panel "fully appreciated"²⁶⁸ the significance of the European Communities' assertion that misuse and abuse in the administration of oestradiol-17 β can add to the risks identified in relation to this substance. However, the Panel correctly considered that additional risks arising from misuse and abuse would only be relevant for its analysis if the European Communities had succeeded in demonstrating that a specific risk arose from the consumption by humans of residues of oestradiol-17 β in meat. Hence, the United States asserts that, consistent with the Appellate Body's findings in *EC – Hormones*, the Panel did not *a priori* exclude misuse and abuse from the scope of application of Articles 5.1 and 5.2 of the *SPS Agreement*. Rather, the Panel acknowledged the fact that the European Communities had taken those factors into account, recognized that such factors were not relevant to the initial inquiry regarding whether a specific risk had been identified, and provided a detailed account of its reasoning.

125. The United States maintains further that the Panel correctly held that the European Communities had not evaluated specifically the risks arising from the consumption of meat and meat products containing residues of oestradiol-17 β as a result of cattle being treated with hormones for growth-promotion purposes. The Panel's examination of whether the European Communities had demonstrated the potential for adverse effects arising specifically from the presence of hormone

²⁶⁷United States' appellee's submission, para. 53.

²⁶⁸*Ibid.*, para. 54 (referring to European Communities' appellant's submission, paras. 319 and 331).

residues in meat was based on a "careful tracing"²⁶⁹ of the Appellate Body's interpretation of a "risk assessment" under Article 5.1, as defined by Annex A, paragraph 4, to the *SPS Agreement*. The United States rejects the European Communities' assertion that the Panel's articulation of the "specificity" test would require the demonstration of actual effects in humans. Rather, it is possible to perform tests on laboratory animals and extrapolate the results to human beings, and the European Communities recognizes that other countries have found ways to evaluate the possibility of adverse effects arising from the consumption by humans of hormone residues in meat by performing tests on laboratory animals. The United States also contends that "one expert's statement, divorced from the rest of the evidentiary record" is not sufficient to demonstrate that the European Communities has evaluated the specific risk arising from residues of oestradiol-17 β in meat.²⁷⁰ Instead, the evidentiary record supported the Panel's conclusion that the European Communities had identified only "general risks"²⁷¹ and had failed to address the specific risk as required by the *SPS Agreement*, that is, 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 β as a result of the cattle being treated with the hormone for growth promotion purposes."²⁷² The Panel's finding that the European Communities had failed to show the specificity required of a risk assessment resulted from an analytical process that was appropriately grounded in the precepts of scientific inquiry and prior Appellate Body reports.

126. In addition, the United States refutes the European Communities' argument that the Panel required the quantification of risks by focusing its inquiry on whether the European Communities had demonstrated the "potential occurrence of these adverse effects".²⁷³ According to the United States, the Panel did not preclude that a qualitative risk assessment could be sufficient for purposes of Article 5.1. Instead, the Panel's reference to "potential occurrence" of risks focused on whether the European Communities' risk assessment was "sufficiently specific to the case at hand".²⁷⁴ The United States asserts that the Panel's finding that the European Communities' risk assessment did not have the required specificity is a finding of fact, which the European Communities cannot succeed in

²⁶⁹United States' appellee's submission, para. 57.

²⁷⁰*Ibid.*, para. 60 (referring to European Communities' appellant's submission, para. 342, in turn referring to reply of Dr. Guttenplan to Question 13 posed by the Panel to the scientific experts, Panel Report, *US – Continued Suspension*, para. 7.523, and Panel Report, *Canada – Continued Suspension*, para. 7.495).

²⁷¹*Ibid.*, para. 61.

²⁷²*Ibid.*, para. 65 (quoting European Communities' appellant's submission, para. 344, in turn quoting Panel Report, *US – Continued Suspension*, para. 7.537 (emphasis added by the European Communities omitted)).

²⁷³*Ibid.*, para. 62 (quoting Panel Report, *US – Continued Suspension*, para. 7.521).

²⁷⁴*Ibid.*, para. 64 (quoting Appellate Body Report, *EC – Hormones*, para. 200).

disturbing on the basis of its allegation that the Panel imposed some kind of "quantification' requirement".²⁷⁵

127. The United States argues furthermore that the Panel did not err in allocating the burden of proof under Article 5.1 of the *SPS Agreement*. The Panel properly noted that "one of the particularities of this case"²⁷⁶ was that the European Communities' claim under Article 22.8 of the DSU was premised on the assertion by the European Communities that it had brought itself into conformity with the *SPS Agreement* through Directive 2003/74/EC. For this reason, and taking into account the European Communities' concern that it should not be required to "prove a negative", the Panel was justified in allocating to the European Communities the burden of establishing a *prima facie* case of conformity with the *SPS Agreement*, including Article 5.1 of that Agreement. Once the Panel found that the European Communities had established such a *prima facie* case, the burden of proof shifted to the United States. The Panel then rightly found that the United States had rebutted the European Communities' *prima facie* case of consistency through positive evidence of breach of the *SPS Agreement*. The United States agrees with the Panel's finding that, consistent with the "particularities"²⁷⁷ of the European Communities' claim under Article 22.8, "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."²⁷⁸ The United States further agrees with the Panel's approach that it would "weigh all the evidence before it"²⁷⁹ in considering whether an allegation had been proven. In so doing, the Panel did not state or consider that it had placed the burden of proof on the European Communities.

128. The United States argues that the Panel did not fail to conduct an objective assessment of the matter, as required by Article 11 of the DSU, in reaching its finding that the European Communities' permanent ban on oestradiol-17 β was not based on a risk assessment within the meaning of Article 5.1. According to the United States, the more deferential "reasonableness"²⁸⁰ standard that the European Communities posits should apply to "measures adopted by governments or specialised agencies in highly complex or technical matters"²⁸¹ finds no support in the text of the *SPS Agreement*. This Agreement "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

²⁷⁵United States' appellee's submission, para. 66.

²⁷⁶*Ibid.*, para. 93 (quoting Panel Report, *US – Continued Suspension*, para. 7.384).

²⁷⁷*Ibid.*, para. 94.

²⁷⁸*Ibid.* (referring to Panel Report, *US – Continued Suspension*, para. 7.386).

²⁷⁹*Ibid.* (quoting Panel Report, *US – Continued Suspension*, para. 7.386). (emphasis omitted)

²⁸⁰*Ibid.*, para. 36 (referring to European Communities' appellant's submission, para. 223).

²⁸¹*Ibid.*, para. 37 (quoting European Communities' appellant's submission, para. 223).

authority".²⁸² Moreover, the United States recalls that the Appellate Body rejected the European Communities' attempt to introduce a "deferential 'reasonableness' standard" in *EC – Hormones*, finding that "[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 WTO Members and the jurisdictional competences retained by Members for themselves.²⁸³

129. The United States additionally rejects the European Communities' argument that panels must apply the "generally applicable standard of review"²⁸⁴ differently, depending upon the specific provision of the *SPS Agreement* that is being applied to the facts. The United States recalls the standard of review proposed by the European Communities for a claim arising under Article 5.1 of the *SPS Agreement*, according to which a panel must defer to a Member's risk assessment "if the evidence before the panel provides for at least one scientifically plausible set of conclusions under which an adverse effect might occur."²⁸⁵ In the United States' view, the European Communities' formulation has no support in the covered agreements and "conflates the concept of 'standard of review' and the application of law to facts".²⁸⁶ On this basis, the United States submits that the standards of review proposed by the European Communities "are products of [its own] wishful thinking and find no support in the DSU, the *SPS Agreement*, or the findings of the Appellate Body".²⁸⁷

130. The United States observes that the Appellate Body has consistently held that the standard of review to be applied by panels to their fact-finding in SPS disputes is "neither *de novo* review, as such, nor 'total deference', but rather the 'objective assessment of the facts'".²⁸⁸ The United States emphasizes that 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.²⁸⁹ This requires "more than just an error of judgement in the appreciation of evidence, but rather an 'egregious error that calls into question the good faith of a panel'".²⁹⁰ Moreover, panels "enjoy a 'margin of discretion' as triers of fact" and are "not required to accord to factual evidence of

²⁸²United States' appellee's submission, para. 34 (referring to Appellate Body Report, *EC – Hormones*, paras. 114-116).

²⁸³*Ibid.*, para. 37 (quoting Appellate Body Report, *EC – Hormones*, para. 115).

²⁸⁴*Ibid.*, para. 38.

²⁸⁵*Ibid.*, para. 38 (quoting European Communities' appellant's submission, para. 229).

²⁸⁶*Ibid.*, para. 39.

²⁸⁷*Ibid.*, para. 39.

²⁸⁸*Ibid.*, para. 40 (quoting Appellate Body Report, *EC – Hormones*, para. 117).

²⁸⁹*Ibid.*, para. 41 (quoting Appellate Body Report, *EC – Hormones*, para. 133).

²⁹⁰*Ibid.*, para. 41 (quoting Appellate Body Report, *EC – Hormones*, para. 133).

the parties the same meaning and weight as do the parties", and may properly "determine that certain elements of evidence should be accorded more weight than other elements".²⁹¹

131. The United States rejects the European Communities' contention that the Panel exceeded the bounds of its discretion under Article 11 of the DSU in its appreciation of the evidence. The Panel's statement that "its situation [was] similar"²⁹² to that of a risk assessor does not support the European Communities' allegation that the Panel impermissibly conducted a *de novo* review. Rather, the Panel considered itself to be in a situation "similar" to that of a risk assessor insofar as it would benefit from hearing a full spectrum of scientific experts to obtain a complete picture of both mainstream and divergent scientific views.²⁹³ The United States also dismisses the European Communities' allegation that the Panel exceeded the bounds of its discretion in choosing to rely on the views expressed by the "majority of experts", or on the "most specific" or "best supported" view.²⁹⁴ The United States asserts that the Panel's exercise of judgement in evaluating the evidence was "part and parcel of the Panel's duty to make an objective assessment of the facts".²⁹⁵ Moreover, the Panel could not have realistically referred to all statements made by the experts advising it and should have had a substantial margin of discretion as to which statements to refer to explicitly. The United States submits that the Panel's findings in relation to: (i) exposure to hormones from multiple sources; (ii) the genotoxicity of oestradiol-17 β ; (iii) the specificity of the risk assessment; and (iv) the role of misuse and abuse of hormones as factors in a risk assessment were all within the bounds of its discretion as the trier of facts and should therefore be upheld by the Appellate Body.

132. The United States additionally contends that the European Communities' challenges raised under Article 11 of the DSU to the Panel's fact-finding appear 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. However, no such claim of error under Article 12.7 has been made by the European Communities on appeal. For this reason, to the extent that the European Communities' challenges raised under Article 11 should properly have been raised under Article 12.7 instead, those claims should be disregarded as not properly subject to review by the Appellate Body.

²⁹¹United States' appellee's submission, para. 42 (quoting Appellate Body Report, *Japan – Apples*, para. 221, in turn quoting Appellate Body Report, *EC – Asbestos*, para. 161, and Appellate Body Report, *Australia – Salmon*, para. 267).

²⁹²*Ibid.*, para. 44 (quoting Panel Report, *US – Continued Suspension*, para. 7.418).

²⁹³*Ibid.*, para. 44.

²⁹⁴Panel Report, *US – Continued Suspension*, para. 7.420; Panel Report, *Canada – Continued Suspension*, para. 7.411.

²⁹⁵United States' appellee's submission, para. 47.

133. The United States concludes that the Panel did not err in finding that Directive 2003/74/EC is inconsistent with Article 5.1 of the *SPS Agreement*, and requests the Appellate Body to reject the European Communities' appeal concerning the Panel's findings.

8. Article 5.7 of the *SPS Agreement*

134. The United States argues that the Panel correctly found that the relevant scientific evidence on the five hormones subject to the provisional ban was not "insufficient" within the meaning of Article 5.7 of the *SPS Agreement*. The United States requests the Appellate Body to dismiss this ground of the European Communities' appeal for the following reasons.

135. The United States argues that the Panel correctly interpreted Article 5.7, taking account of the context provided by Articles 3.2 and 3.3 of the *SPS Agreement*. The United States recalls that, pursuant to Article 3.2, a measure conforming to an international standard shall be deemed to be consistent with the relevant provisions of the *SPS Agreement*. Thus, the Panel was justified in finding that the existence of international standards demonstrated that there had been sufficient scientific evidence to conduct a risk assessment within the meaning of Article 5.1. Indeed, it would not make sense that the *SPS Agreement* 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 proper risk assessment. In any event, the United States charges the European Communities with failing to take into account that, "in this case, the international standards for the hormones in question are unquestionably supported by proper risk assessments."²⁹⁶

136. The United States contends furthermore that the European Communities' desired level of SPS protection was irrelevant for the Panel's determination of whether the scientific evidence was "insufficient" within the meaning of Article 5.7. First, the United States submits that the European Communities had failed to show that its appropriate level of protection is different from the level of protection that the Codex standards are designed to achieve. Secondly, the United States notes that a risk assessment is a scientific process aimed at identifying whether a risk exists, and risk assessors "need not have any particular level of protection in mind in conducting the risk assessment".²⁹⁷ Therefore, the question of whether the relevant scientific evidence is "insufficient" within the meaning of Article 5.7 is a matter entirely separate "from the 'appropriate level of [SPS] protection'"²⁹⁸ that a Member chooses to set. In addition, the United States considers remarkable the European Communities' statement that "[s]cience is essentially about measuring past fact and hypothesizing

²⁹⁶United States' appellee's submission, para. 70. (original emphasis)

²⁹⁷*Ibid.*, para. 72.

²⁹⁸*Ibid.*, para. 73.

about the future, including postulating about future risk."²⁹⁹ The United States argues that this statement reveals the European Communities' "fundamental misunderstanding of science", because the scientific method is about "rigorously testing a hypothesis using experimentation rather than 'measuring past fact' or 'hypothesizing about the future'".³⁰⁰

137. The United States maintains that the Panel did not err in finding that a "critical mass of new evidence" is required to render previously sufficient scientific evidence "insufficient" within the meaning of Article 5.7. The United States observes that the Panel did not impose a quantitative requirement by referring to the "critical mass" of new evidence. Instead, the Panel used this 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", such that new scientific information is "at the origin of a change in the understanding of a scientific issue".³⁰¹ The United States points out that the five hormones subject to the provisional ban had been studied intensively for decades and the international standards for four of them had existed for over 20 years. The United States additionally recalls that, in *EC – Hormones*, the European Communities argued that the scientific evidence concerning the same five hormones 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."³⁰² Under these circumstances, it was "appropriate" for the Panel to focus on the question of "whether relevant scientific evidence had *become* insufficient".³⁰³ The United States adds that there was "plentiful" evidence in the record demonstrating that the relevant scientific evidence "[was] and remains sufficient" to conduct a risk assessment for the five hormones.³⁰⁴

138. The United States asserts that the Panel correctly allocated the burden of proof in its analysis under Article 5.7. As it argues in respect of Article 5.1³⁰⁵, the United States submits that the Panel properly noted that "one of the particularities of this case"³⁰⁶ was that the European Communities' claim under Article 22.8 of the DSU was premised on an assertion by the European Communities that it had brought itself into conformity with the *SPS Agreement* through the adoption of Directive 2003/74/EC. For this reason, and taking into account the European Communities' concern that it should not be required to "prove a negative", the Panel was justified in allocating on the

²⁹⁹United States' appellee's submission, para. 74 (quoting European Communities' appellant's submission, para. 398).

³⁰⁰*Ibid.*, para. 74.

³⁰¹*Ibid.*, para. 78 (quoting Panel Report, *US – Continued Suspension*, para. 6.141). (emphasis omitted)

³⁰²*Ibid.*, para. 80 (quoting Panel Report, *EC – Hormones (US)*, para. 4.239).

³⁰³*Ibid.* (original emphasis)

³⁰⁴*Ibid.*, para. 81.

³⁰⁵See *supra*, para. 127.

³⁰⁶United States' appellee's submission, para. 93 (quoting Panel Report, *US – Continued Suspension*, para. 7.384; and Panel Report, *Canada – Continued Suspension*, para. 7.381).

European Communities the burden of establishing a *prima facie* case of conformity with the *SPS Agreement*, including with Article 5.7 of that Agreement. The United States agrees with the Panel 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."³⁰⁷ The United States further agrees with the Panel's approach that it would "weigh all the evidence before it"³⁰⁸ in considering whether an allegation had been proved. Furthermore, the United States observes that "the Panel did not state or consider that it had placed the burden of proof on the [European Communities]."³⁰⁹ Thus, the United States dismisses as "speculation"³¹⁰ the European Communities' assertion that the Panel treated Article 5.7 as an exception to Article 5.1.

139. Finally, the United States argues that the Panel did not fail to conduct an objective assessment of the facts as required by Article 11 of the DSU in reaching its findings under Article 5.7 of the *SPS Agreement*. As noted earlier³¹¹, the United States argues that the "reasonableness approach"³¹² that the European Communities posits should apply to "measures adopted by governments or specialised agencies in highly complex or technical matters"³¹³ has no support in the text of the *SPS Agreement*. Moreover, the United States submits that the Panel did not conduct a *de novo* review and, instead, acted within the bounds of its discretion by attributing to the different pieces of evidence a different weight and significance than that attributed by the European Communities.³¹⁴ As regards certain statements by the experts concerning the "sufficiency" of the relevant scientific evidence on which the European Communities relies, the United States asserts that these 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".³¹⁵ According to the United States, the experts were not instructed to limit their remarks to certain hormones and, in fact, the statements of the experts quoted by the European Communities either explicitly addressed oestradiol-17 β or did not specify to which of the hormones the experts' statements made reference.³¹⁶ The United States reiterates that "there was plentiful evidence in the record demonstrating that the relevant scientific

³⁰⁷United States' appellee's submission, para. 94 (referring to Panel Report, *US – Continued Suspension*, para. 7.386).

³⁰⁸*Ibid.* (quoting Panel Report, *US – Continued Suspension*, para. 7.386; and Panel Report, *Canada – Continued Suspension*, para. 7.383). (emphasis omitted)

³⁰⁹*Ibid.*, para. 96.

³¹⁰*Ibid.*

³¹¹See *supra*, para. 128.

³¹²United States' appellee's submission, para. 37 (referring to European Communities' appellant's submission, para. 223).

³¹³*Ibid.* (quoting European Communities' appellant's submission, para. 223).

³¹⁴See *supra*, paras. 130 and 131.

³¹⁵United States' appellee's submission, para. 81.

³¹⁶*Ibid.* (referring to statements by Drs. Sippell, Guttenplan, Cogliano, and Boisseau, quoted in European Communities' appellant's submission, paras. 422, 423, 424, and 425, respectively).

evidence"³¹⁷ remains sufficient to conduct a risk assessment for these five hormones, including statements by the experts acknowledging that the data were sufficient to conduct risk assessments for the five hormones subject to the provisional ban. Thus, the United States concludes that the Panel's consideration of whether there was a "'critical mass of new evidence' was proper and well-supported".³¹⁸ Finally, the United States maintains that, to the extent the European Communities' challenges raised under Article 11 of the DSU "should properly have been raised under [Article 12.7 of the DSU] instead, those claims should be disregarded as not properly subject to review by the Appellate Body."³¹⁹

140. The United States concludes that the Panel did not err in finding that Directive 2003/74/EC is inconsistent with Article 5.7 of the *SPS Agreement*, and requests the Appellate Body to reject the European Communities' appeal concerning the Panel's findings.

C. *Arguments of Canada – Appellee*

1. Procedural Issue – Public Observation of the Oral Hearing

141. Canada requests that the Appellate Body open the hearing in these proceedings to public observation. Canada observes that, if "[r]ead out of context", the first sentence of Article 17.10 "may appear to require closed oral hearings before the Appellate Body".³²⁰ However, Canada argues that when the key terms of the sentence—"proceedings" and "confidential"—are properly interpreted in accordance with the customary rules of treaty interpretation, in the context of the entire DSU and, in particular, Article 17 itself, it can be seen that the sentence does not, and was not intended to, operate as a bar to open hearings.

142. In Canada's submission, the term "proceedings" in Article 17.10 "encompasses the entire appellate process".³²¹ As regards the term "confidential", Canada states that an examination of the context of Article 17.10 and the practice of WTO dispute settlement demonstrates that this provision does not require that the entire appellate process must remain strictly secret and out of the public's knowledge. Canada adds that if Article 17.10 required absolute confidentiality, then all of the steps within an appeal would have to remain out of the public knowledge, including the initial Notice of Appeal and the final Appellate Body report. However, both of these documents are made public upon

³¹⁷United States' appellee's submission, para. 81 (referring to comments by the United States on the replies of the scientific experts, Codex, JECFA, and IARC to questions posed by the Panel, Panel Reports, Annex F, paras. 47 and 48).

³¹⁸*Ibid.*, para. 82.

³¹⁹*Ibid.*, para. 49.

³²⁰Canada's request for an open hearing, para. 4.

³²¹*Ibid.*, para. 5.

circulation. Moreover, Appellate Body reports, which are made public, include summaries of the participants' written submissions and refer to the participants' arguments made during the oral hearing. Canada thus concludes that many aspects of the Appellate Body's proceedings during the "substantive portion"³²² of the appellate process are actually revealed to the public and are not subject to confidentiality under Article 17.10.

143. Canada also draws attention to Article 18.2 of the DSU, which "permits parties to reveal their positions to the public".³²³ Canada asserts that, "[a]s was recognized by the Panel, all three parties, by making a unanimous request for a public oral hearing in these two parallel appeals, are relying on their right, stated in ... Article 18.2, to make their oral arguments public."³²⁴ Canada adds that Article 18.2 does not prescribe a specific means of making a party's arguments public and, consequently, it does not matter whether such right is exercised after the oral hearing or contemporaneously with the oral hearing.

144. Canada submits that the *Rules of Conduct* "do not present an obstacle"³²⁵ to the Appellate Body holding open hearings. Furthermore, Canada considers that, under Rule 16(1) of the *Working Procedures*, "[t]he Appellate Body has discretion ... to respond favourably to the unanimous request by all three parties to the appeal in this case and to open the oral hearing to the public."³²⁶

145. Canada additionally asserts that open hearings are an important contribution to the legitimacy and the perception of legitimacy of the WTO dispute settlement system. Canada cautions that "[t]he legitimacy of the WTO dispute settlement system would suffer if the oral hearing at the appellate level were to be closed while at the panel stage the hearings were open."³²⁷

146. In response to the comments of the third participants, Canada asserts that the third participants that oppose the request to open the hearing seek to divorce the term "proceedings" from its context and ignore the meaning of "confidential" altogether.³²⁸ Canada further notes that, given the entitlement of parties under Article 18.2 to disclose their written submissions, oral statements, and answers to questions, "it would be absurd to find that where those parties agree that they wish to present their positions at an appellate hearing in open session, they may not do so."³²⁹ Canada also objects to the argument that the Appellate Body's decision on this issue would prejudice the outcome

³²²Canada's request for an open hearing, para. 7.

³²³*Ibid.*, para. 9.

³²⁴*Ibid.*, para. 14.

³²⁵*Ibid.*, para. 15.

³²⁶*Ibid.*, para. 19.

³²⁷*Ibid.*, para. 24.

³²⁸Canada's comments on third participants' comments, para. 8.

³²⁹*Ibid.*, para. 10.

of the DSU review negotiations. This argument, according to Canada, misconstrues the nature and scope of the participants' request, because they are not asking the Appellate Body to decide that all appellate hearings must be open to the public. Canada observes, moreover, that the argument is premised on the incorrect notion that "whenever a matter in dispute settlement is or might be the subject of negotiations among the membership, panels and the Appellate Body should decline to consider the matter lest it 'prejudge' the outcome of the negotiations."³³⁰

147. Accordingly, Canada requests that the Appellate Body allow public observation of the hearing in these proceedings. Canada states that, in order to accommodate any third participants wishing to retain the confidentiality of their oral submissions, a "practical solution" would be to have "a video link between the room in which the oral hearing takes place and a second room in which the public can watch the oral hearing"³³¹ and to interrupt the broadcast if a third participant so wishes.

2. Articles 23.2(a) and 21.5 of the DSU

148. Canada submits that the Panel correctly found that "recourse to dispute settlement" within the meaning of Article 23.2(a) of the DSU is not limited to Article 21.5 panel proceedings and that Articles 21.5, 23.1, and 23.2(a) did not require Canada to initiate a compliance panel proceeding for purposes of examining the compatibility of Directive 2003/74/EC with the *SPS Agreement*.

149. According to Canada, the European Communities' characterization of this dispute as a "disagreement as to the existence or consistency with a covered agreement of measures taken to comply", within the meaning of Article 21.5, "ignores ... that the essence of this dispute is not specifically about a 'disagreement' over the [European Communities'] alleged compliance measure".³³² Rather, Canada argues that Article 22.8 is the provision of the DSU that specifically applies to the post-retaliation stage and that it is for the European Communities, as the party seeking termination of the suspension of concessions, to demonstrate that it has removed its WTO-inconsistent measure within the meaning of Article 22.8. Canada maintains that the European Communities' unilateral assertion of compliance by virtue of Directive 2003/74/EC does not compel Canada to initiate an Article 21.5 proceeding, and does not require Canada to lift the suspension of concessions. Canada submits that to allow a unilateral declaration of compliance to displace the multilateral authorization to suspend concessions "would contravene the very rule against unilateralism that the [European Communities] accuses Canada of breaching".³³³

³³⁰Canada's comments on third participants' comments, para. 15.

³³¹Canada's request for an open hearing, para. 29.

³³²Canada's appellee's submission, paras. 7 (referring to European Communities' appellant's submission, para. 49) and 8.

³³³*Ibid.*, para. 9.

150. Canada further submits that the European Communities has the option of initiating an Article 21.5 proceeding itself. This is confirmed by the fact that the panel in *EC – Bananas III (Article 21.5 – EC)* did not decline jurisdiction, even though the proceeding was initiated by the European Communities, the respondent in the original proceedings. Canada recalls that the panel report in *EC – Bananas III (Article 21.5 – EC)* was not adopted because the European Communities, the only party that participated in that proceeding, did not request its adoption. Consequently, the European Communities' assertion that "subsequent practice" confirms that Article 21.5 panel proceedings may not be initiated by the original respondent "is without any foundation".³³⁴ Canada disagrees with the European Communities' argument that the panel's inability to compel other parties to participate in *EC – Bananas (Article 21.5 – EC)* shows why an original respondent may not initiate Article 21.5 proceedings, because "no panel can ever compel a party to a dispute to appear"³³⁵ in any panel proceeding.

151. Canada asserts that the Panel correctly found that, while recourse to an Article 21.5 panel was one of the procedural mechanisms available to the European Communities to demonstrate that it had "removed" its WTO-inconsistent measure and obtain the termination of Canada's suspension of concessions, the European Communities had several other procedural avenues available to it. These include good offices and consultations, arbitration under Article 25 of the DSU, and recourse to a panel *de novo*. The availability of a new panel proceeding is demonstrated by the fact that the European Communities initiated the present dispute and put the issue of whether Directive 2003/74/EC had brought it into compliance "squarely before the Panel"³³⁶ through its conditional claims. Thus, contrary to the European Communities' assertion that an Article 21.5 panel proceeding is the only procedure providing finality to the dispute, the fact that the European Communities put the issue of actual compliance "squarely" before the Panel in this case demonstrates its own belief that the Panel was in a position to adjudicate "the central matter at issue" in this dispute.³³⁷

152. On this basis, Canada requests the Appellate Body to reject the European Communities' appeal regarding the Panel's finding that Articles 21.5 and 23.2(a) did not require Canada to initiate an Article 21.5 panel proceeding for purposes of examining the WTO-consistency of Directive 2003/74/EC.

³³⁴Canada's appellee's submission, para. 11 (referring to the European Communities' appellant's submission, para. 91).

³³⁵*Ibid.*, para. 12.

³³⁶*Ibid.*, para. 15.

³³⁷*Ibid.*, para. 15.

3. Article 22.8 of the DSU

153. Canada argues that, contrary to the European Communities' claims, the Panel correctly interpreted Article 22.8 of the DSU by concluding that the phrase "until such time as the measure found to be inconsistent with a covered agreement has been removed" means that the illegality itself must be removed, and not only the originally impugned measure.

154. According to Canada, the European Communities "advocates an overly narrow and formalistic interpretation that fails to situate Article 22.8 in its proper context"³³⁸ when arguing that the "mere existence"³³⁹ of an implementing measure and its subsequent notification would be enough to satisfy the requirement under Article 22.8 that the WTO-inconsistent measure is removed. In contrast, the Panel properly took into account the context of Article 22.8 when finding that the removal of the inconsistent measure, under the first scenario in Article 22.8, required actual compliance with the DSB's recommendations and rulings before the suspension of concessions could be terminated. Canada maintains that the second and third scenarios requiring termination of the suspension of concessions under Article 22.8 "contemplate situations where the issue of the nullification or impairment caused by ... non-compliance with [the covered agreements] has been satisfactorily addressed".³⁴⁰ Furthermore, Canada asserts that the Panel correctly found that the ongoing surveillance by the DSB of the implementation of the recommendations and rulings, as provided in the second sentence of Article 22.8, was intended to ensure that Members fully implement the DSB's recommendations and rulings. Canada also submits that surveillance by the DSB would be rendered meaningless if its role were to be reduced to one of a passive observer that would "simply take note of the 'existence' of an alleged implementing measure, without ensuring that its recommendations and rulings have indeed been implemented".³⁴¹ Canada adds that the Panel's interpretation was also consistent with the principle of "prompt" compliance with the DSB's recommendations and rulings expressed in Articles 21.1 and 3.2 of the DSU.

155. Canada further submits that the Panel's interpretation of Article 22.8 was consistent with the object and purpose of the DSU to provide security and predictability to the multilateral trading system as set forth in Article 3.2. This is because, in Canada's view, "Article 22.8 is the linchpin for ensuring that the suspension of concessions achieves the objective of inducing full compliance"³⁴², and Article 22.8 should not be interpreted so narrowly as to weaken the effectiveness of the suspension of concessions. Canada contends that the interpretation of Article 22.8 advocated by the European

³³⁸Canada's appellee's submission, para. 21.

³³⁹*Ibid.*, para. 18 (quoting European Communities' appellant's submission, para. 101).

³⁴⁰*Ibid.*, para. 25.

³⁴¹*Ibid.*, para. 26.

³⁴²*Ibid.*, para. 33.

Communities would require the immediate termination of Canada's suspension of concessions upon the mere unverified assertion and unilateral declaration of compliance with the DSB's recommendations and rulings and would require "the initiation by Canada of new litigation" in order not to "displace Canada's multilaterally authorized suspension of concessions".³⁴³ If it is eventually established that the alleged implementing measure does not comply with the DSB's recommendations and rulings, the Member seeking compliance "will continue to suffer, without any relief, the nullification or impairment caused by the failure of the non-compliant Member to bring itself into compliance".³⁴⁴ Thus, Canada argues, the interpretation of Article 22.8 advocated by the European Communities should be rejected in order to avoid "a cycle of 'recurrent litigation'".³⁴⁵

156. Canada therefore requests the Appellate Body to reject the European Communities' appeal of the Panel's finding that Article 22.8 of the DSU requires actual compliance with the DSB's recommendations and rulings before the suspension of concessions must be terminated.

4. The Panel's Terms of Reference

157. Canada contends that the European Communities' claim that the Panel exceeded its terms of reference when it assumed a role similar to that of a compliance panel confuses the issue of the Panel's jurisdiction with the issue of the sequence of the European Communities' claims. Canada notes that, under its alternative and conditional claim, the European Communities implicitly acknowledged that the Panel had jurisdiction to examine the compatibility of Directive 2003/74/EC with the *SPS Agreement*. Thus, the real contention underlying the European Communities' claim that the Panel exceeded its terms of reference is not that the Panel improperly examined the consistency of Directive 2003/73/EC with the *SPS Agreement*, but, rather, that the Panel did so in addressing the European Communities' second series of main claims.

158. Canada maintains that the Panel correctly found that it had no choice but to review the consistency of Directive 2003/74/EC with the *SPS Agreement*, because the presumption of good faith compliance, which the European Communities relied upon in making its second series of main claims, was rebuttable by Canada. Canada recalls the Panel's observation that its examination of Directive 2003/74/EC under the *SPS Agreement* was "not the result of ... disregarding the order in which"³⁴⁶ the European Communities presented its claims, but was done for the purpose of addressing the European Communities' second series of main claims under Articles 23.1, 22.8, and 3.7 of the

³⁴³Canada's appellee's submission, para. 34.

³⁴⁴*Ibid.*, para. 35.

³⁴⁵*Ibid.* (quoting Panel Report, *Canada – Continued Suspension*, para. 7.230).

³⁴⁶*Ibid.*, para. 40 (quoting Panel Report, *Canada – Continued Suspension*, para. 7.357).

DSU. Hence, the Panel's approach was not a result of it disregarding the sequence of the European Communities' claims, but the result of a reasoned analysis of the second series of main claims.

159. Canada further argues that, although the European Communities' panel request did not refer to provisions of the *SPS Agreement*, the Panel correctly found that the compatibility of Directive 2003/74/EC with the *SPS Agreement* was *ipso facto* an issue before the Panel. Thus, the Panel did not breach Article 7 of the DSU, because this provision requires panels to address the relevant provisions of the covered agreement cited by the parties. Canada recalls that the European Communities' second series of main claims was premised on a violation of Article 22.8 by Canada, which in turn depended on a finding that the measure found to be inconsistent with the *SPS Agreement* in *EC – Hormones* had been removed. Consequently, Article 22.8 required the Panel to consider the consistency of Directive 2003/74/EC with the *SPS Agreement* as a condition precedent to a finding of violation by Canada of Article 22.8. In addition, Canada maintains that the Panel's approach was consistent with the Appellate Body's finding in *Argentina – Footwear (EC)* that a panel cannot make an "objective assessment of the matter" if it only refers in its reasoning to the "specific provisions cited by the parties in their claims".³⁴⁷ Canada observes, moreover, that the Panel considered that the issue of the substantive compliance of the European Communities' implementing measure was raised "early in the proceedings" and therefore "no party to the dispute could claim that it did not have the opportunity to address the legal arguments of the other."³⁴⁸

160. On this basis, Canada requests the Appellate Body to reject the European Communities' claim that the Panel exceeded its terms of reference under Articles 7 and 21.5 of the DSU when examining the compatibility of Directive 2003/74/EC with the *SPS Agreement*.

5. The Panel's Suggestion for Implementation

161. In its appellee's submission, Canada did not address the European Communities' request that the Appellate Body modify the Panel's suggestion for implementation. However, in its other appellant's submission, Canada requests the Appellate Body to reverse the Panel's suggestion for implementation, because the suggestion was contradictory to the Panel's findings under Article 22.8.³⁴⁹

³⁴⁷Canada's appellee's submission, para. 43 (quoting Appellate Body Report, *Argentina – Footwear (EC)*, para. 74).

³⁴⁸*Ibid.* (referring to Panel Report, *Canada – Continued Suspension*, para. 7.371).

³⁴⁹See also *infra*, para. 206.

6. The Panel's Selection of Experts

162. Canada rejects the European Communities' argument that Section VI of the *Rules of Conduct* sets forth the relevant legal standard.³⁵⁰ Rather, Canada submits that the only standard governing conflict of interest questions is found in Section II (Governing Principle) of the *Rules of Conduct*. That provision requires that all persons covered under the *Rules of Conduct*, including experts, "shall be independent and impartial", and "shall avoid direct or indirect conflicts of interest". Moreover, Canada asserts that Drs. Boisseau and Boobis met the disclosure requirement under the Working Procedures for Consultations with Scientific and/or Technical Experts (the "Experts Working Procedures") developed by the Panel, and that, in particular, both complied with the requirements by disclosing their involvement in JECFA. In Canada's view, "it was up to the Panel to evaluate whether this had an impact [on] the independence and impartiality of these candidates in this case."³⁵¹

163. Canada submits that the Panel correctly found that Drs. Boisseau and Boobis were independent and impartial. Canada recalls that the Panel "expressly addressed"³⁵² the allegation that these two experts were defending their prior work when it explained that the purpose of consulting them was to obtain advice about the substance of JECFA's risk assessment, and to help identify the extent to which concerns raised by the European Communities had been considered in JECFA's risk assessment. Canada also highlights the Panel's explanations that it was asking the experts about JECFA's consensual view, which may differ from the experts' personal views, and that both experts admitted to the Panel that the state of scientific knowledge can evolve.

164. Canada observes that the conflict of interest alleged by the European Communities is not covered by the Illustrative List of Information to be Disclosed set out in Annex 2 of the *Rules of Conduct*. Therefore, according to Canada, "an expert's previous participation in JECFA would not put the person in a conflict-of-interest situation when he or she provides advice to the Panel."³⁵³ In Canada's view, participation by these experts both in JECFA and as advisers to the Panel occurred in a personal, independent, professional capacity and for no monetary gain. Moreover, Canada submits, it is inaccurate to portray participation by Drs. Boisseau and Boobis in JECFA committees as "giving them an (almost proprietary) interest in the outcome of the JECFA process that they would have felt compelled to defend when advising the Panel".³⁵⁴ Canada maintains that the JECFA process "is a diffuse one, in which a number of scientists participate but the precise outcome is uncertain

³⁵⁰Canada's appellee's submission, para. 47 (referring to European Communities' appellant's submission, para. 195).

³⁵¹*Ibid.*, para. 49.

³⁵²*Ibid.*, para. 54.

³⁵³*Ibid.*, para. 55.

³⁵⁴*Ibid.*, para. 56.

beforehand".³⁵⁵ The experts, Canada submits, were contributors to a process "aimed at reaching a consensus out of what may initially be a variety of scientific views", which is "very different" from scientific conclusions arrived at through the efforts of, and published by, an individual scientist.³⁵⁶

165. Canada considers that the practical consequence of the Panel excluding Drs. Boisseau and Boobis as experts would have been that "the pool of eligible experts would have been shrunk significantly, such that it would have become very difficult for the Panel to appoint experts in all the areas of expertise that it had identified."³⁵⁷ Pointing to an example in which a particular scientist had examined issues relating to genetically modified organisms for both the European Food Safety Authority and JECFA, Canada avers that this is consistent with its view that independent scientific experts serving in their personal capacity may advise different international bodies (or national bodies) on the same subject matter without compromising their independence and impartiality.

166. Canada therefore requests the Appellate Body to reject the European Communities' claim that the Panel acted inconsistently with the principle of due process, the requirements of the *Rules of Conduct*, and Article 11 of the DSU in selecting Drs. Boisseau and Boobis, and to reject the request to reverse the Panel's findings that relied on the advice of these two experts.

7. Article 5.1 of the *SPS Agreement*

167. Canada argues that the Panel was correct in finding that the European Communities' permanent ban on meat and meat products from cattle treated with oestradiol-17 β for growth-promoting purposes was not based on a risk assessment within the meaning of Article 5.1 of the *SPS Agreement*. Canada requests the Appellate Body to dismiss the European Communities' appeal.

168. Canada argues that the Panel correctly interpreted Article 5.1 of the *SPS Agreement*, as informed by Article 5.2 of the *SPS Agreement*, and did not ignore in its analysis the European Communities' arguments regarding misuse and abuse in the administration of hormones. Canada maintains that the European Communities did not provide evidence demonstrating that it had evaluated misuse and abuse in the administration of oestradiol-17 β as a specific risk in relation to the consumption of meat from cattle treated with this hormone for growth-promotion purposes. Therefore, "it is even unreasonable to presume misuse/abuse of hormones"³⁵⁸ for purposes of the Panel's examination of Article 5.1 in this dispute. In addition, Canada asserts that the Panel was correct in finding that the issue of misuse and abuse was relevant "only to the extent that it [could]

³⁵⁵Canada's appellee's submission, para. 56.

³⁵⁶*Ibid.*

³⁵⁷*Ibid.*, para. 57.

³⁵⁸*Ibid.*, para. 87.

lead to an increased concentration of hormone residues in meat and meat products than would otherwise occur if good veterinary practices are applied."³⁵⁹ The Panel found in this regard that the European Communities had not evaluated the potential for adverse effects arising from the consumption of meat containing residues of oestradiol-17 β as a result of cattle being treated with this hormone for growth-promotion purposes. Thus, because the European Communities had not specifically assessed the risk arising from consumption of meat containing hormone residues, the Panel rightly found that whether the concentrations of residues of oestradiol-17 β in meat could be higher as a result of misuse and abuse did not need to be addressed. Canada rejects the European Communities' argument that the Panel placed undue emphasis on the Codex standards, which assume good veterinary practices. Canada submits that the Panel did not perceive its task as evaluating the SCVPH Opinions against the assessments by JECFA; rather, once it had found that the European Communities had taken Codex into account, thereby complying with the terms of Article 5.1 of the *SPS Agreement*, the Panel was correct in using Codex's approach to risk assessment as a general reference.

169. Canada contends moreover that the Panel did not exclude *a priori* from its analysis evidence on possible misuse and abuse in the administration of hormones, which was the legal error identified by the Appellate Body in *EC – Hormones*. Rather, the Panel "properly confined its inquiry to the assessment that was material to the context of this case".³⁶⁰ Canada submits that the Panel properly rejected the European Communities' attempt to interpret the Appellate Body's finding in *EC – Hormones*—that risk assessments may include matters not susceptible of quantitative analysis—as allowing "risk management" considerations to be taken into account in a "risk assessment" within the meaning of Article 5.1.³⁶¹ According to Canada, the European Communities' arguments relating to "risk management" seek "to distract from the main weakness of its case: that it did not assess the specific risk".³⁶²

170. Canada asserts that the Panel correctly held that the European Communities' risk assessment was not sufficiently specific to the particular risk at issue, that is, the adverse effects to human health arising from consumption of meat from cattle treated with oestradiol-17 β for growth-promotion purposes. Canada draws attention to the Appellate Body's findings in *EC – Hormones* that the scientific evidence considered in a risk assessment must be "sufficiently specific"³⁶³ to the substance

³⁵⁹Canada's appellee's submission, para. 88 (referring to Panel Report, *Canada – Continued Suspension*, para. 6.154).

³⁶⁰*Ibid.*

³⁶¹*Ibid.*, para. 93 (referring to Panel Report, *Canada – Continued Suspension*, paras. 7.491 and 7.492).

³⁶²*Ibid.*, para. 93.

³⁶³*Ibid.*, para. 97 (quoting Appellate Body Report, *EC – Hormones*, para. 200).

at issue in order for it to "sufficiently warrant" or "reasonably support" the SPS measure.³⁶⁴ Canada maintains that the European Communities was not absolved from conducting a quantitative assessment of such risk simply because the SCVPH Opinions indicate that oestradiol-17 β is genotoxic. This is because the evidence referred to in the SCVPH Opinions relates to the genotoxicity of oestradiol-17 β *in vitro*³⁶⁵, which does not indicate that it is genotoxic *in vivo*.³⁶⁶ Canada rejects the European Communities' allegation that the Panel ignored Dr. Guttenplan's statement that the scientific evidence was specific in relation to the relevant risk. This statement must be interpreted as referring only to the "hazard identification"³⁶⁷ phase of a risk assessment, and Dr. Guttenplan subsequently stated that "the evidence evaluating the occurrence of adverse effects is weak."³⁶⁸ Canada also notes that two other experts indicated very clearly that the European Communities "did not have scientific evidence to support the assertion of the specific risk".³⁶⁹ Therefore, the Panel had a "solid basis"³⁷⁰ for finding that the risk assessments were not sufficiently specific to the relevant risk arising from hormone residues in meat.

171. Canada also contests the European Communities' assertion that the Panel erred in requiring a quantification of risks. Canada observes that, although the Appellate Body recognized in *EC – Hormones* that a risk assessment could be performed either quantitatively or qualitatively, it also held that a risk assessment is a process "characterized by systematic, disciplined and objective enquiry and analysis".³⁷¹ Therefore, a qualitative risk assessment must be "done in a scientifically rigorous fashion"³⁷², and the European Communities could not make a qualitative assessment on the basis of unproven assumptions where the available quantitative data go against those assumptions. The European Communities' risk assessment did not meet this standard, because it did not contain either quantitative or qualitative evidence of the genotoxic potential of oestradiol-17 β *in vivo*. In addition, the European Communities failed to substantiate its assertion that no threshold could be identified for

³⁶⁴Canada's appellee's submission, para. 98 (quoting Appellate Body Report, *EC – Hormones*, para. 193). (underlining omitted)

³⁶⁵*In vitro* means outside of the body, usually in a cell-based system in a test tube or culture dish.. (Panel Report, *US – Continued Suspension*, footnote 509 to para. 7.393(d); and Panel Report, *Canada – Continued Suspension*, footnote 500 to para. 7.390(d) (referring to transcript of the Panel meeting with the scientific experts, Panel Reports, Annex G, para. 96))

³⁶⁶*In vivo* means in the whole organism, the intact organism (Panel Report, *US – Continued Suspension*, footnote 585 to para. 7.472 (referring to transcript of the Panel meeting with the scientific experts, Panel Reports, Annex G, para. 96))

³⁶⁷Canada's appellee's submission, para. 99.

³⁶⁸*Ibid.* (quoting Panel Report, *Canada – Continued Suspension*, para. 7.495).

³⁶⁹*Ibid.* (referring to replies to questions posed by the Panel to the scientific experts, Panel Reports, Annex D, paras. 129-144).

³⁷⁰*Ibid.*, para. 99.

³⁷¹*Ibid.*, para. 101 (quoting Appellate Body Report, *EC – Hormones*, para. 187).

³⁷²*Ibid.*, para. 102.

oestradiol-17 β , because it did not provide evidence suggesting that this hormone is a "direct-acting genotoxicant".³⁷³

172. Canada submits furthermore that the Panel's examination of whether the European Communities had evaluated the "potential occurrence of adverse effects"³⁷⁴ does not express a preference for a quantitative analysis of risk and is consistent with the *SPS Agreement*. This is because the only possible way to examine the "potential" for adverse effects, within the meaning of Annex A, paragraph 4, to the *SPS Agreement*, is to "ask whether those adverse effects could ever occur".³⁷⁵ Canada also points out that the Panel recognized that "potential" is a lesser threshold than "likelihood".³⁷⁶ Canada adds that the Panel's approach is consistent with the Appellate Body's finding in *EC – Hormones*, because the Appellate Body did not fault the panel in that dispute for finding that a risk assessment under Annex A, paragraph 4, requires an evaluation of "the potential ... of occurrence of such effects".³⁷⁷ Canada additionally recalls the Appellate Body's reasoning that Article 5.1 is "intended as a countervailing factor in respect of the right of Members to set their appropriate level of protection"³⁷⁸ pursuant to Article 3.3 of the *SPS Agreement*. By contrast, the European Communities seems to be arguing for an "unqualified right to define its own level of protection"³⁷⁹ by asserting that the Panel erred in favouring quantitative methods over qualitative ones when examining the risk assessment performed by the European Communities.

173. Canada asserts that the Panel made an objective assessment of the matter in reaching its finding that the European Communities' permanent ban on oestradiol-17 β was not based on a risk assessment within the meaning of Article 5.1. As the trier of facts, the Panel was entitled to accord more weight to the views of those experts it found to be credible and persuasive. Canada emphasizes that, under the Appellate Body's interpretation, an objective assessment under Article 11 of the DSU implies, among other things, that a "panel must consider all the evidence presented to it, assess its credibility, determine its weight, and ensure that its factual findings have a proper basis in that evidence."³⁸⁰ Within these parameters, "panels enjoy discretion as the trier of facts, including in disputes involving the evaluation of scientific evidence"³⁸¹ and, in the exercise of this discretion, are

³⁷³Canada's appellee's submission, para. 106.

³⁷⁴*Ibid.*, para. 107 (referring to European Communities' appellant's submission, para. 340, in turn quoting Panel Report, *US – Continued Suspension*, para. 7.521, and Panel Report, *Canada – Continued Suspension*, para. 7.493). (emphasis omitted)

³⁷⁵*Ibid.*, para. 107. (original underlining)

³⁷⁶*Ibid.*, para. 108 (referring to Panel Report, *Canada – Continued Suspension*, para. 7.481).

³⁷⁷*Ibid.* (referring to Appellate Body Report, *EC – Hormones*, para. 183). (emphasis omitted)

³⁷⁸*Ibid.*, para. 109 (referring to Appellate Body Report, *EC – Hormones*, para. 177).

³⁷⁹*Ibid.*, para. 109.

³⁸⁰*Ibid.*, para. 61 (quoting Appellate Body Report, *Brazil – Retreaded Tyres*, para. 185).

³⁸¹*Ibid.*, para. 62 (referring to Appellate Body Report, *Japan – Apples*, paras. 166 and 221).

entitled "to determine that certain elements of evidence should be accorded more weight than other elements".³⁸² Thus, "[r]equiring panels, in their assessment of the evidence before them, to give precedence to the importing Member's evaluation of scientific evidence and risk is not compatible with this well-established principle."³⁸³ Canada underscores that, given the discretion afforded to panels to appreciate the value of the evidence before them, the Appellate Body has made clear that "not every error in the appreciation of the evidence ... may be characterized as a failure to make an objective assessment of the facts."³⁸⁴

174. Canada maintains that the European Communities has failed to demonstrate that the Panel exceeded the bounds of its discretion as the trier of facts in reaching its factual findings regarding the consistency with the *SPS Agreement* of the permanent ban on meat from cattle treated with oestradiol-17 β imposed pursuant to Directive 2003/74/EC. Canada does not view the Panel's statement that it was in a situation "similar"³⁸⁵ to that of a risk assessor as an indication that the Panel "drifted into a *de novo* review"³⁸⁶ of the European Communities' risk assessment. Rather, the Panel made use of the advice given by the experts as context to assess the alleged compliance of the European Communities' measure with the recommendations and rulings of the DSB in *EC – Hormones*. In this regard, the Panel specifically acknowledged that it was poorly suited to engage in a *de novo* review of the European Communities' risk assessment.³⁸⁷ According to Canada, as the trier of facts, the Panel was entitled to give greater weight to the advice of certain experts, and was under no obligation to treat all advice received from the experts "on an equal footing".³⁸⁸ Thus, rather than "picking and choosing"³⁸⁹ between the opinions of the experts, the Panel weighed the advice received from the different experts and carried out an objective assessment of the matter before it, in conformity with Article 11 of the DSU.

175. Turning to the specific allegations of error made by the European Communities under Article 11 of the DSU, Canada characterizes as "simply false"³⁹⁰ the European Communities' allegation that the Panel did not take into account evidence related to exposure to hormones from multiple sources. The Panel "specifically acknowledge[d] that it had considered the issue [of multiple

³⁸²Canada's appellee's submission, para. 62 (quoting Appellate Body Report, *EC – Asbestos*, para. 161).

³⁸³*Ibid.* (quoting Appellate Body Report, *Japan – Apples*, para. 166). (emphasis omitted)

³⁸⁴*Ibid.*, para. 64 (quoting Appellate Body Report, *EC – Hormones*, para. 133). (emphasis omitted) Canada also refers to Appellate Body Report, *Brazil – Retreaded Tyres*, para. 186; and Appellate Body Report, *Chile – Price Band System (Article 21.5 – Argentina)*, para. 240. (Canada's appellee's submission, paras. 63 and 67)

³⁸⁵*Ibid.*, para. 71 (quoting Panel Report, *Canada – Continued Suspension*, para. 7.409).

³⁸⁶*Ibid.*, para. 72 (quoting European Communities' appellant's submission, para. 237).

³⁸⁷*Ibid.*, para. 72 (referring to Panel Report, *Canada – Continued Suspension*, paras. 7.107, 7.405, 7.406, 7.571, and 7.630).

³⁸⁸*Ibid.*, para. 73.

³⁸⁹*Ibid.*, para. 74 (quoting European Communities' appellant's submission, para. 239).

³⁹⁰*Ibid.*, para. 77.

exposure]"³⁹¹ in its analysis of the European Communities' risk assessment under Article 5.1, and for this reason did not fail to conduct an objective assessment as required by Article 11.

176. Furthermore, Canada rejects the European Communities' contention that the Panel imposed an incorrect "specificity" or "direct causality" requirement.³⁹² Rather than requiring the "demonstration of actual effects"³⁹³, the Panel correctly required the European Communities "to evaluate the possibility that the identified adverse effect came into being, originated, or resulted from the presence of residues of oestradiol-17 β in meat or meat products as a result of the cattle being treated with the hormone for growth promoting purposes."³⁹⁴ According to Canada, this neither amounts to a requirement that the European Communities demonstrate "actual effects"³⁹⁵, nor is it a violation of Article 11 by the Panel.

177. Finally, Canada maintains that the Panel "extensively dealt" with the evidence³⁹⁶ related to the genotoxicity of oestradiol-17 β in its report and concluded that the scientific evidence referred to in the SCVPH Opinions did not "support the European Communities' conclusion that for oestradiol-17 β genotoxicity had already been demonstrated explicitly", nor did it "support the conclusion that the presence of residues of oestradiol-17 β in meat and meat products as a result of the cattle being treated with the hormone for growth promotion purposes leads to increased cancer risk".³⁹⁷ Therefore, Canada asserts that the Panel carefully considered all the evidence before it on the genotoxicity of oestradiol-17 β , and did not fail to conduct an objective assessment of the matter as required by Article 11 of the DSU.

178. Canada concludes that the Panel correctly interpreted and applied Article 5.1 of the *SPS Agreement* and did not fail to make an objective assessment of the matter under Article 11 of the DSU. Canada therefore requests the Appellate Body to dismiss the appeal of the European Communities regarding the Panel's findings under Article 5.1 of the *SPS Agreement*.

8. Article 5.7 of the *SPS Agreement*

179. Canada argues that the Panel properly found that the relevant scientific evidence on the five hormones subject to the provisional ban was not "insufficient" within the meaning of Article 5.7 of

³⁹¹Canada's appellee's submission, para. 77 (referring to Panel Report, *Canada – Continued Suspension*, para. 7.501).

³⁹²*Ibid.*, para. 79 (referring to European Communities' appellant's submission, paras. 259-270).

³⁹³*Ibid.* (referring to European Communities' appellant's submission, para. 261).

³⁹⁴*Ibid.*, para. 80 (quoting Panel Report, *Canada – Continued Suspension*, para. 7.485). (underlining omitted)

³⁹⁵*Ibid.* (quoting European Communities' appellant's submission, para. 261).

³⁹⁶*Ibid.*, para. 81.

³⁹⁷*Ibid.* (quoting Panel Report, *Canada – Continued Suspension*, para. 7.540). (underlining omitted)

the *SPS Agreement*. Canada requests the Appellate Body to dismiss this ground of the European Communities' appeal.

180. Canada submits that the Panel correctly considered the relevance of international standards in determining that the scientific evidence on risks posed by the five hormones was not "insufficient" within the meaning of Article 5.7. Canada observes that the Panel did not find that the existence of international standards created an irrebuttable presumption of the sufficiency of scientific evidence and amounted to a "legal bar"³⁹⁸ to the adoption of provisional measures under Article 5.7. Rather, the Panel was "expressing a presumption, not a conclusion"³⁹⁹, when it found that the existence of international standards "implies" that sufficient evidence existed to complete a risk assessment. This is borne out by the Panel's recognition that previously sufficient evidence could subsequently become "insufficient" within the meaning of Article 5.7 when it is "unsettled"⁴⁰⁰ by new studies. Therefore, contrary to the European Communities' contention, the Panel explicitly recognized that, despite the existence of international standards, there could be situations where relevant scientific evidence becomes insufficient to conduct an adequate risk assessment. On that basis, the Panel went on to assess whether the "insufficiencies" identified by the European Communities were enough to render insufficient the previously sufficient evidence upon which the JECFA assessments were based.

181. In addition, Canada suggests that the Panel correctly excluded from the scope of its analysis under Article 5.7 the level of protection chosen by the European Communities. The Panel was correct in finding that the ability of the European Communities to conduct a risk assessment on four of the provisionally banned hormones could not "hinge on"⁴⁰¹ its decision to apply a higher level of protection than that reflected in the international standards. The European Communities' argument that the "sufficiency" of scientific evidence under Article 5.7 depends on the acceptable level of risk adopted by a Member⁴⁰² undermines the "basic logic" of the *SPS Agreement*, according to which Article 5.7 operates as a "temporary 'safety valve'"⁴⁰³ in situations where there is insufficient scientific evidence to allow a Member to conduct a risk assessment that fulfils the requirements of Articles 2.2 and 5.1. The European Communities' approach would allow Members "to effectively exclude from the available pool of relevant scientific evidence, any evidence that does not support their chosen level of protection"⁴⁰⁴ for purposes of evaluating whether there is sufficient scientific evidence to conduct a risk assessment. Canada argues that a Member's desired level of protection is not relevant

³⁹⁸Canada's appellee's submission, para. 117.

³⁹⁹*Ibid.*, para. 118. (underlining omitted)

⁴⁰⁰*Ibid.*, para. 119 (referring to Panel Report, *Canada – Continued Suspension*, para. 7.598).

⁴⁰¹*Ibid.*, para. 122.

⁴⁰²*Ibid.*, para. 121 (referring to European Communities' appellant's submission, para. 397; and Panel Report, *Canada – Continued Suspension*, paras. 7.618 and 7.619).

⁴⁰³*Ibid.*, para. 122.

⁴⁰⁴*Ibid.*, para. 123.

for determining whether the scientific evidence is "insufficient" within the meaning of Article 5.7, because the "autonomous right"⁴⁰⁵ of WTO Members to introduce measures that result in a higher level of protection than the one achieved by measures based on international standards under Article 3.3 is subject to the requirement that such measures be based on a risk assessment.

182. Canada maintains that the Panel did not err in allocating to the European Communities the burden of proving the insufficiency of the scientific evidence under Article 5.7. Canada considers that the Panel correctly characterized Article 5.7 as a "qualified exemption"⁴⁰⁶ from the obligation under Article 2.2 not to maintain SPS measures without sufficient scientific evidence. Article 5.7 is not an option that can be freely chosen by a Member. Rather, it operates as a "temporary 'safety valve'"⁴⁰⁷ in situations where some evidence exists but are not enough to complete a full risk assessment. The Panel shifted the burden of proof under Article 5.7 to the European Communities only once it was satisfied that Canada had sufficiently refuted the European Communities' allegation of compliance through positive evidence of a breach of Article 5.7. Canada posits further that this allocation of the burden of proof is consistent with the Appellate Body's ruling in *US – Wool Shirts and Blouses*, because it was for the European Communities, as the party alleging a breach of Article 22.8 of the DSU, to demonstrate that its implementing measure complied with Article 5.7 of the *SPS Agreement*.⁴⁰⁸

183. Furthermore, Canada argues that the Panel did not err in finding that, in situations where international risk assessments have been conducted for the substances at issue, a "critical mass" of new evidence would be required to render the relevant scientific evidence "insufficient" for the purposes of Article 5.7. Canada dismisses the European Communities' argument that the "critical mass" standard excludes *a priori* the possibility that a WTO Member base its risk assessment on respectable minority views. Canada recalls the Appellate Body's finding that a measure conforming to the requirements of Article 5.1 may be based on minority opinions.⁴⁰⁹ In these situations, Canada argues, there is "inherently"⁴¹⁰ sufficient evidence to perform a risk assessment that provides a basis for the SPS measure. Article 5.7, in contrast, only applies to situations where there is "insufficient" scientific evidence to conduct a risk assessment "at all", regardless of whether a measure is based on

⁴⁰⁵Canada's appellee's submission, para. 124 (quoting Appellate Body Report, *EC – Hormones*, para. 172).

⁴⁰⁶*Ibid.*, para. 114 (quoting Appellate Body Report, *Japan – Agricultural Products II*, para. 80. (emphasis omitted))

⁴⁰⁷*Ibid.*, para. 122.

⁴⁰⁸*Ibid.*, para. 115 (referring to Appellate Body Report, *US – Wool Shirts and Blouses*, p. 14, DSR 1997:I, 323, at 335).

⁴⁰⁹*Ibid.*, para. 127 (referring to Appellate Body Report, *EC – Hormones*, para. 194; and Appellate Body Report, *EC – Asbestos*, para. 178).

⁴¹⁰*Ibid.*, para. 127.

"minority" or "mainstream" scientific opinions.⁴¹¹ Therefore, contrary to the European Communities' contention, "the concept of critical mass as applied by the Panel cannot be assimilated with the findings of the Appellate Body on the validity of basing an SPS measure on minority views."⁴¹² Canada adds that the notion of "critical mass" used by the Panel does not specify how much evidence would be needed to make insufficient scientific evidence that was previously sufficient, nor does it exclude the possibility that one "new study or series of studies could call into question the scientific assumptions underpinning the current understanding of a scientific issue."⁴¹³ Thus, Canada submits, the Panel's "critical mass" standard "correctly sets a high threshold"⁴¹⁴ reflecting the presumption in this dispute that the available scientific evidence had been sufficient to adopt the relevant international standards.

184. Finally, Canada argues that the Panel did not fail to conduct an objective assessment of the facts under Article 11 of the DSU in reaching its findings under Article 5.7 of the *SPS Agreement*. Canada asserts that the European Communities' allegation that the Panel acted inconsistently with Article 11 appears to have "lost sight of the process that the Panel was engaged in"⁴¹⁵, which was to arrive at an objective determination of the facts in accordance with Article 11 of the DSU. Canada refers to its earlier arguments that, as the trier of facts, the Panel had the discretion to determine what weight to attach to the statements made by the experts in the course of the proceedings, and to assess the experts' expertise and credibility.⁴¹⁶ Canada rejects the European Communities' allegations that the Panel "systematically downplay[ed]"⁴¹⁷ the expert opinions indicating that the scientific evidence was insufficient to carry out a risk assessment. According to Canada, such allegations fail to take into account the fact that, in addition to reviewing the written answers by the experts to the Panel's questions, the Panel was able to "observe these experts" during the meetings with them and was able to "arrive at an assessment of their respective expertise and their credibility in particular areas".⁴¹⁸ Thus, it was on this basis that the Panel was entitled to rely more on the views expressed by some experts than those of others. Therefore, the Panel's reliance on the views of these experts was fully consistent with its function as the trier of facts, and thus was consistent with Article 11 of the DSU.

185. Canada concludes that the Panel correctly interpreted and applied Article 5.7 of the *SPS Agreement* and did not fail to make an objective assessment of the matter under Article 11 of the

⁴¹¹Canada's appellee's submission, para. 127.

⁴¹²*Ibid.*, para. 128.

⁴¹³*Ibid.*

⁴¹⁴*Ibid.*

⁴¹⁵*Ibid.*, para. 129.

⁴¹⁶See also *supra*, paras. 173 and 174.

⁴¹⁷Canada's appellee's submission, para. 130 (quoting European Communities' appellant's submission, para. 427, and referring to para. 429).

⁴¹⁸*Ibid.*, para. 130.

DSU. Canada therefore requests the Appellate Body to dismiss the appeal of the European Communities regarding the Panel's findings under Article 5.7 of the *SPS Agreement*.

D. *Claims of the United States – Other Appellant*

186. The United States claims that the Panel erred in finding that the United States has acted inconsistently with Articles 23.1 and 23.2(a) of the DSU by "seeking the redress" of a violation in relation to Directive 2003/74/EC and by making a determination of violation without recourse to the rules and procedures of the DSU. The United States requests the Appellate Body to reverse these findings of the Panel.

1. Alleged Discrepancies in the Panel's Description of the Measure at Issue

187. The United States submits that conceptual difficulties and apparent discrepancies exist in the Panel's description of the measure at issue and in the Panel's identification of the relevant timeframes associated with the suspension of concessions. The Panel described the measure at issue as the "suspension of concessions ... continued without recourse to the procedures under the DSU", or the "continued application by the United States ... of its decision to apply ... import duties in excess of bound rates ... without recourse to the procedures under the DSU."⁴¹⁹ These descriptions are not only different, but confuse the legal claims made by the European Communities with what should be a factual description of the measure. The relevant timeframe of the measure was identified as from the "adoption of Directive 2003/74/EC", or "after the notification to the DSB of Directive 2003/74/EC".⁴²⁰ Such discrepancies, in the United States' view, reflect a conceptual difficulty with the Panel's approach and show that the Panel appeared to be struggling to explain how it could find that the suspension of concessions authorized by the DSB is inconsistent with the United States' obligations under the WTO. According to the United States, "the Panel appear[ed] to be trying to characterize the measure not as the duties themselves, but as something else, something that changed in the measure once the [European Communities] notified its (inaccurate) claim of compliance"⁴²¹; nonetheless, there was no new measure as a result of the European Communities' claim of compliance and no modification or other alteration in the duties.

⁴¹⁹United States' other appellant's submission, para. 21 (quoting Panel Report, *US – Continued Suspension*, paras. 2.7 and 7.151).

⁴²⁰*Ibid.*, para. 26 (quoting Panel Report, *US – Continued Suspension*, paras. 2.7 and 7.151). (emphasis omitted)

⁴²¹*Ibid.*, para. 27.

2. The Panel's Findings under Article 23.1 of the DSU

188. The United States argues that the Panel "simply err[ed]" when it found that the application of the suspension of concessions was "without recourse to the procedures under the DSU".⁴²² The United States observes that, before it was authorized by the DSB to suspend concessions, it had extensive and lengthy recourse to multiple procedures under the DSU and "had fully complied with all relevant rules and procedures of the DSU ... in bringing the *EC – Hormones* dispute, determining the applicable [reasonable period of time] for compliance, determining the appropriate level of suspension of concessions, and obtaining the authorization of the DSB to suspend concessions".⁴²³ The United States emphasizes that the DSB's authorization to suspend concessions, which it was granted on 26 July 1999, "has never been revoked and the [United States'] application of duties pursuant to that authorization has continued, unchanged", to this day.⁴²⁴

189. The United States asserts that, by finding that the United States was seeking the redress of a violation in relation to Directive 2003/74/EC, the Panel "re-characteriz[ed]"⁴²⁵, without any legal basis, the United States' suspension of concessions as now being directed against Directive 2003/74/EC. The United States further submits that the European Communities' notification of Directive 2003/74/EC to the DSB was a mere unilateral declaration of compliance, and that such a declaration does not fulfil any of the three conditions under Article 22.8 that must be satisfied before the DSB's authorization would cease to operate. The United States explains, moreover, that the Panel seemed to have improperly inferred that there was "some deadline by which a Member must respond to such a unilateral declaration"⁴²⁶, when no such deadline was provided for in the DSU. Therefore, the United States argues that the Panel erroneously permitted the unilateral declaration of compliance to transform the legal justification for the suspension of concessions maintained by the United States. Given that the Panel found that the inconsistent measure has in fact not been removed, the multilateral DSB authorization remains in place and effective.

190. In the United States' view, the Panel's re-characterization of the legal justification for the suspension of concessions, as now directed against Directive 2003/74/EC, is "fatally flawed"⁴²⁷ for several reasons. First, the Panel's finding is inconsistent with the ordinary meaning of the term "authorized", which is defined as "legally or formally sanctioned or appointed"⁴²⁸, and with the fact

⁴²²United States' other appellant's submission, para. 29.

⁴²³*Ibid.*, para. 17.

⁴²⁴*Ibid.*, para. 18.

⁴²⁵*Ibid.*, para. 31.

⁴²⁶*Ibid.*, para. 37.

⁴²⁷*Ibid.*, para. 40.

⁴²⁸*Ibid.*, para. 43 (quoting *The New Shorter Oxford English Dictionary*, 4th edn, L. Brown (ed.) (Clarendon Press, 1993), Vol. 1, p. 151).

that an "authorized" act is by definition consistent with the law. Therefore, the Panel's finding that the United States' suspension of concessions, which remains authorized, could constitute a violation of Article 23.1 was based on the paradoxical proposition that an act permitted by the law can simultaneously be prohibited by the law. Secondly, the Panel's analysis relied on a "false dichotomy"⁴²⁹: where a measure taken to comply is notified, a complaining party either terminates the suspension of concessions because it concludes that the measure is consistent with the covered agreements, or continues the suspension of concessions because it considers that the measure does not bring the implementing Member into compliance. In the United States' view, such a false dichotomy lacks a basis in the DSU because the DSU does not require a Member to form definitive conclusions regarding the validity of a unilateral declaration of compliance. The United States simply kept the duties in place and maintained the *status quo* on the basis that the European Communities' declaration of compliance has not been multilaterally confirmed.

191. In addition, the United States asserts that the Panel erred in the allocation of the burden of proof as it relieved the European Communities of the duty to make a *prima facie* case of inconsistency under Article 23.1 of the DSU. Furthermore, the United States recalls that, in rejecting the United States' argument that the European Communities has failed to show that the conditions under Article 22.8 for terminating the suspension of concessions have been met, the Panel reasoned that it is the obligation of the Member suspending concessions to ensure that the suspension is applied only until such time as foreseen in Article 22.8. The United States contends that Article 22.8 does not assign such responsibility to the Member suspending concessions and does not specify the procedures for determining whether the conditions in Article 22.8 are met. To the United States, "[w]hat is clear"⁴³⁰ under Article 22.8 is that there is no basis to find that a multilateral authorization to suspend concessions is to be terminated by a unilateral declaration of compliance. A responding Member should not be able to escape the suspension of concessions and force the complaining party to engage in dispute settlement "simply by notifying a claim of compliance".⁴³¹

192. The United States submits that the Panel's findings under Article 23.1 lead to "fundamentally problematic"⁴³² consequences, because, simply by claiming compliance, a Member could escape the application of the suspension of concessions and force the complaining party to initiate another dispute settlement proceeding, potentially creating an "endless loop"⁴³³ of litigation. The United States additionally submits that the Panel "effectively read[s] into [Article 22.8 of the DSU] an obligation" on the Member suspending concessions "to take steps by some deadline to ascertain

⁴²⁹United States' other appellant's submission, para. 45.

⁴³⁰*Ibid.*, para. 57.

⁴³¹*Ibid.*, para. 62.

⁴³²*Ibid.*, para. 60.

⁴³³*Ibid.*, para. 65.

whether the conditions in Article 22.8 have been met".⁴³⁴ Consequently, the Panel's approach "would add to the rights and obligations of Members in contravention of"⁴³⁵ Article 19.2 of the DSU. The United States asserts that the DSU does not specify the rules applicable to the situation in the post-suspension stage where an original responding party has declared itself to be in compliance four years after the reasonable period of time for implementation has expired. Thus, panels and the Appellate Body "should not supplant the work and efforts of Members to provide clarifications or improvements to the DSU".⁴³⁶ The United States observes that the DSU "does not leave parties in a post-suspension state of play bereft of tools to obtain redress and resolution"⁴³⁷, and recourse to a normal panel proceeding remains an option to Members in the post-retaliation stage, as the European Communities chose to do in this dispute.

3. The Panel's Findings under Article 23.2(a) of the DSU

193. The United States also takes issue with the Panel's finding that the statements made by the United States at the DSB meetings constituted a unilateral "determination" to the effect that a violation occurred within the meaning of Article 23.2(a) of the DSU. This conclusion, according to the United States, was neither consistent with the ordinary meaning of the term "determination" in its context and in the light of the object and purpose of the DSU, nor supported by the negotiating history of the DSU. According to its ordinary meaning, a "determination" is a "final and definitive" decision that results from some kind of deliberative process and leads to a significant consequence.⁴³⁸ The United States finds contextual support for this interpretation in the final clause of Article 23.2(a), which requires that determinations be consistent with the recommendations and rulings of the DSB, and thus confirms that a determination must be final and definitive. The United States argues that its statements made at the DSB meetings did not constitute a "determination", because these statements did not embody any definitiveness or finality and were, instead, punctuated with equivocation. Due to the complexity of making any good faith attempt to examine the European Communities' claim that Directive 2003/74/EC is consistent with the *SPS Agreement*, the United States needed time for review and could not be expected to have made a determination within a mere few weeks of the notification of Directive 2003/74/EC by the European Communities. Turning to the negotiating history of Article 23.2(a), the United States maintains that the "determination" that the negotiators intended to target under Article 23.2(a) was of the type and nature of the unilateral determinations made under

⁴³⁴United States' other appellant's submission, para. 66.

⁴³⁵*Ibid.*

⁴³⁶*Ibid.*, para. 69.

⁴³⁷*Ibid.*, para. 70.

⁴³⁸*Ibid.*, paras. 74-78.

Section 301 of the United States Trade Act of 1974⁴³⁹, which were made at the conclusion of formal investigations and which resulted in certain legal consequences.⁴⁴⁰ In addition, the United States contends that subjecting Members' DSB statements, which "are generally diplomatic or political in nature and prepared ... independently of any ... deliberative proceedings", to the discipline of Article 23.2(a) "will undoubtedly result in a 'chilling' effect on those statements".⁴⁴¹

194. Furthermore, the United States alleges that a "determination" within the meaning of Article 23.2(a) cannot be inferred or implied, and the Panel erred in making such an inference from the United States' "inaction" regarding the suspension of concessions.⁴⁴² The United States adds that the Panel's inference "effectively reads into Article 23 a deadline by which a determination will be imputed to a Member"⁴⁴³, even though Article 23 contains no such deadline and the Panel itself struggled to identify the proper timeframe after which the "continuation of suspension" would be considered to be inconsistent with Article 23. For the United States, "[t]he Panel's findings appear[ed] to require complaining parties and other Members to be silent in the face of a claim of compliance or risk having any reaction other than agreement be construed to be a 'determination'."⁴⁴⁴ The United States additionally observes that, "even if the reaction is not sufficient to be a 'determination', it appears that a Member would risk such a reaction ripening into a 'determination' based simply on the passing of an unspecified deadline, which the Panel acknowledged does not exist."⁴⁴⁵

4. The Scope of the Panel's Mandate and the Panel's Suggestion

195. In the event the Appellate Body upholds the Panel's findings under Articles 23.2(a) and 23.1, the United States requests the Appellate Body to reverse the Panel's "erroneous suggestion"⁴⁴⁶ that the United States must bring itself into conformity by having recourse to the rules and procedures of the DSU without delay. The United States contends that the Panel engaged in a detailed review of Directive 2003/74/EC and its consistency with both the DSB's recommendations and rulings and the *SPS Agreement*. Thus, recourse to the rules and procedures of the DSU has already been achieved, because "a fair and objective reading of the language in Articles 23.1 and 23.2(a) does not exclude instances"⁴⁴⁷ in which a Member may "have recourse" by participating in a dispute settlement proceeding initiated by another WTO Member, as the United States did in this dispute. The United

⁴³⁹United States Trade Act of 1974, Public Law No. 93-618, 88 Stat. 1978 (1975), *United States Code*, Title 19, section 2101.

⁴⁴⁰United States' other appellant's submission, para. 88.

⁴⁴¹*Ibid.*, paras. 93 and 95.

⁴⁴²*Ibid.*, paras. 98-104.

⁴⁴³*Ibid.*, para. 105.

⁴⁴⁴*Ibid.*, para. 106.

⁴⁴⁵*Ibid.*, para. 106.

⁴⁴⁶*Ibid.*, para. 108.

⁴⁴⁷*Ibid.*, para. 111.

States observes that requiring re-litigation of the matters that have already been "reviewed and considered"⁴⁴⁸ in these proceedings would not be an efficient use of the WTO dispute settlement system, and would be contrary to the objective of "prompt settlement" of disputes set out in Article 3.3 of the DSU.

196. The United States further submits that the Panel erred in finding that it had no jurisdiction to rule on the compatibility of Directive 2003/74/EC with the *SPS Agreement*. The United States argues that the Panel improperly limited the scope of its mandate on the basis that the European Communities had articulated its claim under Article 22.8 as a conditional claim. The United States asserts that "[a] panel's terms of reference, once determined at the outset of the dispute, cannot be narrowed or otherwise modified by a complaining party."⁴⁴⁹ According to the United States, the relevant provision governing the terms of reference of a panel is Article 7 of the DSU, which "does not provide for a change to the terms of reference based on the complaining party's submissions".⁴⁵⁰ Therefore, in the United States' view, this finding by the Panel should be reversed, and the Panel's findings regarding the WTO-inconsistency of Directive 2003/74/EC, made in the context of addressing the European Communities' second series of main claims, should be considered "direct" findings.⁴⁵¹

5. Conclusion

197. In sum, the United States requests the Appellate Body to: (i) reverse the Panel's findings that the United States has acted inconsistently with Articles 23.1 and 23.2(a) of the DSU; (ii) reverse the Panel's suggestion that the United States should have recourse to the rules and procedures of the DSU without delay; and (iii) reverse the Panel's conclusion that it was not empowered to make a direct determination of the consistency of Directive 2003/74/EC with the *SPS Agreement*. The United States nevertheless clarifies that the Appellate Body need not reach the last two issues if it reverses the Panel's findings that the United States has acted inconsistently with Articles 23.1 and 23.2(a) of the DSU.

E. *Claims of Canada – Other Appellant*

198. Canada requests the Appellate Body to reverse the Panel's finding that Canada has acted inconsistently with Articles 23.1 and 23.2(a) of the DSU by maintaining the suspension of concessions after the notification of Directive 2003/74/EC by the European Communities. Canada

⁴⁴⁸United States' other appellant's submission, para. 113.

⁴⁴⁹*Ibid.*, para. 117.

⁴⁵⁰*Ibid.*

⁴⁵¹*Ibid.*, para. 119.

submits that the Panel erred in addressing the European Communities' claims of violation under Articles 23.1 and 23.2(a) completely separately from the requirements of Article 22.8 of the DSU. Even if the Panel did not err in examining Article 23 in isolation from Article 22.8, Canada argues that the Panel erred in finding that Canada has breached Articles 23.1 and 23.2(a) by seeking the redress of a violation without recourse to the rules and procedures of the DSU.

1. The Panel's Examination of Articles 23.1 and 23.2(a) "In Isolation" from Article 22.8 of the DSU

199. Canada alleges that the "fundamental legal error"⁴⁵² of the Panel is its examination of the European Communities' claim under Articles 23.1 and 23.2(a) in isolation from its analysis under Article 22.8 of the DSU. According to Canada, the "[k]ey to this case is Article 22.8 of the DSU"⁴⁵³, which, as *lex specialis* applicable to the post-retaliation phase of a dispute, sets out the three conditions that must be met in order to have the suspension of concessions terminated, one of the conditions being actual compliance with the DSB's recommendations and rulings. Canada maintains that the "continuous involvement of the DSB", pursuant to the second sentence of Article 22.8, "suggests that [the DSB] retains jurisdiction over the matter until its recommendations and rulings have been fully implemented".⁴⁵⁴ Canada explains that "[t]his is consistent with the ongoing obligation on the Member being retaliated against to comply with its WTO obligations, including the requirement to comply promptly with the recommendations and rulings of the DSB."⁴⁵⁵

200. As regards Article 23, Canada submits that this provision begins by setting out general obligations that apply to what it refers to as the pre-dispute settlement stage of a dispute and then proceeds by setting out specific obligations (*lex specialis*) applicable through the compliance and retaliation stages of dispute settlement proceedings. Whereas the examples of prohibited unilateral conduct contained in Article 23.2 are not exhaustive, the structure of the Article indicates that, when a particular dispute has entered the compliance or retaliation stages, the relevant obligations are those in subparagraphs (b) and (c) of Article 23.2, and the general obligations contained in Articles 23.1 and 23.2(a) are no longer pertinent. Indeed, Canada observes, the only way for a complaining Member to have reached the compliance or retaliation stage is to have already satisfied those general obligations by having engaged in the WTO dispute settlement process and obtained a DSB ruling that the responding Member has violated its obligations. Canada additionally notes that the *travaux préparatoires* provide a further indication that the DSU negotiators did not contemplate that Article 23 would apply to a post-retaliation situation. Canada thus argues that, in this case, since it

⁴⁵²Canada's other appellant's submission, para. 6.

⁴⁵³*Ibid.*, para. 35.

⁴⁵⁴*Ibid.*, para. 36.

⁴⁵⁵*Ibid.* (footnote omitted)

has had recourse to the rules and procedures of the DSU in the *EC – Hormones* dispute and is suspending concessions pursuant to a DSB authorization, Canada has already satisfied the obligations contained in Articles 23.1 and 23.2(a). Therefore, as suggested by the text of Article 23.2(c), the Panel should have turned first to the provisions of Article 22, including the specific requirements of Article 22.8 that apply to the question of whether the suspension of concessions should be terminated. By failing to do so, the Panel's approach resulted in "contradictory findings"⁴⁵⁶ that, on the one hand, Canada has breached Articles 23.1 and 23.2(a) of the DSU by continuing the suspension of concessions and, on the other hand, that Canada has the right to continue the suspension of concessions pursuant to Article 22.8 because the European Communities' inconsistent measure has not been removed.

201. Canada asserts, moreover, that the Panel failed to consider the object and purpose of the DSU. By considering Article 23 in isolation from other provisions of the DSU, the Panel arrived at findings that ultimately lessen the effectiveness of the WTO dispute settlement mechanism. The result is that "a non-compliant WTO Member could avoid the duly authorized suspension of concessions by another Member merely by adopting an alleged implementing measure, notifying such measure to the DSB and waiting to be challenged."⁴⁵⁷ In Canada's view, such a result has the effect of undermining DSB-authorized retaliation, thereby weakening an important incentive for Members to bring their measures promptly into compliance. Canada contends that only a further multilateral determination of compliance by the DSB can set aside the DSB's prior authorization to suspend concessions. In Canada's view, the European Communities has the burden of initiating a panel proceeding—either an Article 21.5 proceeding or a *de novo* action against the suspension of concessions—to obtain such a multilateral determination.

202. Canada further maintains that, in examining the European Communities' claims under Articles 23.1 and 23.2(a) of the DSU in isolation from its examination of Article 22.8, the Panel erroneously followed the order of analysis proposed by the European Communities, even though such order of analysis is contrary to the principle of *lex specialis*, according to which the specific terms of a treaty must prevail over the general provisions.⁴⁵⁸ The application of the *lex specialis* principle should have led the Panel to begin its analysis by determining whether the conditions for the

⁴⁵⁶Canada's other appellant's submission, para. 43.

⁴⁵⁷*Ibid.*, para. 47.

⁴⁵⁸*Ibid.*, paras. 52-57. Canada refers to the Appellate Body's statement in *Canada – Wheat Exports and Grain Imports* that "panels are free to structure the order of their analysis as they see fit" but they "may find it useful to take account of the manner in which a claim is presented to them" by the complaining party; however, Canada contends that "panels must be careful not to simply follow the order of analysis as pleaded by a complainant", which may itself contain errors of law, especially if the relationship between two provisions mandates a certain sequence of analysis. (*Ibid.*, paras. 54 and 55 (quoting Appellate Body Report, *Canada – Wheat Exports and Grain Imports*, paras. 109 and 126))

termination of the suspension of concessions set out in Article 22.8 have been met. Canada criticizes the Panel for using "two different and inconsistent manners of identifying the [European Communities'] implementing measure at issue".⁴⁵⁹ Canada explains that, while examining the second series of the European Communities' main claims, the Panel gave a broad interpretation to the term "measure" in Article 22.8 of the DSU and recognized that the phrase "until such time as the measure found to be inconsistent with a covered agreement has been removed" means that the "illegality itself" and not only the originally impugned measure had been removed. By contrast, in its approach to the first series of the European Communities' main claims, the Panel based its finding of a violation of Articles 23.1 and 23.2(a) of the DSU on the fact that the European Communities had notified a measure that had not yet been subject to dispute settlement.

203. Canada also criticizes the Panel for ignoring the procedural history of the case. According to Canada, Directive 2003/74/EC should be situated in the post-retaliation context and should not be considered as "a new measure *ab initio*".⁴⁶⁰ Given that Canada had obtained DSB authorization to suspend concessions, the onus should be placed on the European Communities to demonstrate its compliance to a WTO panel. The Panel's findings that Canada has breached Articles 23.1 and 23.2(a) lead to a "manifestly absurd or unreasonable" interpretation that the mere adoption and notification of an alleged implementing measure by a WTO Member, which failed to bring itself into compliance within the reasonable period of time, could render the suspension of concessions authorized by the DSB inconsistent with the DSU. Canada asserts that the Panel's finding under Articles 23.1 and 23.2(a) renders ineffective the substantive requirements set out in Article 22.8 regarding the suspension of concessions, contrary to the principle of effectiveness that should govern treaty interpretation.

2. The Panel's Findings under Article 23.1 of the DSU

204. Canada contends that, even if the Panel was correct in considering Articles 23.1 and 23.2(a) in isolation, the Panel erred in finding that Canada was "seeking the redress" of a WTO violation by continuing the suspension of concessions in respect of a measure that had not yet been subject to recourse to the DSU. According to Canada, the Panel's finding ignored the fact that Canada had "sought and obtained"⁴⁶¹ DSB authorization to suspend concessions as a result of the inconsistencies found in *EC – Hormones*, and that Canada has taken no action to "seek the redress" of any alleged WTO-inconsistency of the European Communities' purported implementing measure. Canada further asserts that simply because Directive 2003/74/EC is a new measure does not imply that the legal basis

⁴⁵⁹Canada's other appellant's submission, para. 63.

⁴⁶⁰*Ibid.*, para. 64.

⁴⁶¹*Ibid.*, para. 80.

for Canada's continued suspension of concessions has changed and that the suspension is now aimed at seeking the redress for any violations caused by Directive 2003/74/EC. Because Canada's suspension of concessions was authorized by the DSB, it is "by definition"⁴⁶² WTO-consistent. In Canada's view, "[t]he Panel erred in imputing alleged WTO inconsistencies of the [European Communities'] purported implementing measure as the reasons for Canada's continued suspension of concessions in this case."⁴⁶³ Such an outcome would, in Canada's view, severely hinder the security and predictability of the WTO dispute settlement system, as Members would be unsure as to when, or for how long, they could properly rely on a DSB authorization to suspend concessions.

3. The Panel's Findings under Article 23.2(a) of the DSU

205. Furthermore, Canada alleges that the Panel erred in finding that Canada made a unilateral determination that a violation occurred in relation to Directive 2003/74/EC, contrary to Article 23.2(a), on the basis of Canada's statements at the DSB meetings and its continued application of the suspension of concessions. According to Canada, there is an insufficient amount of "firmness or immutability" with respect to the statements made by Canada at the DSB meetings for the Panel to conclude that Canada made "more or less a final decision" regarding the WTO-inconsistency of Directive 2003/74/EC.⁴⁶⁴ Canada also argues that, because it had obtained DSB authorization to suspend concessions, it did not see the need to take a decision regarding the WTO-consistency of Directive 2003/74/EC, and that it was up to the European Communities to establish that it had implemented the DSB's recommendations and rulings in *EC – Hormones*. Therefore, the Panel erroneously found that Canada's continuation of the suspension of concessions "corroborate[d]"⁴⁶⁵ the fact that Canada made a determination of violation in relation to Directive 2003/74/EC, because it is the DSB's authorization, rather than Canada's expression of views on the WTO-consistency of this Directive, that formed the basis of Canada's continued suspension of concessions.

4. The Scope of the Panel's Mandate and the Panel's Suggestion

206. Finally, should the Appellate Body uphold the Panel's finding that Canada has breached Articles 23.1 and 23.2(a) of the DSU, Canada requests the Appellate Body to reverse the Panel's finding that it did not have jurisdiction to determine the compatibility of Directive 2003/74/EC with

⁴⁶²Canada's other appellant's submission, para. 84.

⁴⁶³*Ibid.*, para. 80. Canada adds that the Panel's finding is flawed because it was not based on the notion of malfeasance (*ibid.*, para. 81 (referring to Panel Report, *EC – Commercial Vessels*, para. 7.188)) but, rather, was based on the notion of "non-feasance, whereby Canada's inaction, *i.e.*, failure to terminate its suspension of concessions following the notification of [Directive 2003/74/EC] would be construed as 'seeking redress' of a violation pursuant to Article 23.1 of the DSU." (*Ibid.*, para. 81)

⁴⁶⁴*Ibid.*, paras. 87-89 (quoting Panel Report, *US – Section 301 Trade Act*, footnote 657 to para. 7.50; and referring to statements made at the DSB meetings held on 7 November and 1 December 2003).

⁴⁶⁵*Ibid.*, para. 91 (quoting Panel Report, *Canada – Continued Suspension*, para. 7.224).

the *SPS Agreement*. Canada explains that the Panel specifically acknowledged that Article 22.8 of the DSU required it to consider, as a condition precedent to finding a breach of this provision by Canada, the consistency of Directive 2003/74/EC with the *SPS Agreement*. In addition, Canada considers that this finding contradicts the Panel's finding that was made in the context of its examination of the European Communities' second series of main claims. In that context, the Panel found that Canada has not breached Article 22.8, because the European Communities has not removed the inconsistency found in *EC – Hormones*.

207. Canada further requests the Appellate Body to reverse the Panel's suggestion that Canada should have recourse to the rules and procedures of the DSU without delay. Canada asserts that the Panel's suggestion ignores the fact that, earlier in its report, the Panel conducted an extensive review of the compatibility of the European Communities' implementing measure with the *SPS Agreement*. Nor does such recommendation contribute to a "prompt settlement" of the dispute as required by Article 3.3 of the DSU, because it would require a new panel proceeding to look at an issue that is already being dealt with in the context of the current proceedings. Finally, in Canada's view, this suggestion is contradictory to the Panel's findings under Article 22.8, and its statement that it was performing a function similar to that of an Article 21.5 panel. The suggestion is also inconsistent with Article 19.2 of the DSU, because it diminishes Canada's right to suspend concessions pursuant to the authorization given by the DSB.

5. Conclusion

208. In sum, Canada requests the Appellate Body to reverse the Panel's findings under Articles 23.1 and 23.2(a) of the DSU that Canada was "seeking the redress" of a violation and made a "determination" of violation with respect to Directive 2003/74/EC. Canada requests the Appellate Body to find, instead, that: (i) Articles 23.1 and 23.2(a) of the DSU do not apply to a situation where, following the adoption of an alleged implementing measure after the reasonable period of time has elapsed, a Member continues the suspension of concessions pursuant to the DSB's authorization; (ii) Canada has not acted inconsistently with Articles 23.1 and 23.2(a) because the European Communities failed to demonstrate that it brought itself into compliance, in accordance with Article 22.8 of the DSU; and (iii) the Panel erred in finding that it was bound by the manner in which the European Communities presented its two main claims. Should the Appellate Body uphold the Panel's findings under Articles 23.1 and 23.2(a) of the DSU, Canada requests the Appellate Body to reverse the Panel's finding that it did not have jurisdiction to determine the compatibility of

Directive 2003/74/EC with the covered agreements, and to remove the suggestion that Canada should have recourse to the rules and procedures of the DSU without delay.⁴⁶⁶

F. *Arguments of the European Communities – Appellee*

209. The European Communities submits that the Panel correctly found that the United States and Canada have breached Articles 23.1 and 23.2(a) of the DSU by maintaining the suspension of concessions after the notification of Directive 2003/74/EC, and requests the Appellate Body to dismiss Canada's and the United States' other appeals "in their entirety".⁴⁶⁷

210. The European Communities makes two preliminary arguments. First, the European Communities observes that the United States and Canada do not appear to dispute that Directive 2003/74/EC is a "measure taken to comply with the recommendations and rulings" of the DSB in the *EC – Hormones* dispute. Secondly, the European Communities asserts that the United States and Canada "entirely ignore"⁴⁶⁸ the fact that the European Communities' first series of main claims included Article 21.5, but did not include Article 22.8 of the DSU. The European Communities adds that the error in the Panel's reasoning was to ignore Article 21.5, rather than Article 22.8, as the United States and Canada allege, although this error does not undermine the correctness of the Panel's conclusions of violation of Articles 23.2(a) and 23.1.

1. The "Harmonious" Interpretation of Articles 21, 22, and 23 of the DSU in the Post-Suspension Stage of a Dispute

211. The European Communities maintains that the "general and fundamental"⁴⁶⁹ provisions of Article 23 of the DSU apply throughout the implementation stage of a dispute. The European Communities rejects the distinction made by Canada between "a new measure *ab initio*" and "a measure taken"⁴⁷⁰ to implement the DSB's recommendations and rulings, as well as Canada's assertion that Articles 23.1 and 23.2(a) apply only to a new measure. The European Communities submits that such a distinction lacks a textual basis in the covered agreements. The European Communities recalls that Article XVI:4 of the *WTO Agreement* requires Members to ensure the conformity of their laws with their WTO obligations, and maintains that, in the light of this provision, the multilateral dispute settlement system "relies on good faith compliance and the presumption of conformity of measures taken by WTO Members"⁴⁷¹, which does not change in the post-retaliation

⁴⁶⁶Canada's other appellant's submission, paras. 99-101.

⁴⁶⁷European Communities' appellee's submission, para. 148.

⁴⁶⁸*Ibid.*, para. 29.

⁴⁶⁹*Ibid.*, para. 36.

⁴⁷⁰*Ibid.*, para. 39 (quoting Canada's other appellant's submission, para. 64).

⁴⁷¹*Ibid.*, para. 40.

stage of a dispute. Therefore, the European Communities argues, where a Member has taken a measure to implement the DSB's recommendations and rulings, the Member suspending the concessions bears the burden of proving the WTO-inconsistency of the implementing measure.⁴⁷² The general burden of proving that a measure is WTO-inconsistent cannot be reversed simply because the original complainant has taken retaliatory measures. The European Communities additionally contends that Canada, by stating that "Article 23.1 is concerned with measures in respect of which no WTO dispute settlement proceedings have taken place"⁴⁷³, effectively reduces the scope of application of Article 23.1 and makes it "essentially meaningless in the implementation stage".⁴⁷⁴

212. The European Communities further submits that the interpretation of Articles 21 and 22, referenced in Article 23.2(b) and (c), should not change depending on the stage of the dispute settlement process, including when the dispute reaches the post-suspension stage. The European Communities asserts that the *lex specialis* applicable to its first series of main claims is Article 21.5, and not Article 22.8, as Canada argues. Article 22.8 "was part of and context for"⁴⁷⁵ the European Communities' second series of main claims. The European Communities emphasizes that Directive 2003/74/EC, as a measure taken to comply, must be presumed to be compliant with the covered agreements until shown otherwise through an Article 21.5 proceeding. The European Communities maintains that a Member suspending concessions must ensure that the suspension "complies at all times with the conditions laid down in Article 22.8".⁴⁷⁶ On this basis, the European Communities argues that the adoption of a measure taken to comply triggers the following duties of the original complaining party: (i) to cease the suspension of concessions; (ii) to form a view on whether the measure found to be inconsistent has been removed; and (iii) to have recourse to Article 21.5 proceedings if it considers that the measure taken to comply is not consistent with the covered agreements. The European Communities considers that its understanding of Members' obligations in the post-suspension stage results from a "harmonious"⁴⁷⁷ interpretation of Articles 21, 22, and 23 of the DSU that gives effect to each of these provisions. The European Communities emphasizes that the WTO dispute settlement system is based on adversarial procedures where a Member claims the inconsistency of a measure taken by another Member, and is not applicable to requests for an abstract confirmation of the consistency of a measure.

213. The European Communities maintains that the object and purpose of the DSU, according to Articles 3.7 and 3.3, is to secure a positive solution to, and prompt settlement of, a dispute. Thus, the

⁴⁷²European Communities' appellee's submission, para. 40.

⁴⁷³*Ibid.*, para. 43 (quoting Canada's other appellant's submission, para. 38).

⁴⁷⁴*Ibid.*, para. 43.

⁴⁷⁵*Ibid.*, para. 51.

⁴⁷⁶*Ibid.*, para. 62.

⁴⁷⁷*Ibid.*, para. 36.

United States' and Canada's suggestion that they can simply wait until the European Communities brings a dispute to prove the consistency of its implementing measure goes fundamentally against the object and purpose of the DSU. The European Communities emphasizes that, upon the adoption of a measure taken to comply, the Member suspending concessions is required to cease the application of the suspension while it fulfils its obligation to have recourse to dispute settlement procedures under Article 21.5. Such an interpretation is consistent with the function of the dispute settlement system, which is for adjudicating disputes and not for maintaining retaliatory measures where a measure to comply is taken in good faith. The European Communities disagrees with the United States' and Canada's argument that the European Communities' interpretation would fail to give effect to Article 22.8 of the DSU. It explains that, on the contrary, where a good faith measure has been taken to comply, as the European Communities did in this case by adopting Directive 2003/74/EC, there is no legitimate interest in continuing the suspension of concessions, because the suspension would have achieved its objective and the suspension "does nothing to induce compliance".⁴⁷⁸ The European Communities additionally submits that allowing a Member to continue the suspension of concessions despite the adoption of a measure taken to comply effectively allows that Member to "extort"⁴⁷⁹ more than what it is entitled to under the covered agreements. By maintaining the suspension of concessions, the United States and Canada "in truth"⁴⁸⁰ wish to see the European Communities remove the import ban imposed on meat treated with hormones, even though removal of the ban is not required under the covered agreements as long as the ban is based on a risk assessment consistent with the *SPS Agreement*. Finally, the European Communities submits that its position is consistent with the approach taken in the Articles on Responsibility of States for Internationally Wrongful Acts⁴⁸¹ (the "Articles on State Responsibility"), which require that countermeasures be suspended if the internationally wrongful act has ceased and the dispute is pending before a tribunal that has the authority to make decisions binding upon the parties.⁴⁸²

214. The European Communities sums up its position on the proper interpretation of Articles 21, 22, and 23 as follows. The fact that the suspension of concessions was authorized, and subsequently also applied, does not change the proper interpretation and application of Articles 21 and 23. The original complaining Member remains under an obligation to have recourse to a compliance procedure under Article 21.5 if it disagrees with the existence or consistency of a measure

⁴⁷⁸European Communities' appellee's submission, para. 81.

⁴⁷⁹*Ibid.*, para. 83.

⁴⁸⁰*Ibid.*, para. 84.

⁴⁸¹Articles on Responsibility of States for Internationally Wrongful Acts, adopted by the International Law Commission at its fifty-third session (2001) (Exhibit EC-136 submitted by the European Communities to the Appellate Body), Article 52.3. The text of the Articles are annexed to United Nations General Assembly Resolution, A/RES/56/83, 29 January 2002 (Exhibit EC-135 submitted by the European Communities to the Appellate Body).

⁴⁸²See European Communities' appellee's submission, paras. 94-96.

taken to comply with a covered agreement. If it fails to do so, and simply waits and continues to apply the suspension of concessions, it necessarily is seeking redress and makes a unilateral determination that a violation has occurred in respect of the implementing measure within the meaning of Articles 23.2(a) and 23.1. In such a situation, the continued application of the suspension of concessions is simultaneously, *first*, evidence that the original complaining Member disagrees with the existence or consistency with a covered agreement of the measure taken to comply while refusing to have recourse to a compliance procedure under Article 21.5 (thus, making a "determination" that the new measure is WTO-inconsistent); and, *secondly*, a breach of Article 23.1, read together with Articles 22.8 and 3.7, because it seeks redress following its unilateral determination that the measure found to be inconsistent with the covered agreements has not been removed.

2. The Panel's Findings under Article 23.1 of the DSU

215. With respect to the Panel's finding that the United States is seeking the redress of a violation within the meaning of Article 23.1, the European Communities recalls the United States' contention that the Panel erroneously re-characterized the suspension of concessions as now directed against Directive 2003/74/EC. The European Communities asserts that this contention is without merit, because the United States could no longer maintain its suspension of concessions once the European Communities had removed Directive 96/22/EC. The Panel confirmed the removal of Directive 96/22/EC, and the United States has not appealed this finding. Additionally, the European Communities argues that "the United States ignores that there is a presumption of good faith compliance by WTO Members", and that the adoption of an implementing measure in good faith "triggers" an obligation to remove the suspension of concessions and requires the complaining Member to initiate Article 21.5 proceedings in case there is disagreement as to the WTO-consistency of the new measure.⁴⁸³ The European Communities observes, moreover, that "even the United States acknowledged that it was maintaining its suspension of concessions against the new measure".⁴⁸⁴ The European Communities further submits that, contrary to the United States' assertion, the Panel's finding does not lead to a paradoxical result that the authorized suspension of concessions can be both consistent and inconsistent with the covered agreements at the same time. Rather, the European Communities argues, the suspension of concessions was initially WTO-consistent, and subsequently became WTO-inconsistent in the light of the notification of Directive 2003/74/EC and the removal of the measure found to be WTO-inconsistent in *EC – Hormones*, namely, Directive 96/22/EC. Therefore, the continued application of sanctions in the presence of a compliance measure that the DSB has not found to be WTO-inconsistent implies that a Member is seeking to redress a violation.

⁴⁸³European Communities' appellee's submission, para. 104. (emphasis omitted)

⁴⁸⁴*Ibid.*, para. 106 (referring to Panel Report, *US – Continued Suspension*, paras. 7.219-7.221 and footnote 438 thereto).

216. Turning to the Panel's finding that Canada is seeking the redress of a violation within the meaning of Article 23.1, the European Communities disagrees with Canada's argument that the notification of Directive 2003/74/EC does not change the legal basis of Canada's suspension of concessions. The European Communities submits that, contrary to Canada's assertion, Article 22.8 of the DSU does not specify that it is for the respondent to show that it has removed the original measure. According to the European Communities, "[i]f anything, Article 22.8 of the DSU seems to indicate that such an assessment should be carried out by the complaining Member, since it is the one suspending concessions".⁴⁸⁵ The European Communities adds that the use of the passive tense in the phrase "[t]he suspension of concessions ... shall only be applied" appears to indicate the obligation for the Member suspending concessions to terminate those measures when the original measure has been removed. The European Communities contends that, in any event, it has effectively shown that the inconsistent measure, namely, Directive 96/33/EC, was removed, and both the Panel and Canada recognized that Directive 2003/74/EC was a different measure.

3. The Panel's Findings under Article 23.2(a) of the DSU

217. As regards the Panel's finding that the United States made a determination within the meaning of Article 23.2(a), the European Communities considers that the United States' appeal is based on a "wrong reading of the Panel's findings", because the Panel did not make its finding based only on the statements made by the United States at the DSB meetings.⁴⁸⁶ Instead, the Panel took into account the statements made by the United States at the DSB meetings and its decision to maintain its suspension of concessions as *evidence* that the United States had made a "determination" prohibited by Article 23.2(a) of the DSU.⁴⁸⁷ The European Communities disagrees with the United States that the statements made at the DSB meetings lacked definitiveness. On the contrary, the United States expressed a "*definitive judgement*"⁴⁸⁸ concerning the WTO-consistency of Directive 2003/74/EC. The European Communities dismisses the United States' argument that it could not have made a determination within weeks of the notification of Directive 2003/74/EC, contending, instead, that the term "determination" does not contain any temporal connotation. The European Communities also disagrees with the United States' view that the Panel inferred the existence of a "determination" from inaction. According to the European Communities, the United States "actively considered" that Directive 2003/74/EC was WTO-inconsistent and "actively continued" the suspension of concessions.⁴⁸⁹ The European Communities further submits that, even if the negotiators of the DSU referred to Section 301 of the United States Trade Act of 1974, they did so as an example that was not

⁴⁸⁵European Communities' appellee's submission, para. 114.

⁴⁸⁶*Ibid.*, para. 119.

⁴⁸⁷*Ibid.*, para. 122. (original emphasis)

⁴⁸⁸*Ibid.*, para. 126. (original emphasis)

⁴⁸⁹*Ibid.*, para. 133. (emphasis omitted)

intended to be an exhaustive illustration of the types of unilateral conduct prohibited by Article 23. The European Communities, moreover, rejects the United States' contention that statements made at DSB meetings are diplomatic in nature and have no legal effects, referring to the Appellate Body's observation in *US – Upland Cotton (Article 21.5 – Brazil)* that certain statements by the United States Government indicated that it was taking a measure for the purpose of complying.⁴⁹⁰ Additionally, the European Communities notes that the United States' statements at the DSB meetings occurred in the particular context of seeking redress of a violation by continuing its application of sanctions against the European Communities. The European Communities also rejects the United States' argument that the Panel failed to establish when the United States had made a determination in breach of Article 23.2(a). In the European Communities' view, the Panel properly observed that the deadline by which a Member shall have recourse to the DSU in accordance with Article 23 "was not an issue before the Panel".⁴⁹¹

218. The European Communities further argues that the Panel correctly found that Canada made a determination to the effect that a violation has occurred within the meaning of Article 23.2(a). The European Communities maintains that Canada's statements at DSB meetings that it was not removing the suspension of concessions, together with the fact that it has maintained the suspension of concessions, provide a sufficient amount of firmness or immutability indicating that Canada made a more or less final decision regarding the WTO-inconsistency of Directive 2003/74/EC. The European Communities explains that, because it had notified a new measure, which was different both legally and in substance, Canada needed to take a final decision regarding its conformity with the WTO agreements, which it did (as confirmed by its statements and the continuation of its suspension of concessions, as concluded by the Panel), and thus Canada made a "determination" in the sense of Article 23.2(a) without having recourse to the DSU.

4. The Scope of the Panel's Mandate and the Panel's Suggestion

219. Finally, the European Communities reiterates that, by ignoring the sequence of the legal claims made by the European Communities, the Panel exceeded its terms of reference in examining the consistency of Directive 2003/74/EC with the *SPS Agreement*, contrary to Articles 7 and 21.5 of the DSU.⁴⁹² Moreover, the European Communities repeats its request that the Appellate Body improve the Panel's suggestion—that the United States and Canada should have recourse to the rules and procedures of the DSU—by making it explicit that they must resort to Article 21.5 proceedings and cease the suspension of concessions without delay.

⁴⁹⁰European Communities' appellee's submission, para. 131 (referring to Appellate Body Report, *US – Upland Cotton (21.5 – Brazil)*, para. 204).

⁴⁹¹*Ibid.*, para. 134 (quoting Panel Report, *US – Continued Suspension*, para. 7.232).

⁴⁹²See *supra*, paras. 55-58.

G. *Arguments of the Third Participants*

1. Australia

(a) Procedural Issue – Public Observation of the Oral Hearing

220. Australia supports the request of the participants to allow public observation of the oral hearing in these proceedings. Australia considers that enhancing the transparency of WTO dispute settlement proceedings can enhance the credibility of the dispute settlement system, and endorses the participants' arguments as to the value of open hearings. Australia submits that, although the first sentence of Article 17.10 "would seem to preclude a request that hearings of the Appellate Body be held in public", this provision must be read together with other provisions in the DSU, in particular, Article 17.10, second sentence, Article 17.14, and Article 18.2.⁴⁹³ According to Australia, "[i]n order to allow meaning to be given to these other provisions, the apparent injunction in the first sentence of Article 17.10 cannot be absolute."⁴⁹⁴ Australia observes that Article 17.10, second sentence, foresees that Appellate Body reports will contain sufficient information concerning the parties' statements and arguments to provide a basis for the Appellate Body's findings. It adds that the requirement in Article 17.14 that Appellate Body reports be circulated to WTO Members prior to adoption "would not be possible if the first sentence of Article 17.10 imposed an absolute requirement of confidentiality".⁴⁹⁵ Australia also refers to Article 18.2 of the DSU and states that there is no difference between parties disclosing statements contemporaneously by publishing them on a website and disclosing them by making them in an open hearing. Finally, Australia observes that in the absence of an express prohibition in the DSU precluding an open hearing, the Appellate Body should authorize the participants' request, which "would be fully consonant with the object and purpose of the DSU".⁴⁹⁶

(b) Articles 21, 22, and 23 of the DSU

221. Australia submits that, although the DSU does not expressly provide procedures to be followed in the post-retaliation stage of a dispute, parties' actions should continue to be guided by the following two fundamental principles: (i) multilateral determination of non-compliance; and (ii) that the party asserting non-compliance bears the burden of establishing a *prima facie* case.

222. Australia asserts that Article 23.1 of the DSU establishes an overarching obligation for Members to have recourse to the rules and procedures of the DSU, including Article 21.5 of the DSU.

⁴⁹³ Australia's comments on participants' request for an open hearing, p. 1.

⁴⁹⁴ *Ibid.*, p. 2.

⁴⁹⁵ *Ibid.*

⁴⁹⁶ *Ibid.*

Australia emphasizes that Article 21.5 is the governing provision in cases of disagreement regarding the WTO-consistency of a measure taken to comply with the DSB's recommendations and rulings, and it also applies to disagreements as to whether an inconsistent measure has been removed within the meaning of Article 22.8 of the DSU. Thus, Australia agrees with the European Communities that the disagreement regarding whether Directive 2003/74/EC removed the measure found to be inconsistent with the covered agreements in *EC – Hormones* should have been resolved through recourse to Article 21.5 panel proceedings. On this basis, Australia submits that the Panel erred in finding that the procedure under Article 21.5 of the DSU could be merely one of the mechanisms available.

223. Australia notes that the DSU is silent as to whether the suspension of concessions should cease when disputes arise regarding the removal of an inconsistent measure within the meaning of Article 22.8. According to Australia, it is open to a Member to continue the suspension of concessions pending the outcome of the Article 21.5 panel proceedings. Despite recognizing that Article 21.5 does not expressly address the issue of which party may initiate Article 21.5 proceedings, Australia argues that the Panel erred in relying on the unadopted panel report in *EC – Bananas III (Article 21.5 – EC)* for its finding that "proceedings under Article 21.5 are [not] open only to the original complainant."⁴⁹⁷

224. Australia notes that panels cannot rule on claims that have not been brought by the complaining party. Australia argues that none of the provisions of the *SPS Agreement* were within the Panel's terms of reference, and the Panel had no jurisdiction to consider the consistency of Directive 2003/74/EC with that Agreement. Australia contends that allowing claims under the *SPS Agreement* in this dispute would effectively reverse the burden of proof between the parties and "is inconsistent with the fundamental principle ... that the party asserting non-compliance with a covered agreement bears the burden of establishing a *prima facie* case".⁴⁹⁸

(c) The Panel's Selection of Experts

225. Australia agrees with the argument of the European Communities that panels must observe due process in both selecting and consulting with experts. Australia contends that fundamental fairness and due process "permeates all aspects of the WTO dispute settlement process, including a panel's use of experts".⁴⁹⁹ Australia then maintains that the principle of due process equally informs Articles 11 and 13.2 of the DSU and Article 11.2 of the *SPS Agreement* and that, in selecting and

⁴⁹⁷Australia's third participant's submission, paras. 11-13 (quoting Panel Report, *US – Continued Suspension*, para. 7.355; and Panel Report, *Canada – Continued Suspension*, para. 7.353).

⁴⁹⁸*Ibid.*, para. 25.

⁴⁹⁹*Ibid.*, para. 48.

consulting experts under these provisions, a panel is "duty bound to ensure that due process is respected".⁵⁰⁰

226. Citing the Appellate Body's finding in *US – 1916 Act* that the discretionary authority to grant enhanced participatory rights to third parties is "circumscribed, for example, by the requirements of due process"⁵⁰¹, Australia submits that a panel's discretion in the use of experts under Article 13.2 of the DSU and Article 11.2 of the *SPS Agreement* must be similarly circumscribed by the requirements of due process. Due process, Australia argues, requires that panels "seek, and take *full* account of, the views of the parties on the types of experts required and the suitability of individual experts".⁵⁰² They must also take full account of the views of the parties on the substance of the advice to be sought from the experts and must not seek advice from any particular expert on matters outside their field of expertise. WTO Members have recognized in the *Rules of Conduct* that experts must be "independent and impartial" and "avoid direct and indirect conflicts of interest".⁵⁰³

(d) Articles 5.1 and 5.7 of the *SPS Agreement*

227. Australia asserts that the *SPS Agreement* balances the right to take measures to protect human, animal, or plant life or health against the trade liberalization goals of the WTO. It adds that "[t]his balance cannot be maintained if panels fail to apply appropriate standards of review."⁵⁰⁴ Australia therefore agrees with the European Communities that the application of the appropriate standard of review by panels is fundamental to their assessment of the consistency of a Member's measure with its obligations under the *SPS Agreement*. The standard of review applicable in this case refers to the nature and appropriate intensity of scrutiny of a panel's evaluation of a Member's regulatory judgement or an assessment made by a competent body relied upon by that Member. The applicable standard of review addresses the threshold circumstance in which a panel may legitimately interfere in that judgement or factual assessment. As the Appellate Body has explained, the standard of objective assessment of the facts provided in Article 11 of the DSU "precludes [either] a *de novo* review or 'total deference' by a panel to the findings of a national authority".⁵⁰⁵ Australia also agrees with the European Communities that the appropriate standard of review to be applied in a given dispute shall be informed "by both Article 11 of the DSU and the particular covered agreement(s) and obligations at issue".⁵⁰⁶ Australia argues that this is supported by the Appellate Body's finding in *US – Softwood Lumber VI (Article 21.5 – Canada)* that the proper standard of review to be applied by

⁵⁰⁰Australia's third participant's submission, para. 49.

⁵⁰¹*Ibid.*, para. 50 (quoting Appellate Body Report, *US – 1916 Act*, para. 150).

⁵⁰²*Ibid.*, para. 51. (original emphasis)

⁵⁰³*Ibid.*, para. 51.

⁵⁰⁴*Ibid.*, para. 28.

⁵⁰⁵*Ibid.*, para. 30 (referring to Appellate Body Report, *EC – Hormones*, para. 117).

⁵⁰⁶*Ibid.*, para. 31 (referring to European Communities' appellant's submission, para. 224).

a panel must "be understood in the light of the specific obligations of the relevant agreements that are at issue".⁵⁰⁷

228. Australia maintains that the standard of review to be applied by panels "may vary between different obligations under the *SPS Agreement*" and must reflect the "balance between regulatory autonomy and international supervision"⁵⁰⁸ that is reflected in that Agreement. In Australia's view, the most significant limitation imposed by the text of the *SPS Agreement* on a panel's fact-finding jurisdiction is provided in Article 5.1. Article 5.1 imposes a "positive obligation on Members to obtain and rely upon a risk assessment that is appropriate to the circumstances".⁵⁰⁹ This obligation requires that a "rigorous investigative and fact-finding process *compulsorily precedes*"⁵¹⁰ any review by a WTO panel of the relevant SPS measure. Therefore, a panel may not "usurp the role of a risk assessor"⁵¹¹ by conducting the risk assessment itself, because doing so would "nullif[y]"⁵¹² the competence retained by Members under Article 5.1 of the *SPS Agreement* and would amount to a *de novo* review inconsistent with Article 11 of the DSU. According to Australia, panels must accord "considerable deference (but not total deference)" to a Member's risk assessment where that Member has performed a "comprehensive and transparent" risk assessment.⁵¹³ This is consistent with the requirement in Article 5.1 that a risk assessment be "as appropriate to the circumstances". This requirement suggests that risk assessors may tailor their risk assessment to the specific circumstances of a case, and that a panel may not attempt to choose between such a risk assessment and an alternative assessment that is not "similarly embedded"⁵¹⁴ in the specific circumstances.

229. Australia submits that, where the available scientific evidence may be susceptible to more than one interpretation by a "qualified and respected source"⁵¹⁵, a panel must accord deference to a Member's risk assessment, even where the panel's own preferred view appears to be supported by the "'preponderant' weight of the evidence".⁵¹⁶ Accordingly, a panel must not interfere with a Member's risk assessment solely because it might have drawn different conclusions on the basis of the available evidence, and must limit the scope of its review to determining whether "the risk assessor's decision [is] objective and credible".⁵¹⁷ For these reasons, Australia agrees with the European Communities

⁵⁰⁷ Australia's third participant's submission, para. 31 (quoting Appellate Body Report, *US – Softwood Lumber VI (Article 21.5 – Canada)*, para. 92).

⁵⁰⁸ *Ibid.*, para. 34.

⁵⁰⁹ *Ibid.*, para. 35.

⁵¹⁰ *Ibid.*, para. 36. (original emphasis)

⁵¹¹ *Ibid.*, para. 36.

⁵¹² *Ibid.*

⁵¹³ *Ibid.*

⁵¹⁴ *Ibid.*, para. 37.

⁵¹⁵ *Ibid.*, para. 38 (quoting Appellate Body Report, *EC – Hormones*, para. 194).

⁵¹⁶ *Ibid.* (referring to Appellate Body Report, *EC – Asbestos*, para. 178).

⁵¹⁷ *Ibid.*, para. 39.

that the Panel in this dispute misunderstood and misapplied the appropriate standard of review under Article 5.1 of the *SPS Agreement*. Although the Panel may have benefited from obtaining divergent scientific views for purposes of its background understanding, it could not deliberately place itself in a position whereby it could choose the scientific opinion it preferred. Yet, the Panel's various statements suggest that the Panel erroneously considered that its role was "to choose a position from among the different scientific views".⁵¹⁸ For example, the Panel stated that "its situation [was] similar"⁵¹⁹ to that of a risk assessor and that it "followed the majority of experts expressing concurrent views" or accepted the "most specific" or "best supported"⁵²⁰ views among the experts. Australia maintains that the Panel should have focused on "whether the European Communities' risk assessment represented an objective and credible view"⁵²¹ from a qualified and respected source.

230. In addition, Australia contends that a particular risk assessment may support a range of possible measures, and that Members retain the discretion to select the most appropriate measure to address a particular risk "taking into account the relevant circumstances and its appropriate level of protection".⁵²² Australia submits that the "fundamental importance of the non-trade objectives of SPS measures" warrants "considerable deference"⁵²³ by panels to the regulatory decision-making of Members, in particular, where the scientific evidence supports more than one credible interpretation.

231. Furthermore, Australia shares the European Communities' concerns regarding the relevance attributed by the Panel to the existence of international standards for four of the hormones subject to the provisional ban. Although international standards may be relevant in interpreting provisions of the *SPS Agreement*, they are not "dispositive"⁵²⁴ of the meaning of these provisions and should not be "elevated"⁵²⁵ to binding treaty obligations. For this reason, Australia agrees with the European Communities that the "existence of international standards is not determinative of whether there is sufficient evidence to conduct a risk assessment under the first requirement of Article 5.7."⁵²⁶ Australia considers that the Panel's approach failed to adequately take into account Article 3.3 of the *SPS Agreement*, which permits Members to take SPS measures that result in a higher level of protection than would be achieved by measures based on the relevant international standards.

⁵¹⁸ Australia's third participant's submission, para. 42.

⁵¹⁹ *Ibid.*, para. 41 (quoting Panel Report, *US – Continued Suspension*, para. 7.418; and Panel Report, *Canada – Continued Suspension*, para. 7.409).

⁵²⁰ *Ibid.*, para. 42 (quoting Panel Report, *US – Continued Suspension*, para. 7.420; and Panel Report, *Canada – Continued Suspension*, para. 7.411).

⁵²¹ *Ibid.*, para. 42.

⁵²² *Ibid.*, para. 44 (referring to Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.1525).

⁵²³ *Ibid.*, para. 45.

⁵²⁴ *Ibid.*, para. 54 (referring to Panel Report, *EC – Approval and Marketing of Biotech Products*, paras. 7.241, 7.300, and 7.314).

⁵²⁵ *Ibid.*, para. 54.

⁵²⁶ *Ibid.*, para. 55 (referring to European Communities' appellant's submission, paras. 392 and 393).

2. Brazil

(a) Procedural Issue – Public Observation of the Oral Hearing

232. Brazil "strongly disagrees"⁵²⁷ with the participants' request that the Appellate Body allow public observation of the oral hearing in these proceedings.

233. Brazil observes that the term "proceedings" is defined as "the business transacted by a court"⁵²⁸, whereas "deliberations" is defined as "careful consideration, weighing up with a view to decision; ... consideration and discussion of a question by a legislative assembly, a committee, etc.; debate".⁵²⁹ According to Brazil, the ordinary meaning leaves no doubt that the terms "proceedings" and "deliberations" are "not interchangeable", and that "proceedings" is a far broader concept than "deliberations" and encompasses the latter and a wide variety of steps taken by Members or conducted by the Appellate Body, including hearings.⁵³⁰ Brazil further argues that the participants' interpretation of the term "proceedings" "runs counter to case-law", and notes that, in *Canada – Aircraft*, the Appellate Body interpreted the term "proceedings" as including "the conduct of the oral hearing".⁵³¹ Brazil observes, moreover, that Rule 28(1) of the *Working Procedures* "clearly sets out that the oral hearing is part of the appellate proceedings".⁵³²

234. Brazil asserts that in the light of the ordinary meaning of Article 17.10, the case-law, and the *Working Procedures*, there is no room for finding that "proceedings" are limited to "internal work" and exclude oral hearings, as alleged by the participants.⁵³³ Therefore, Brazil considers that the first sentence of Article 17.10 "must be construed as requiring the confidentiality of any written submissions, legal memoranda, written responses to questions, oral statements, oral hearings, deliberations, exchange of views and all internal workings of the Appellate Body"⁵³⁴ and, consequently, opening the oral hearings to the public in the appellate review stage is inconsistent with multilateral trading rules, despite the participants' efforts to prove the contrary.

235. Brazil does not see Article 18.2 as providing support for the participants' request to open the oral hearing to public observation. Brazil describes Article 18.2 as granting a right to parties to disclose their own statements to the public. According to Brazil, the participants fail to show how a

⁵²⁷Brazil's comments on participants' request for an open hearing, para. 2.

⁵²⁸*Ibid.*, para. 7 (referring to *The New Shorter Oxford English Dictionary*, 1990, p. 1204).

⁵²⁹*Ibid.*, para. 8 (referring to *The New Shorter Oxford English Dictionary*, 4th edn, L. Brown (ed.) (Clarendon Press, 1993), p. 624).

⁵³⁰*Ibid.*, para. 9.

⁵³¹*Ibid.*, para. 10 (quoting Appellate Body Report, *Canada – Aircraft*, para. 143).

⁵³²*Ibid.*, para. 11.

⁵³³*Ibid.*, para. 12 (referring to European Communities' request for an open hearing, para. 15).

⁵³⁴*Ibid.*, para. 12.

right granted by Article 18.2 to Members can modify the obligation established in Article 17.10, an obligation that is applicable not only to WTO Members, but also to the Appellate Body. Brazil cautions that accepting the participants' request "would lead to the absurd conclusion that, by mutual consent, the parties to a dispute can override multilateral rules".⁵³⁵ Brazil adds that, by this logic, "mutual consent" would be a "blanket authorization" to some Members to achieve goals not necessarily permitted by the multilaterally agreed rules; in fact, "mutual consent", when *contra legem*, would undermine the whole purpose of a multilateral framework.

236. Lastly, Brazil notes that transparency is an issue being discussed in the negotiations on the review of the DSU. Brazil submits that, in the light of the different positions of Members on this issue and its impact on the functioning of the dispute settlement mechanism, "the authority to make a decision on whether or not to open panels' and Appellate Body's proceedings to the public should lie with the WTO Membership as a whole, rather than being introduced through the 'back door', as the result of a series of 'stand-alone requests'".⁵³⁶

(b) Articles 21, 22, and 23 of the DSU

237. Brazil asserts that the Panel erred in analyzing the European Communities' claims under Articles 21.5, 23.1, and 23.2(a) of the DSU in "complete isolation" from the post-suspension context of this dispute and from the "systemic non-compliance" by the European Communities. Brazil also considers that the Panel erred in its acceptance, at least in part, of the European Communities' argument that this dispute is about a procedural violation. According to Brazil, the focus of the dispute should not be the retaliatory measures by the United States and Canada; rather, the focus should remain on whether the European Communities has complied with the DSB's recommendations and rulings in *EC – Hormones*. Brazil notes that Article 22.8 of the DSU sets out three conditions that must be met before termination of the suspension of concessions is required, with the first condition being the removal of the inconsistent measure. Brazil contends that, because none of the conditions set out in Article 22.8 have been fulfilled, the DSB's authorization to suspend concessions granted to the United States and Canada remains in place. In Brazil's view, "the multilateral authorization to suspend concessions can only be revoked by an equally *multilateral* ruling."⁵³⁷

238. Brazil disagrees with the Panel's finding that the United States and Canada were seeking redress of a violation within the meaning of Article 23.1 of the DSU by continuing the multilaterally authorized suspension of concessions after the adoption of Directive 2003/74/EC. According to Brazil, the European Communities' unilateral declaration that its implementing measure complies with

⁵³⁵Brazil's comments on participants' request for an open hearing, para. 17.

⁵³⁶*Ibid.*, para. 18 (referring to Canada's request for an open hearing, para. 20).

⁵³⁷Brazil's third participant's submission, para. 12. (original emphasis)

the DSB's recommendations and rulings, or the alleged presumption of good faith compliance, cannot turn the suspension of concessions authorized by the DSB into an illegal measure. Brazil adds that the authorization to suspend concessions was in effect at the time of the European Communities' declaration, and that the United States and Canada "were simply exercising a right duly and previously authorized".⁵³⁸ Brazil also takes issue with the Panel's interpretation of the term "determination" in Article 23.2(a) of the DSU. Noting that the "determinations" prohibited under Article 23.2(a) are unilateral assessments of the kind examined in the *US – Section 301 Trade Act* dispute⁵³⁹, Brazil states that this provision is not intended to capture "[s]imple interventions and statements made at DSB or other WTO meetings".⁵⁴⁰ Brazil adds that the suspension of concessions, authorized by the DSB and obtained through recourse to dispute settlement, cannot be considered to be a unilateral "determination".

239. Turning to the Panel's analysis under Article 22.8 of the DSU, Brazil agrees with the Panel that the removal of the measure found to be inconsistent must be understood as requiring substantive compliance. Consequently, Brazil argues, the Panel's analysis of Directive 2003/74/EC in the light of the *SPS Agreement* is of "paramount importance for providing an effective solution to the dispute".⁵⁴¹ Brazil considers, in this regard, that panels have authority to examine issues or legal provisions not included in the terms of reference to the extent necessary for providing a prompt solution to the dispute.

240. Finally, Brazil asserts that, in the post-retaliation stage of a dispute, the original respondent bears the burden of proving that its implementing measure is WTO-consistent. According to Brazil, once an authorization is granted to a Member under Article 22.6 of the DSU to suspend concessions or other obligations, a turning point has been reached in the procedures established in the DSU. Thus, Brazil argues, where the original respondent has not complied with WTO rules for a long period of time despite the DSB's recommendations and rulings, the burden of making a *prima facie* case of compliance rests upon that party. Brazil submits that this "would not be a disproportionate burden" on the non-complying party because, in the "post-retaliation" stage, this Member "will have maintained an inconsistent measure for many years and the dispute settlement system should take this into consideration".⁵⁴² Brazil is also of the view that the original respondent can initiate Article 21.5 proceedings to establish compliance. Brazil argues that such an interpretation is consistent with the rationale that underpins Article 22.6 of the DSU, which places the burden on the original respondent

⁵³⁸Brazil's third participant's submission, para. 18.

⁵³⁹*Ibid.*, para. 21 (referring to Panel Report, *US – Section 301 Trade Act*, footnote 657 to para. 7.50).

⁵⁴⁰*Ibid.*, para. 21.

⁵⁴¹*Ibid.*, para. 29.

⁵⁴²*Ibid.*, para. 34.

to demonstrate that the level of the suspension of concessions proposed by the complaining Member is not justified under the DSU.

3. China

241. Pursuant to Rule 24(2) of the *Working Procedures*, China chose not to submit a third participant's submission.

242. China submits that the request made by the participants to open the oral hearing to public observation should be rejected by the Appellate Body. China disagrees with the participants' interpretation of the term "proceedings" in Article 17.10. China states that the drafters of the DSU intentionally used the different terms "deliberations" and "proceedings" in Articles 14.1 and 17.10, respectively. China does not understand the term "proceedings" in Article 17.10 as referring "only to the internal work of the Appellate Body".⁵⁴³ China observes that the term "proceedings" is also used in Article 17.5 of the DSU, which provides that "the proceedings shall not exceed 60 days from the date a party to the dispute formally notifies its decision to appeal to the date the Appellate Body circulates its report". Article 17.12 requires that the Appellate Body "address each of the issues raised in accordance with paragraph 6 during the appellate proceeding". These provisions do not provide contextual support for the interpretation of "proceedings" put forward by the participants. In China's view, the requirement in Article 17.10 that the proceedings of the Appellate Body be confidential must be interpreted to mean that only the participants and third participants may be present at the oral hearing, and all written submissions to the Appellate Body are treated as confidential.

243. China asserts, furthermore, that the purpose of the oral hearing is to provide all participants with adequate opportunity to present and argue their case before the Division with the aim of clarifying the legal issues in the appeal. Accordingly, China considers that the "main task [of] the Division, when dealing with the oral hearing issues, is to provide such opportunity to all participants and secure their right and obligation under the current DSU."⁵⁴⁴ China emphasizes that any determination by the Appellate Body in this appeal "shall not prejudice" the position of Members in the ongoing negotiations on the review of the DSU.⁵⁴⁵

4. India

244. India stresses that the Appellate Body should reject the participants' request to allow public observation of the oral hearing in these proceedings. India submits that "the issue of external

⁵⁴³China's comments on participants' request for an open hearing, p. 1.

⁵⁴⁴*Ibid.*, p. 2.

⁵⁴⁵*Ibid.*

transparency" is being discussed in the negotiations on the review of the DSU and that "[t]hese negotiations have not yet been completed, and there is no consensus on whether and which form of external transparency is acceptable to the entire WTO Membership."⁵⁴⁶ India argues that until such consensus is achieved, panel and Appellate Body proceedings have to be held in closed sessions. India emphasizes that the confidentiality of the panel and Appellate Body proceedings provided under the DSU is a "substantive" matter⁵⁴⁷, and any decision by the Appellate Body to open its proceedings to public observation necessarily involves consultations with, and decisions by, WTO Members, and not just the participants and third participants.

5. Mexico

245. Pursuant to Rule 24(2) of the *Working Procedures*, Mexico chose not to submit a third participant's submission.

246. Mexico disagrees with the request made by the participants to allow public observation of the oral hearing in these proceedings. Mexico observes that its position is supported by Article 17.10 of the DSU, which states that "[t]he proceedings of the Appellate Body shall be confidential."

6. New Zealand

(a) Procedural Issue – Public Observation of the Oral Hearing

247. New Zealand supports the request of the participants to allow public observation of the oral hearing in these proceedings. New Zealand observes that Rule 27 of the *Working Procedures*, which regulates the oral hearing, "makes no mention of confidentiality".⁵⁴⁸ New Zealand additionally notes that the DSU does not mention hearings at the Appellate Body stage and therefore does not explicitly preclude opening such a hearing. New Zealand also agrees with the participants that Article 17.10, "read in accordance with the rules of treaty interpretation and in the context of other provisions in the DSU" does not preclude public observation of the oral hearing. Therefore, New Zealand considers that the joint request of the participants to open the hearing of the Appellate Body in these consolidated appeals is neither inconsistent with, nor precluded by, the DSU, the other covered agreements, or the *Working Procedures*.

⁵⁴⁶India's comments on participants' request for an open hearing, p. 1.

⁵⁴⁷*Ibid.*

⁵⁴⁸New Zealand's comments on participants' request for an open hearing, p. 1.

(b) Articles 21, 22, and 23 of the DSU

248. New Zealand submits that the Panel erred in finding that the United States and Canada have acted inconsistently with Articles 23.1 and 23.2(a) of the DSU. In New Zealand's view, the Panel should have interpreted Articles 23.1 and 23.2(a) in the context of the other provisions of the DSU, in particular Article 22.8, which sets out three conditions that must be met in order to have the suspension of concessions terminated. New Zealand maintains that the first condition under Article 22.8, which is the relevant one in this dispute, refers to situations where the inconsistent measure has actually been removed, and not where the measure is merely claimed to have been removed. Thus, New Zealand submits, because the Panel found that the European Communities has not removed the inconsistent measure within the meaning of Article 22.8, the United States and Canada have every right to continue the suspension of concessions. New Zealand contends that, by comparison, Article 23 is the "framework provision setting up the requirement to have recourse to dispute settlement"⁵⁴⁹ and does not address the specific situation in this case, where the United States and Canada have already had recourse to dispute settlement. New Zealand adds that Article 23 does not impose an obligation on the United States and Canada to cease the suspension of concessions or to resort to Article 21.5 proceedings.

249. New Zealand maintains that, in reaching its finding of violation under Articles 23.1 and 23.2(a) of the DSU, the Panel failed to consider the object and purpose of the DSU, which is to provide security and predictability to the multilateral trading system. New Zealand observes that the Panel's finding leads to the result that the Member authorized to suspend concessions must terminate the suspension whenever the non-compliant Member notifies its adoption of an implementing measure to the DSB and then waits to be challenged. New Zealand adds that the Panel's approach "would almost inevitably give rise to the situation where an implementing Member could continually impose successive rounds of litigation at will, merely by asserting that it had complied"⁵⁵⁰, thus undermining the predictability of the suspension of concessions and its importance in inducing prompt compliance. New Zealand also argues that the Panel's examination of Articles 23.1 and 23.2(a) in isolation from Article 22.8 "reduce[s]" the latter provision "to redundancy or inutility".⁵⁵¹

250. New Zealand submits that the Panel's suggestion that the United States and Canada should have recourse to the rules and procedures of the DSU without delay "is simply not tenable".⁵⁵² Such a suggestion undermines the authorization to suspend concessions that the United States and Canada have obtained from the DSB. This is incompatible with the objective of "prompt settlement" of

⁵⁴⁹New Zealand's third participant's submission, para. 3.21.

⁵⁵⁰*Ibid.*, para. 3.30.

⁵⁵¹*Ibid.*, para. 3.36.

⁵⁵²*Ibid.*, para. 3.62.

disputes envisaged in Article 3.3 of the DSU, because it would result in a "redundant" proceeding in which a new panel would look at "an issue that was already dealt with in the context of the current proceedings".⁵⁵³

(c) Terms of Reference

251. New Zealand contends that the Panel erred in stating that it did not have jurisdiction to rule on the compatibility of Directive 2003/74/EC with the covered agreements. New Zealand submits that the Panel should have explicitly determined the compatibility of Directive 2003/74/EC with the covered agreements because it had substantively reviewed the Directive and had concluded that the measure found to be inconsistent with the *SPS Agreement* in *EC – Hormones* had not been removed by the European Communities. In New Zealand's view, the Panel Report is sufficiently comprehensive for the Appellate Body to determine explicitly the compatibility of Directive 2003/74/EC with Articles 5.1 and 5.7 of the *SPS Agreement*.

(d) Articles 5.1 and 5.7 of the *SPS Agreement*

252. New Zealand "strongly"⁵⁵⁴ disagrees with the European Communities' arguments in relation to Articles 5.1 and 5.7 of the *SPS Agreement* because they would "seriously undermine the principles and obligations"⁵⁵⁵ of that Agreement. The *SPS Agreement* imposes a "very important" requirement that SPS measures be developed and implemented in a manner that is "transparent, consistent, scientifically-based, and the least trade-restrictive"⁵⁵⁶, and this requirement is at the "forefront"⁵⁵⁷ of this dispute. New Zealand recalls that Article 2.2 of the *SPS Agreement* imposes a general obligation that SPS measures be based on scientific principles and not maintained without sufficient scientific evidence. This obligation is given specific application by Article 5.1, which requires that SPS measures be "based on" a risk assessment, which, according to the Appellate Body's interpretation, entails that there must be a "rational relationship between the measure and the risk assessment" whereby the results of the risk assessment sufficiently warrant the SPS measures at stake.⁵⁵⁸ In New Zealand's view, the Panel correctly concluded that Directive 2003/74/EC was not based on a risk assessment within the meaning of Article 5.1. The Panel's findings were supported by an exhaustive overview of all relevant scientific evidence, drawing upon the expertise and knowledge of a group of eminent scientific and technical experts.

⁵⁵³New Zealand's third participant's submission, para. 3.62 (quoting Canada's other appellant's submission, para. 96).

⁵⁵⁴*Ibid.*, para. 3.42.

⁵⁵⁵*Ibid.*, para. 3.43.

⁵⁵⁶*Ibid.*, para. 3.44.

⁵⁵⁷*Ibid.*, para. 3.45.

⁵⁵⁸*Ibid.*, para. 3.46 (referring to Appellate Body Report, *EC – Hormones*, para. 193).

253. New Zealand states that the risk assessment at issue in this dispute is the second type of risk assessment provided for in paragraph 4 of Annex A to the *SPS Agreement*, which is "designed to protect from risks arising from additives, contaminants, toxins or disease-causing organisms in foodstuffs".⁵⁵⁹ New Zealand recalls that, with regard to this type of risk assessment, the Appellate Body indicated in *EC – Hormones* that a Member is required to "identify the adverse effects on human or animal health (if any) arising from the presence of such additives, contaminants, toxins or disease-causing organisms in foodstuffs", and, "if any adverse effects exist, evaluate the potential (or possibility) of the occurrence of such effects."⁵⁶⁰ The Appellate Body also found that "the 'risk' evaluated in a risk assessment must be ascertainable—theoretical uncertainty is not the kind of risk which ... is to be assessed".⁵⁶¹ New Zealand also refers to the panel's finding in *Japan – Apples* that a panel's review of a measure under Article 5.1 would also involve an evaluation of whether the risk assessment was "as appropriate to the circumstances", and whether it took into account "risk assessment techniques developed by the relevant international organizations."⁵⁶² New Zealand recalls further the Appellate Body's finding in *EC – Hormones* that the European Communities "did not actually proceed to an assessment, within the meaning of Articles 5.1 and 5.2, of the risks arising from the failure of observance of good veterinary practice combined with problems of control of the use of hormones for growth promotion purposes."⁵⁶³ New Zealand concludes that, as in *EC – Hormones*, the European Communities "once again"⁵⁶⁴ has failed to demonstrate that the risk assessment underlying Directive 2003/74/EC satisfies the requirements of the *SPS Agreement*.

254. New Zealand argues that, as the Member invoking Article 5.7, the European Communities bears the burden of demonstrating that the four requirements of Article 5.7 have been met, including the requirement that the measure be imposed in a situation where relevant scientific evidence is "insufficient".⁵⁶⁵ New Zealand recalls the Appellate Body's finding that these four requirements are "cumulative"⁵⁶⁶, and that, whenever one of them is not met, the measure at issue is inconsistent with Article 5.7. New Zealand asserts that European Communities has failed to demonstrate that it has satisfied any of the requirements under Article 5.7 with respect to Directive 2003/74/EC.

⁵⁵⁹New Zealand's third participant's submission, para. 3.52.

⁵⁶⁰*Ibid.* (referring to Appellate Body Report, *EC – Hormones*, para. 183). (emphasis omitted)

⁵⁶¹*Ibid.*, para. 3.53 (quoting Appellate Body Report, *EC – Hormones*, para. 186).

⁵⁶²*Ibid.*, para. 3.54 (quoting Panel Report, *Japan – Apples*, para. 8.236).

⁵⁶³*Ibid.*, para. 3.55 (quoting Appellate Body Report, *EC – Hormones*, para. 208).

⁵⁶⁴*Ibid.*, para. 3.56.

⁵⁶⁵*Ibid.*, para. 3.58 (referring to Panel Report, *Japan – Apples*, para. 8.212). In addition, the other requirements are: (i) the provisional SPS measure must be adopted on the "basis of available pertinent information"; (ii) the Member seeks to "obtain the additional information necessary for a more objective risk assessment"; and (iii) the Member reviews the measure "accordingly within a reasonable period of time".

⁵⁶⁶*Ibid.*, para. 3.59 (referring to Appellate Body Report, *Japan – Agricultural Products II*, para. 89).

7. Norway

(a) Procedural Issue – Public Observation of the Oral Hearing

255. Norway supports the participants' request that the Appellate Body allow public observation of the oral hearing in these proceedings. Norway asserts that the meaning of the term "proceedings" in isolation is not unequivocal, and resort must be had to context and object and purpose as set out in Article 31(1) of the *Vienna Convention on the Law of Treaties*⁵⁶⁷ (the "*Vienna Convention*"). Turning to Articles 17.5 and 17.12 of the DSU as context, Norway recognizes that these provisions use the term "proceedings" "as 'short-hand' for all stages in an appeal", but it considers that this is "not dispositive in itself".⁵⁶⁸ Norway also recognizes that Article 17.10 is drafted differently from Article 14.1, which uses the term "deliberations", but it does not consider that this implies that the term "proceedings" in the first sentence of Article 17.10 must be read to require confidentiality of the oral hearing before the Appellate Body. Norway asserts that it "cannot see that the object and purpose of Article 17.10 is different from [that of] Article 14.1 of the DSU, which is to protect the internal work of panels" and argues that "[t]he object and purpose thus indicates that the term 'proceedings' in Article 17.10 should be given a restrictive interpretation, focussing on the internal work of the Appellate Body, and not encompass[ing] the oral hearing."⁵⁶⁹ Norway submits that a restrictive interpretation of "proceedings" is also supported by the Spanish and French versions of the DSU referring to the term "*actuaciones*" in Spanish and the term "*travaux*" in French, in accordance with Article 33 of the *Vienna Convention*. Norway finds further support for a restrictive interpretation of the term "proceedings" in the fact that Article 18.2 specifically authorizes parties to a dispute to disclose their submissions and statements to the public. In Norway's view, Article 18.2 cannot be interpreted to require "more confidentiality than the parties require".⁵⁷⁰

256. Norway thus considers that the DSU allows the Appellate Body to open the oral hearing to the public where all participants to the dispute so request and that the Appellate Body has discretion under Rule 16(1) of the *Working Procedures* to respond favourably to the request. Norway states that allowing public observation will bring the Appellate Body more into line with other international tribunals where "open hearings is the norm".⁵⁷¹ Norway further considers that allowing public observation "will be beneficial to the process and to the legitimacy of the Appellate Body's work".⁵⁷²

⁵⁶⁷Done at Vienna, 23 May 1969, 1155 UNTS 331; 8 International Legal Materials 679.

⁵⁶⁸Norway's comments on participants' request for an open hearing, para. 15.

⁵⁶⁹*Ibid.*, para. 23.

⁵⁷⁰*Ibid.*, para. 37.

⁵⁷¹*Ibid.*, para. 39.

⁵⁷²*Ibid.*

(b) Articles 21, 22, and 23 of the DSU

257. Norway maintains that Article 22.8 of the DSU requires that the suspension of concessions be temporary and conditional. Norway emphasizes that once compliance is achieved, be it through a simple revocation of the inconsistent measure or its replacement with another measure that ensures compliance, the right to suspend concessions "*automatically lapses*"⁵⁷³ without a need for formal revocation of the authorization by the DSB. Norway submits that, where the parties disagree as to whether the measure taken to comply actually achieves compliance, as is the case in this dispute, the parties must resort to Article 21.5 panel proceedings. Once a panel (and the Appellate Body, if the panel report is appealed) determines that the implementing measure brings the Member concerned into compliance with the recommendations and rulings of the DSB, "the previous authorization [to suspend concessions] lapses *ipso facto* once the report is adopted, without there being a need for the DSB to revoke it formally as the temporal condition ... no longer exists".⁵⁷⁴

258. Norway further submits that a presumption of good faith compliance is applicable under the DSU, and the original complainant who considers that the measure taken to comply fails to achieve compliance has an obligation to initiate Article 21.5 proceedings. Noting that Articles 22.8 and 21.5 do not set forth any time-limits for initiating Article 21.5 proceedings, Norway claims that this does not mean that the original complainant may simply refuse to launch such proceedings. In Norway's view, beyond a certain point in time, Article 23.2(a) may be breached. To avoid unreasonable delays, Article 21.5 should be interpreted to allow both the original complainant and the original respondent to initiate Article 21.5 proceedings. Norway contends that Article 21.5 is written in the passive form without specifying which party may initiate the proceedings and, consequently, this provision allows both parties to launch Article 21.5 proceedings. The fact that the compliance panel report in *EC – Bananas III (Article 21.5 – EC)* remained unadopted, and that the panel refused to make any recommendations or rulings, does not in itself prove that an original respondent may not invoke Article 21.5, because that case involved particular circumstances that explain the outcome.

259. Norway explains that, in Article 21.5 proceedings launched by the original respondent, the panel may not "make a declaratory judgment based on the presentation of the original respondent, but must make an objective assessment of the matter before it."⁵⁷⁵ However, where the original complainant refuses to participate, any claim that the new measure is inconsistent with other provisions of the covered agreements will not be heard. In such proceedings, the original respondent may be considered as a "complainant" for purposes of Article 6.1 and an "applicant" for purposes of

⁵⁷³Norway's third participant's submission, para. 6. (original emphasis)

⁵⁷⁴*Ibid.*, para. 7.

⁵⁷⁵*Ibid.*, para. 15.

Article 6.2 of the DSU. The requirements of Article 6.2 can be fulfilled by referring to the original panel and Appellate Body reports, together with the identification of the specific measure taken to comply and a description of how it ensures compliance. Norway adds that, in such proceedings, "[o]nly the violations specifically addressed"⁵⁷⁶ in the panel and Appellate Body reports in the original dispute will be within the Article 21.5 panel's terms of reference. This is because the original respondent does not complain about specific violations by other Members, but asks for a "declaratory finding"⁵⁷⁷ of compliance with the DSB's recommendations and rulings in the original dispute. By not launching Article 21.5 panel proceedings first, the original complainant loses certain rights to present new claims that it would have been able to include in the panel's terms of reference if it had initiated the Article 21.5 proceedings and submitted the request for the establishment of a panel. Consequently, Norway submits that allowing the original respondent to launch Article 21.5 proceedings would provide the original complainants with the incentive to launch Article 21.5 panel proceedings first.

8. Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu

260. Pursuant to Rule 24(2) of the *Working Procedures*, the Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu chose not to submit a third participant's submission.

261. The Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu supports the request of the participants to allow public observation of the oral hearing in these proceedings "in the interests of greater transparency".⁵⁷⁸

III. Issues Raised in This Appeal

262. The following issues are raised on appeal by the European Communities:

- (a) Whether the Panel erred in failing to find that the United States and Canada had to initiate proceedings pursuant to Article 21.5 of the DSU in order to comply with their obligations, under Articles 23.1 and 23.2(a), to have recourse to the rules and procedures of the DSU;
- (b) Whether the Panel erred in finding that Article 22.8 of the DSU was not breached by the United States and Canada because the European Communities has failed to comply with the recommendations and rulings of the DSB in *EC – Hormones*, which

⁵⁷⁶Norway's third participant's submission, para. 17.

⁵⁷⁷*Ibid.*, para. 18.

⁵⁷⁸Comments of Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu on participants' request for an open hearing, p. 1.

underlie the authorization given to the United States and Canada to suspend concessions and other obligations;

- (c) Whether the Panel exceeded its terms of reference by examining the compatibility of Directive 2003/74/EC⁵⁷⁹ with Articles 5.1 and 5.7 of the *SPS Agreement*;
- (d) Whether the Panel erred by failing to make the suggestion, pursuant to its authority under Article 19.1 of the DSU, that the United States and Canada cease the suspension of concessions and resort to Article 21.5 proceedings, or any other proceedings to which the parties may agree, to resolve any disagreements as to the consistency of Directive 2003/74/EC with the *SPS Agreement*;
- (e) Whether the Panel failed to respect the principle of due process, and therefore failed to comply with its duties under Article 11 of the DSU, in selecting, and relying upon the advice of, two experts who were not "independent and impartial" as required by the *Rules of Conduct*;
- (f) Whether the Panel erred in interpreting and applying Article 5.1 of the *SPS Agreement* in assessing the consistency of the import ban on meat from cattle treated with oestradiol-17 β for growth-promotion purposes, applied pursuant to Directive 2003/74/EC, in particular by:
 - (i) adopting a narrow interpretation of "risk assessment" and failing to take into account evidence on misuse and abuse in the administration of hormones;
 - (ii) requiring the European Communities to evaluate specifically the risks arising from the presence of residues of oestradiol-17 β in meat or meat products as a result of the cattle being treated with this hormone for growth-promotion purposes;
 - (iii) imposing a quantitative method of risk assessment on the European Communities;
 - (iv) incorrectly allocating the burden of proof; and

⁵⁷⁹Directive 2003/74/EC of the European Parliament and of the Council of 22 September 2003 amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists, *Official Journal of the European Union*, L Series, No. 262 (14 October 2003) 17 (Exhibits EC-1 and US-3 submitted by the European Communities and the United States, respectively, to the Panel).

- (v) failing to make an objective assessment of the matter before it, as required by Article 11 of the DSU, by articulating and applying an incorrect standard of review.

- (g) Whether the Panel erred in interpreting and applying Article 5.7 of the *SPS Agreement* when assessing the consistency of the provisional import ban on meat from cattle treated with testosterone, progesterone, trenbolone acetate, zeranol, and melengestrol acetate ("MGA") for growth-promotion purposes, applied under Directive 2003/74/EC. More specifically, whether the Panel erred in finding that the relevant scientific evidence was insufficient because it:
 - (i) incorrectly found that the determination of whether the relevant scientific evidence is insufficient "must be disconnected" from the chosen level of protection;
 - (ii) articulated and applied an incorrect legal test pursuant to which, where international standards exist for a substance, a "critical mass of new scientific evidence" is required to render the relevant scientific evidence "insufficient";
 - (iii) incorrectly allocated the burden of proof; and
 - (iv) failed to make an objective assessment of the matter before it, as required by Article 11 of DSU.

263. The following issues are raised on appeal by the United States and Canada:

- (a) Whether the Panel erred in finding that the United States and Canada were seeking the redress of a violation within the meaning of Article 23.1 of the DSU, by maintaining the suspension of concessions after the notification of Directive 2003/74/EC by the European Communities;
- (b) Whether the Panel erred in finding that the United States and Canada made a unilateral determination that Directive 2003/74/EC is not consistent with the WTO agreements without recourse to the rules and procedures of the DSU, in breach of Article 23.2(a) of the DSU.

264. In the event that the Appellate Body were to uphold the Panel's finding that the United States and Canada acted inconsistently with Articles 23.2(a) and 23.1 of the DSU, the United States and Canada conditionally appeal the following issues:

- (a) Whether the Panel erred in concluding that it was not called upon, and hence did not have jurisdiction, to determine the compatibility of Directive 2003/74/EC with Articles 5.1 and 5.7 of the *SPS Agreement*;
- (b) Whether the Panel erred in suggesting, pursuant to Article 19.1 of the DSU, that the United States and Canada have recourse to the rules and procedures of the DSU without delay.

IV. The Application of the DSU in the Post-Suspension Stage of a Dispute

A. Introduction

265. We begin with the issues raised on appeal by Canada, the European Communities, and the United States relating to the interpretation and application of several provisions of the DSU in the post-suspension stage of a dispute. This stage refers to the period after a WTO Member has suspended concessions or other obligations to another Member⁵⁸⁰, having received authorization to do so from the DSB. The authorization to suspend concessions stems from the other Member's failure to bring into compliance measures that have been found to be inconsistent with the covered agreements by a panel or the Appellate Body.

266. This appeal relates to the *EC – Hormones* dispute in which, following a complaint by the United States and Canada, the ban imposed by the European Communities on imports of meat from cattle treated with growth-promoting hormones, pursuant to Directive 96/22/EC, was found to be inconsistent with the *SPS Agreement*.⁵⁸¹ Because the European Communities failed to bring itself into compliance within the reasonable period of time, which expired on 13 May 1999⁵⁸², the United States and Canada requested the DSB to authorize suspension of concessions pursuant to Article 22.2 of the DSU.⁵⁸³ The United States and Canada obtained authorization from the DSB to suspend concessions in relation to the European Communities on 26 July 1999, following an arbitration at the European Communities' request.⁵⁸⁴ On 29 July 1999, the United States applied 100 per cent import duties on a range of imports from certain member States of the European Communities.⁵⁸⁵

⁵⁸⁰We will use the term "suspension of concessions" as an abbreviated reference to "the suspension of concessions or other obligations".

⁵⁸¹Appellate Body Report, *EC – Hormones*, para. 253.

⁵⁸²Award of the Arbitrator, *EC – Hormones*, para. 48.

⁵⁸³WT/DS26/19; WT/DS48/17.

⁵⁸⁴Decision by the Arbitrators, *EC – Hormones (Article 22.6 – United States)*, para. 84; Decision by the Arbitrators, *EC – Hormones (Article 22.6 – Canada)*, para. 73. See also WT/DS26/20; WT/DS48/18.

⁵⁸⁵See *supra*, footnote 17.

On 1 August 1999, Canada applied 100 per cent *ad valorem* duties on a similar range of imports from the European Communities.⁵⁸⁶

267. After the adoption of the panel and Appellate Body reports in the *EC – Hormones* dispute, the European Commission commissioned 17 scientific studies to assess the risks to human health posed by the six hormones at issue.⁵⁸⁷ On the basis of these studies and additional scientific information made available to the European Commission, the Scientific Committee on Veterinary Measures relating to Public Health (the "SCVPH") issued three Opinions in 1999, 2000, and 2002 concerning risks to human health posed by the six hormones.⁵⁸⁸ In the light of these Opinions, the European Communities adopted Directive 2003/74/EC on 22 September 2003⁵⁸⁹, which amends Directive 96/22/EC. Directive 2003/74/EC maintains the permanent prohibition on the importation of meat and meat products from animals treated with oestradiol-17 β for growth-promotion purposes originally contained in Directive 96/22/EC.⁵⁹⁰ In relation to the five other hormones—testosterone, progesterone, trenbolone acetate, zeranol, and MGA—Directive 2003/74/EC imposes the prohibition on a provisional basis.⁵⁹¹ Directive 2003/74/EC specifies that, even though the scientific information available showed the existence of risks associated with these substances, "the current state of knowledge does not make it possible to give a quantitative estimate of the risk to consumers".⁵⁹² The prohibition of these five hormones applies "while the Community seeks more complete scientific information from any source, which could shed light and clarify the gaps in the present state of knowledge of these substances".⁵⁹³

268. On 27 October 2003, the European Communities notified the DSB of the adoption, publication, and entry into force of Directive 2003/74/EC, as well as the 1999, 2000, and 2002 Opinions, which it considered provided a sufficient justification for the permanent and provisional prohibitions on the importation of meat from cattle treated with the six hormones under the *SPS Agreement*.⁵⁹⁴ The European Communities therefore claimed that it had fully implemented the DSB's recommendations and rulings in the original *EC – Hormones* dispute, and consequently considered that the suspension of concessions by the United States and Canada was no longer justified. The United States and Canada refused to lift the suspension of concessions imposed pursuant to the authorization obtained from the DSB, because they did not consider that Directive 2003/74/EC had

⁵⁸⁶See *supra*, footnote 18.

⁵⁸⁷See *supra*, footnote 19.

⁵⁸⁸See *supra*, footnotes 20, 21, and 22.

⁵⁸⁹See *supra*, footnote 5.

⁵⁹⁰Directive 2003/74/EC, *supra*, footnote 5, Recital 10 and Article 1 (amending Articles 2 and 3 of Directive 96/22/EC).

⁵⁹¹*Ibid.*

⁵⁹²Directive 2003/74/EC, *supra*, footnote 5, Recital 7.

⁵⁹³*Ibid.*, Recital 10.

⁵⁹⁴WT/DS26/22; WT/DS48/20.

brought the European Communities into compliance with the DSB's recommendations and rulings.⁵⁹⁵ The European Communities initiated the present proceedings alleging that the United States and Canada acted inconsistently with their obligations under the DSU by continuing the suspension of concessions.⁵⁹⁶

269. A summary of the findings of the Panel is provided in section B and the claims and arguments raised on appeal are described in section C. In sections D and E we address the claims raised by the European Communities, including whether Article 22.8 of the DSU required the United States and Canada to cease the application of the suspension of concessions upon the European Communities' notification of Directive 2003/74/EC, and whether the United States and Canada were required to initiate Article 21.5 proceedings if they did not consider that Directive 2003/74/EC is consistent with the covered agreements. Section F addresses the claims raised by the United States and Canada in their other appeals concerning the Panel's findings that they breached Articles 23.2(a) and 23.1 of the DSU by seeking the redress of a violation without recourse to the rules and procedures of the DSU. Section G addresses the conditional claims raised by the United States and Canada in relation to the Panel's finding that it did not have jurisdiction to determine the compatibility of Directive 2003/74/EC with the covered agreements. Finally, section H addresses the issues raised by all three participants concerning the suggestion made by the Panel pursuant to Article 19.1 of the DSU.

B. *The Panel's Findings*

1. Scope of the European Communities' Claims

270. Before the Panel, the European Communities raised "two sets of main claims" against the continued suspension of concessions by the United States and Canada. It asserted that the continued suspension is inconsistent with: (i) Article 23.2(a), read together with Articles 21.5 and 23.1 of the DSU; and (ii) Article 23.1, read in conjunction with Articles 22.8 and 3.7 of the DSU. In addition, the European Communities raised claims under Articles I and II of the GATT 1994.⁵⁹⁷ In the event that the Panel found no violation of Article 23 of the DSU, the European Communities claimed, in the

⁵⁹⁵WT/DSB/M/157; WT/DSB/M/159.

⁵⁹⁶In December 2004, the United States requested information from the European Communities pursuant to Article 5.8 of the *SPS Agreement* concerning the justification underlying Directive 2003/74/EC. (Panel Report, *US – Continued Suspension*, para. 7.227) The Panel was established on 14 January 2005 at the European Communities' request. (Panel Report, *US – Continued Suspension*, para. 1.2; Panel Report, *Canada – Continued Suspension*, para. 1.2)

⁵⁹⁷Panel Report, *US – Continued Suspension*, para. 3.1; Panel Report, *Canada – Continued Suspension*, para. 3.2.

alternative, that the continued suspension by the United States and Canada is inconsistent with Article 22.8 of the DSU.⁵⁹⁸

271. At the outset of its analysis, the Panel made some preliminary remarks concerning the scope of its mandate. The Panel recalled that the matter before it was the alleged failure of the United States and Canada to comply with their obligations under the DSU by maintaining the suspension of concessions authorized by the DSB in the *EC – Hormones* dispute, even though the European Communities had adopted Directive 2003/74/EC and notified this Directive to the DSB as the measure taken to comply.⁵⁹⁹ The Panel noted that, in its first written submission, the European Communities divided its claims into "two main sets of claims" and one conditional claim. Under the first set of claims, the European Communities alleged that the United States and Canada, by maintaining the suspension of concessions, were seeking redress of a perceived violation by the European Communities of the covered agreements without recourse to the rules and procedures of the DSU, in breach of Article 23.2(a), read in conjunction with Articles 21.5 and 23.1 of the DSU.⁶⁰⁰ Under the second set of claims, the European Communities submitted that, because it should be *presumed* to have complied in good faith with the DSB's recommendations and rulings by adopting and notifying Directive 2003/74/EC, the continued application of the suspension of concessions by the United States and Canada is also inconsistent with Article 23.1, read together with Articles 22.8 and 3.7 of the DSU.⁶⁰¹ Finally, in the event that the Panel was not to find "any violation under Articles 23.1, 23.2(a), 3.7, 22.8, and 21.5 of the DSU"⁶⁰², the European Communities raised a conditional claim alleging that the United States and Canada violated Article 22.8 of the DSU *per se* because, by adopting Directive 2003/74/EC, the European Communities had achieved *actual* (rather than *presumed*) compliance requiring termination of the suspension of concession in accordance with Article 22.8.⁶⁰³

272. The Panel considered that this approach, although not specified in the European Communities' request for the establishment of a panel, "is actually a clarification of the claims listed in its request

⁵⁹⁸Panel Report, *US – Continued Suspension*, para. 3.2; Panel Report, *Canada – Continued Suspension*, para. 3.2.

⁵⁹⁹Panel Report, *US – Continued Suspension*, paras. 7.150 and 7.151; Panel Report, *Canada – Continued Suspension*, paras. 7.137 and 7.138.

⁶⁰⁰Panel Report, *US – Continued Suspension*, paras. 7.153 and 7.183; Panel Report, *Canada – Continued Suspension*, paras. 7.140 and 7.165.

⁶⁰¹Panel Report, *US – Continued Suspension*, paras. 7.153 and 7.252; Panel Report, *Canada – Continued Suspension*, paras. 7.140 and 7.245.

⁶⁰²Panel Report, *US – Continued Suspension*, para. 7.155; Panel Report, *Canada – Continued Suspension*, para. 7.142.

⁶⁰³Panel Report, *US – Continued Suspension*, para. 7.156; Panel Report, *Canada – Continued Suspension*, para. 7.143.

for the establishment of a panel and not arguments".⁶⁰⁴ Thus, the Panel considered that the approach outlined in the European Communities' first written submission constituted part of the Panel's terms of reference.⁶⁰⁵ The Panel therefore decided that it would address the two main claims as elaborated by the European Communities in its first written submission, and would address the conditional claim only if the European Communities failed to establish its two main claims.⁶⁰⁶

2. The European Communities' Claim that the United States and Canada Breached Article 23.2(a) of the DSU Read Together with Articles 23.1 and 21.5

273. The Panel first examined the European Communities' claim under Article 23.2(a), read together with Articles 23.1 and 21.5 of the DSU. The Panel referred to the phrase "[i]n such cases", which connects paragraphs 1 and 2 of Article 23, and observed that this phrase indicated that it would have to determine whether the conditions of Article 23.1 were met before it could assess whether the United States and Canada breached Article 23.2(a) of the DSU. In the Panel's view, "Article 23.1 applies in this case only with respect to a determination against a measure which has not yet been subject to a recourse to the rules and procedures of the DSU."⁶⁰⁷ According to the Panel, Directive 2003/74/EC is such a measure.⁶⁰⁸ Noting that Directive 2003/74/EC, like the measure it replaced, imposed an import ban, the Panel recalled that it is not the import ban on meat treated with hormones, but rather the justification for this ban, that was found to be inconsistent with the *SPS Agreement* in *EC – Hormones*. Therefore, the Panel "d[id] not consider that the fact that the ban remains in place means that no new measure has been adopted".⁶⁰⁹ The Panel further found that, although the United States and Canada were authorized to suspend concessions, such "'authorization by the DSB' does not mean [an] 'obligation to suspend concessions'".⁶¹⁰ Thus, in the Panel's view, "the fact that, after the European Communities' notification of Directive 2003/74/EC", the United States and Canada "continue[] to apply [their] suspension of concessions even though [they have] no

⁶⁰⁴Panel Report, *US – Continued Suspension*, para. 7.163; Panel Report, *Canada – Continued Suspension*, para. 7.150.

⁶⁰⁵Panel Report, *US – Continued Suspension*, para. 7.164; Panel Report, *Canada – Continued Suspension*, para. 7.151.

⁶⁰⁶Panel Report, *US – Continued Suspension*, para. 7.164; Panel Report, *Canada – Continued Suspension*, para. 7.151.

⁶⁰⁷Panel Report, *US – Continued Suspension*, para. 7.205; Panel Report, *Canada – Continued Suspension*, para. 7.197.

⁶⁰⁸Panel Report, *US – Continued Suspension*, para. 7.206; Panel Report, *Canada – Continued Suspension*, para. 7.198.

⁶⁰⁹Panel Report, *US – Continued Suspension*, para. 7.207; Panel Report, *Canada – Continued Suspension*, para. 7.199.

⁶¹⁰Panel Report, *US – Continued Suspension*, para. 7.209; Panel Report, *Canada – Continued Suspension*, para. 7.201.

obligation to do so is evidence" that the United States and Canada are "actively" seeking the redress of a violation within the meaning of Article 23.1.⁶¹¹

274. Having found that the conditions for the applicability of Article 23.1 were met, the Panel proceeded to examine whether the United States and Canada had "ma[d]e a determination to the effect that a violation has occurred" within the meaning of Article 23.2(a) in respect of Directive 2003/74/EC. The Panel observed that statements made at two DSB meetings concerning the notification of Directive 2003/74/EC indicated that the United States and Canada reached "a more or less final decision"⁶¹² that the new Directive fails to implement the DSB's recommendations and rulings in *EC – Hormones* and is inconsistent with the *SPS Agreement*. Such statements, in the Panel's view, constitute a "determination" under Article 23.2(a) of the DSU.⁶¹³ The Panel added that, even if such statements were considered provisional, "the subsequent continuation of the suspension of concessions by [the United States and Canada] without alteration and without saying that [they were] still studying [Directive 2003/74/EC]" confirms that they made such a "determination".⁶¹⁴ The Panel further found that, because the DSB's authorization to suspend concessions does not apply to Directive 2003/74/EC⁶¹⁵ and does not amount to "a multilateral determination of inconsistency" regarding that Directive⁶¹⁶, the United States and Canada failed to make a determination through recourse to the rules and procedures of the DSU, in violation of Article 23.2(a) of the DSU. Because the United States and Canada "ha[d] not made any determination through recourse to dispute settlement in accordance with the rules and procedures of the DSU," the Panel concluded *a fortiori* that the United States and Canada "ha[d] failed to make any such determination consistent with the findings contained in the panel or Appellate Body report adopted by the DSB or an arbitration award rendered under the DSU."⁶¹⁷ Therefore, the Panel found that the United States and Canada had breached Article 23.2(a) of the DSU.⁶¹⁸

⁶¹¹Panel Report, *US – Continued Suspension*, para. 7.209; Panel Report, *Canada – Continued Suspension*, para. 7.201.

⁶¹²Panel Report, *US – Continued Suspension*, para. 7.222; Panel Report, *Canada – Continued Suspension*, para. 7.215 (quoting Panel Report, *US – Section 301 Trade Act*, footnote 657 to para. 7.50).

⁶¹³Panel Report, *US – Continued Suspension*, paras. 7.225 and 7.226; Panel Report, *Canada – Continued Suspension*, paras. 7.219, 7.222, and 7.223.

⁶¹⁴Panel Report, *US – Continued Suspension*, para. 7.230; Panel Report, *Canada – Continued Suspension*, para. 7.224.

⁶¹⁵Panel Report, *US – Continued Suspension*, para. 7.234; Panel Report, *Canada – Continued Suspension*, para. 7.228.

⁶¹⁶Panel Report, *US – Continued Suspension*, para. 7.242; Panel Report, *Canada – Continued Suspension*, para. 7.235.

⁶¹⁷Panel Report, *US – Continued Suspension*, para. 7.244; Panel Report, *Canada – Continued Suspension*, para. 7.237. (emphasis omitted)

⁶¹⁸Panel Report, *US – Continued Suspension*, para. 7.245; Panel Report, *Canada – Continued Suspension*, para. 7.238.

275. Next, the Panel turned to the European Communities' claim that the United States and Canada were required to initiate Article 21.5 proceedings if they considered that Directive 2003/74/EC was not consistent with the covered agreements. The Panel stated that recourse to the rules and procedures of the DSU, within the meaning of Article 23.2(a), "encompasses any of the means of dispute settlement provided in the DSU, including consultation, conciliation, good offices and mediation"⁶¹⁹ and is not limited to panel proceedings under Article 21.5 of the DSU. On this basis, the Panel "[did] not find it necessary to make a finding on whether [the United States and Canada] breached Article 21.5 by not having recourse to the procedure under that provision".⁶²⁰

276. On the basis of the above, the Panel concluded that the United States and Canada:

violated Article 23.1 and 23.2(a) of the DSU by seeking redress of a violation of the WTO Agreement through a determination that the [European Communities'] implementing measure did not comply with the DSB recommendations and rulings in the *EC – Hormones* case without having recourse to dispute settlement in accordance with the rules and procedures of the DSU.⁶²¹

3. The European Communities' Claim that the United States and Canada Breached Article 23.1 of the DSU Read Together with Articles 22.8 and 3.7

277. The Panel then turned to the European Communities' claim that the United States and Canada breached Article 23.1, read together with Articles 22.8 and 3.7 of the DSU, by continuing the suspension of concession even though the measure found to be inconsistent in *EC – Hormones* had been removed. The Panel observed that its earlier findings that the United States and Canada committed a "procedural error under the DSU [and] breached Articles 23.1 and 23.2(a)"⁶²² were "completely unrelated to whether the European Communities implemented the DSB recommendations and rulings"⁶²³ in *EC – Hormones* in substance. In contrast, the Panel found that the European Communities' allegation of violations of Articles 22.8, 23.1, and 3.7 of the DSU was premised on the "conformity (presumed or actual) with the *SPS Agreement*"⁶²⁴ of Directive 2003/74/EC. This is because, in the Panel's view, the phrase "until such time as the measure found to be inconsistent ... has

⁶¹⁹Panel Report, *US – Continued Suspension*, para. 7.247; Panel Report, *Canada – Continued Suspension*, para. 7.240.

⁶²⁰Panel Report, *US – Continued Suspension*, para. 7.249; Panel Report, *Canada – Continued Suspension*, para. 7.242.

⁶²¹Panel Report, *US – Continued Suspension*, para. 7.251; Panel Report, *Canada – Continued Suspension*, para. 7.244.

⁶²²Panel Report, *US – Continued Suspension*, para. 7.270; Panel Report, *Canada – Continued Suspension*, para. 7.286.

⁶²³Panel Report, *US – Continued Suspension*, para. 7.272; Panel Report, *Canada – Continued Suspension*, para. 7.288.

⁶²⁴Panel Report, *US – Continued Suspension*, para. 7.272; Panel Report, *Canada – Continued Suspension*, para. 7.288.

been removed" in Article 22.8 implies that what is to be achieved is not the removal of the measure, but actual compliance with the DSB's recommendations and rulings.⁶²⁵ Thus, Article 22.8 may be breached "only if the European Communities has complied with the recommendations and rulings of the DSB and [the United States and Canada] failed to immediately remove [their] suspension of concessions or other obligations."⁶²⁶

278. With respect to the European Communities' argument that it should benefit from "a presumption of good faith compliance"⁶²⁷ regarding Directive 2003/74/EC, the Panel acknowledged that, under general international law, States enjoy a presumption of good faith in the performance of their treaty obligations.⁶²⁸ Nevertheless, the Panel found that this presumption does not mean that the European Communities "actually complied with its treaty obligations"⁶²⁹ and additionally observed that the United States and Canada may also invoke the presumption of good faith with regard to their respective measures.⁶³⁰ Turning to the text of the DSU, the Panel found that "there is no express exclusion of the application of the principle of good faith in the DSU".⁶³¹ The Panel then rejected the United States' and Canada's argument that "the presumption of good faith compliance cannot supersede the multilateral authorization of the DSB ... to suspend concessions."⁶³² According to the Panel, "the removal of the measure found to be inconsistent with a covered agreement supersedes the DSB authorization to suspend concessions", because nothing in Article 22.8 of the DSU suggests that a Member suspending concessions can continue to do so as long as the authorization has not been repealed by the DSB.⁶³³

279. Next, the Panel examined the European Communities' argument that the presumption of good faith compliance is only rebuttable by recourse to Article 21.5 by the United States and Canada. In examining this argument, the Panel considered it important "to determine the extent to which the

⁶²⁵Panel Report, *US – Continued Suspension*, para. 7.284; Panel Report, *Canada – Continued Suspension*, para. 7.300.

⁶²⁶Panel Report, *US – Continued Suspension*, para. 7.285; Panel Report, *Canada – Continued Suspension*, para. 7.301.

⁶²⁷Panel Report, *US – Continued Suspension*, para. 7.310; Panel Report, *Canada – Continued Suspension*, para. 7.310.

⁶²⁸Panel Report, *US – Continued Suspension*, para. 7.318; Panel Report, *Canada – Continued Suspension*, para. 7.318.

⁶²⁹Panel Report, *US – Continued Suspension*, para. 7.322; Panel Report, *Canada – Continued Suspension*, para. 7.322.

⁶³⁰Panel Report, *US – Continued Suspension*, para. 7.323; Panel Report, *Canada – Continued Suspension*, para. 7.323.

⁶³¹Panel Report, *US – Continued Suspension*, para. 7.336; Panel Report, *Canada – Continued Suspension*, para. 7.336.

⁶³²Panel Report, *US – Continued Suspension*, para. 7.342; Panel Report, *Canada – Continued Suspension*, para. 7.342.

⁶³³Panel Report, *US – Continued Suspension*, para. 7.343; Panel Report, *Canada – Continued Suspension*, para. 7.343.

unavailability of any legal recourse for the European Communities in a post retaliation situation may justify that the presumption of good faith compliance be irrebuttable, except through recourse to the procedure provided in Article 21.5 of the DSU."⁶³⁴ The Panel noted, first, that "nowhere does the DSU provide that a presumption of good faith compliance should be rebuttable only through recourse to Article 21.5 of the DSU."⁶³⁵ Secondly, the Panel observed that "it appears that, even under the current DSU, several means seem *a priori* to be available to the European Communities to obtain termination of the suspension of concessions or other obligations", including good offices and consultations, Article 21.5 proceedings, arbitration under Article 25 of the DSU, and recourse to regular panel procedures (as the European Communities had done in the present case).⁶³⁶ For these reasons, the Panel rejected the European Communities' argument "that the presumption of good faith compliance which the European Communities enjoys should be rebuttable only through a recourse by the complainants in the original case to Article 21.5 of the DSU."⁶³⁷ The Panel was not persuaded that Article 21.5 is the "only avenue" for addressing "a claim of compliance by a Member alleging to have complied with DSB recommendations and rulings", nor that Article 21.5 proceedings are "open only to the original complainant".⁶³⁸

280. The Panel concluded:

while we agree with the existence of a presumption of good faith compliance, we do not agree with the European Communities that the presumption of good faith that it enjoys may only be rebutted in an Article 21.5 procedure. We find, on the contrary, that this presumption, because it applies to measures taken by all parties, must be rebuttable before this Panel. Just as the [European Communities'] allegations are intended to rebut the presumption of good faith conformity of the [United States and Canadian] retaliatory measures with Article 22.8 of the DSU, [the United States and Canada] should

⁶³⁴Panel Report, *US – Continued Suspension*, para. 7.348; Panel Report, *Canada – Continued Suspension*, para. 7.346.

⁶³⁵Panel Report, *US – Continued Suspension*, para. 7.349; Panel Report, *Canada – Continued Suspension*, para. 7.347.

⁶³⁶Panel Report, *US – Continued Suspension*, para. 7.350; Panel Report, *Canada – Continued Suspension*, para. 7.348. The Panel noted that the broad language ("such dispute shall be decided through recourse to these dispute settlement procedures") used in Article 21.5 "could be deemed to encompass any procedure available under the DSU for the resolution of disputes". The Panel, however, opined that "other terms in Article 21.5 support the view that the Article 21.5 procedure is actually a panel procedure with a shorter deadline" and read the phrase "including whenever possible resort to the original panel" not as meaning that resort to a panel is generally preferred, but as requesting resort to the panelists that served on the original case, rather than to other individuals. (Panel Report, *US – Continued Suspension*, para. 7.351; Panel Report, *Canada – Continued Suspension*, para. 7.349)

⁶³⁷Panel Report, *US – Continued Suspension*, para. 7.356; Panel Report, *Canada – Continued Suspension*, para. 7.354.

⁶³⁸Panel Report, *US – Continued Suspension*, para. 7.355; Panel Report, *Canada – Continued Suspension*, para. 7.353.

be allowed to rebut the presumption of [European Communities'] compliance by proving actual non-compliance.⁶³⁹

281. The Panel noted that, by invoking a presumption of good faith compliance, the European Communities was supporting its claim that the United States and Canada acted inconsistently with Article 23.1, read together with Articles 22.8 and 3.7, because they failed to terminate the suspension of concessions upon the removal of the measure found to be inconsistent with a covered agreement within the meaning of Article 22.8.⁶⁴⁰ Thus, having determined that the presumption of good faith compliance is rebuttable in these proceedings, the Panel observed that, "for all practical purposes, this amounts to addressing the [European Communities'] 'alternative' claim of violation of Article 22.8 *per se*."⁶⁴¹ The Panel, however, explained that "this is not the result of us merely disregarding the order in which the European Communities wanted us to review this case".⁶⁴² Rather, the Panel considered that it was "still reviewing the [European Communities'] claim of violation of Article 23.1, read together with Articles 22.8 and 3.7" and "not reviewing a claim of violation of Article 22.8 in isolation."⁶⁴³

4. The Panel's Jurisdiction

282. The Panel recognized that its "terms of reference do not include any provision of the *SPS Agreement*"⁶⁴⁴ and that, as a consequence, it was not within its mandate to review the alleged violations of the *SPS Agreement* or to make findings under that Agreement. Nonetheless, the Panel found that it "should address the compatibility of [Directive 2003/74/EC] with the provisions of the *SPS Agreement* referred to by the parties to the extent necessary to determine, with respect to the

⁶³⁹Panel Report, *US – Continued Suspension*, para. 7.357(f); Panel Report, *Canada – Continued Suspension*, para. 7.355(f). The Panel clarified:

In reaching these conclusions, we do not consider that we add to or diminish the rights and obligations of WTO Members. We do not apply the presumption of good faith compliance independently from the obligations of the European Communities under the WTO Agreement. The European Communities has an obligation to comply with the WTO Agreement in general and with the recommendations and rulings of the DSB and the general principle of good faith implies that the European Communities do so in good faith. In doing so we apply the principle of good faith consistently with WTO law and general public international law.

(Panel Report, *US – Continued Suspension*, para. 7.358; Panel Report, *Canada – Continued Suspension*, para. 7.356) (footnotes omitted)

⁶⁴⁰Panel Report, *US – Continued Suspension*, para. 7.332; Panel Report, *Canada – Continued Suspension*, para. 7.332.

⁶⁴¹Panel Report, *US – Continued Suspension*, para. 7.359; Panel Report, *Canada – Continued Suspension*, para. 7.357.

⁶⁴²Panel Report, *US – Continued Suspension*, para. 7.359; Panel Report, *Canada – Continued Suspension*, para. 7.357.

⁶⁴³Panel Report, *US – Continued Suspension*, para. 7.359; Panel Report, *Canada – Continued Suspension*, para. 7.357.

⁶⁴⁴Panel Report, *US – Continued Suspension*, para. 7.360; Panel Report, *Canada – Continued Suspension*, para. 7.358.

[European Communities'] claim relating to Article 22.8, whether the [European Communities'] measure found to be inconsistent in the *EC – Hormones* case has been removed."⁶⁴⁵ Therefore, the Panel considered "that these are sufficient reasons for it to conclude that it has jurisdiction to consider the compatibility of the [European Communities'] implementing measure with the *SPS Agreement* as part of its review of the claim raised by the European Communities with respect to Article 22.8 of the DSU."⁶⁴⁶ The Panel recognized that it was difficult for the European Communities to "identify all potential problems of incompatibility".⁶⁴⁷ Instead, the Panel considered it "preferable, both from a legal and practical point of view, to consider *all* the allegations and arguments raised by each party, as long as the other party had the opportunity to comment on those allegations and arguments".⁶⁴⁸ On this basis, the Panel found that it could review the compatibility of the Directive 2003/74/EC with Articles 5.1, 5.2⁶⁴⁹, 5.7, and 3.3 of the *SPS Agreement*.⁶⁵⁰

5. Burden of Proof

283. Regarding the allocation of burden of proof, the Panel stated that it was for the European Communities to prove its claim that the United States and Canada had breached Article 22.8 of the DSU.⁶⁵¹ This claim was premised on the removal by the European Communities of the measure that

⁶⁴⁵Panel Report, *US – Continued Suspension*, para. 7.375; Panel Report, *Canada – Continued Suspension*, para. 7.372. The Panel was "mindful of the procedural problems raised by this approach", but did not consider that, by proceeding in this manner, it was exceeding its jurisdiction to the extent that such a review is necessary in order to address the European Communities' claims under Article 22.8. (*Ibid.*)

⁶⁴⁶Panel Report, *US – Continued Suspension*, para. 7.379; Panel Report, *Canada – Continued Suspension*, para. 7.376.

⁶⁴⁷Panel Report, *US – Continued Suspension*, para. 7.403; Panel Report, *Canada – Continued Suspension*, para. 7.400.

⁶⁴⁸Panel Report, *US – Continued Suspension*, para. 7.404; Panel Report, *Canada – Continued Suspension*, para. 7.401. (original emphasis)

⁶⁴⁹The Panel reviewed Article 5.2 of the *SPS Agreement* in *US – Continued Suspension* only, because Canada did not make a claim under this provision.

⁶⁵⁰Panel Report, *US – Continued Suspension*, para. 7.411; Panel Report, *Canada – Continued Suspension*, para. 7.402.

⁶⁵¹Panel Report, *US – Continued Suspension*, para. 7.383; Panel Report, *Canada – Continued Suspension*, para. 7.380. The Panel explained:

With respect to the violation of Article 22.8 as such, the Panel considered that it had, in principle, no reason to address burden of proof any differently than any other panel established under Article 6 of the DSU. Indeed, as stated by the [European Communities] itself, this case is about a measure taken by [the United States and Canada, respectively]. The fact that this dispute takes place in the context of the [European Communities'] alleged compliance with the recommendations and rulings of the DSB in the *EC – Hormones* dispute should have no impact on the question of the burden of proof regarding the actual claim before us. This means that the principles identified by the Appellate Body above apply, and that the European Communities must prove its claim that [the United States and Canada] breach[] Article 22.8 of the DSU.

(Panel Report, *US – Continued Suspension*, para. 7.383; Panel Report, *Canada – Continued Suspension*, para. 7.380)

had been found to be inconsistent in *EC – Hormones* and on its allegation that Directive 2003/74/EC was consistent with the *SPS Agreement*. The Panel shared the European Communities' concern that this could generate for the original respondent at the beginning of the proceedings a situation "equivalent to having to 'prove a negative', since the spectrum of provisions against which the legality of the [European Communities'] measure may have to be reviewed remain[ed] very broad" as long as the original complainants had not made their own allegations of inconsistency of the implementing measure.⁶⁵² The Panel noted that the European Communities enjoyed a rebuttable presumption of good faith compliance and thus, once it had established a *prima facie* case on the basis of that presumption, the burden shifted to the United States and Canada to rebut that presumption. The Panel, however, considered that the United States and Canada "sufficiently refuted the [European Communities'] allegation of compliance"⁶⁵³ with the *SPS Agreement* and, subsequently, the European Communities responded to the allegations of violation. Therefore, the Panel believed that the European Communities "never actually had to 'prove a negative' in this case."⁶⁵⁴ In the Panel's view, the "presumptions based on good faith enjoyed by each party ... eventually 'neutralized' each other" such that ultimately, each party had to prove its specific allegations in response to the evidence submitted by the other party and the Panel followed the practice of other panels to weigh all the evidence before it.⁶⁵⁵

284. On this basis, the Panel went on to examine the consistency of Directive 2003/74/EC with the *SPS Agreement*, and found that "it has not been established that the European Communities has removed the measure found to be inconsistent with a covered agreement."⁶⁵⁶ Consequently, the Panel concluded that the European Communities failed to demonstrate a breach of Article 22.8 of the DSU by the United States and Canada and thus there was no violation of Articles 23.1 and 3.7 of the DSU as a result of a breach of Article 22.8.⁶⁵⁷

⁶⁵²Panel Report, *US – Continued Suspension*, para. 7.385; Panel Report, *Canada – Continued Suspension*, para. 7.382.

⁶⁵³Panel Report, *US – Continued Suspension*, para. 7.385; Panel Report, *Canada – Continued Suspension*, para. 7.382.

⁶⁵⁴Panel Report, *US – Continued Suspension*, para. 7.385; Panel Report, *Canada – Continued Suspension*, para. 7.382.

⁶⁵⁵Panel Report, *US – Continued Suspension*, para. 7.386; Panel Report, *Canada – Continued Suspension*, para. 7.383.

⁶⁵⁶Panel Report, *US – Continued Suspension*, para. 7.847; Panel Report, *Canada – Continued Suspension*, para. 7.832. The Panel's analysis is summarized *infra*, in sections VI and VII.

⁶⁵⁷Panel Report, *US – Continued Suspension*, paras. 7.850 and 7.851; Panel Report, *Canada – Continued Suspension*, paras. 7.385 and 7.836. Having found a violation of Articles 23.2(a) and 23.1 of the DSU and addressed the alleged violation of Article 22.8 as part of its review of the European Communities' second main claim, the Panel considered it unnecessary to address the European Communities' conditional claim of violation of Article 22.8 of the DSU *per se* in the alternative. (Panel Report, *US – Continued Suspension*, paras. 7.855; Panel Report, *Canada – Continued Suspension*, para. 7.840)

6. The Panel's Suggestion

285. After setting out its conclusions, the Panel observed that the parties had "apparently diverging opinions as to how this report should be implemented by the respondent".⁶⁵⁸ The Panel then noted that, although it had "performed functions similar to that of an Article 21.5 panel, this was done only in order to determine whether Article 22.8 of the DSU had been breached" and that it "was not called upon, nor [did] it have jurisdiction, to determine the compatibility of Directive 2003/74/EC with the covered agreements".⁶⁵⁹ Thus, the Panel suggested that, "in order to implement its findings under Article 23 and in order to ensure the prompt settlement of this dispute, [the United States and Canada] should have recourse to the rules and procedures of the DSU without delay."⁶⁶⁰

C. *Claims and Arguments on Appeal*

1. Appeal by the European Communities

286. The European Communities raises three claims of error on appeal. First, the European Communities submits that the Panel erred by failing to find that Article 23.2(a), read together with Articles 21.5 and 23.1 of the DSU, required the United States and Canada to initiate Article 21.5 proceedings if they considered that Directive 2003/74/EC did not bring the European Communities into compliance with the DSB's recommendations and rulings in *EC – Hormones*.⁶⁶¹ The European Communities maintains that recourse to procedures under Article 21.5 is required in order to examine the consistency of Directive 2003/74/EC with the *SPS Agreement*, and Article 21.5 proceedings may only be initiated by the original complainants, in this case, the United States and Canada.⁶⁶² Secondly, the European Communities asserts that Article 22.8 required the termination of the suspension of concessions upon the adoption and the subsequent notification of Directive 2003/74/EC to the DSB.⁶⁶³ Thus, the European Communities considers that the Panel erred in finding that its claim under Article 23.1, read together with Articles 22.8 and 3.7 of the DSU, was premised on the actual conformity of Directive 2003/74/EC with the *SPS Agreement*⁶⁶⁴; as a result, the Panel also erred in finding that the United States and Canada did not breach Article 22.8 of the DSU, even though they continued to suspend concessions without having recourse to Article 21.5. Thirdly, the

⁶⁵⁸Panel Report, *US – Continued Suspension*, para. 8.3; Panel Report, *Canada – Continued Suspension*, para. 8.3.

⁶⁵⁹Panel Report, *US – Continued Suspension*, para. 8.3; Panel Report, *Canada – Continued Suspension*, para. 8.3.

⁶⁶⁰Panel Report, *US – Continued Suspension*, para. 8.3; Panel Report, *Canada – Continued Suspension*, para. 8.3.

⁶⁶¹European Communities' appellant's submission, para. 94.

⁶⁶²*Ibid.*, paras. 49 and 73.

⁶⁶³*Ibid.*, para. 155.

⁶⁶⁴*Ibid.*, paras. 99 and 100 (referring to Panel Report, *US – Continued Suspension*, para. 7.272; and Panel Report, *Canada – Continued Suspension*, para. 7.288).

European Communities alleges that the Panel went beyond its terms of reference and erroneously assumed the functions of an Article 21.5 panel by examining the compatibility of Directive 2003/74/EC with the *SPS Agreement*.⁶⁶⁵ In addition to these three claims of error, the European Communities requests the Appellate Body to "improve"⁶⁶⁶ the Panel's suggestion that the United States and Canada "should have recourse to the rules and procedures of the DSU without delay"⁶⁶⁷, so as to make it clear that the United States and Canada must cease applying their suspension of concessions and have recourse to Article 21.5 of the DSU, or other dispute settlement proceedings to which the parties may agree, in order to seek multilateral resolution of any remaining disagreements over the European Communities' import ban.⁶⁶⁸

287. The United States maintains that the Panel correctly interpreted the phrase "recourse to dispute settlement in accordance with the rules and procedures of this Understanding" in Article 23.2(a) as encompassing all procedures under the DSU, rather than relating exclusively to Article 21.5 panel proceedings.⁶⁶⁹ The United States further submits that Article 21.5 refers to "these dispute settlement procedures" without specifying any particular subset of the procedures provided in the DSU.⁶⁷⁰ In addition, the United States argues that the Panel correctly interpreted Article 22.8 of the DSU when finding that the United States did not breach its obligation under that provision. The United States asserts that the European Communities "simply switched" the legal instruments underlying the import ban and, in so doing, failed to remove the ban, that is, the inconsistent measure within the meaning of Article 22.8.⁶⁷¹ The United States further claims that the European Communities specifically asked the Panel to review whether the United States acted inconsistently with Article 22.8. Thus, in order to adjudicate that claim, the Panel correctly interpreted and applied Article 22.8 by examining the consistency of Directive 2003/74/EC with the *SPS Agreement* and did not exceed its terms of reference.⁶⁷² Moreover, the United States argues that the Panel's suggestion does not require it to terminate the suspension of concessions. Finally, the United States observes that "improving" the suggestion, as requested by the European Communities, "is not within the purview of what the Appellate Body is called upon to do with respect to panel reports".⁶⁷³

⁶⁶⁵European Communities' appellant's submission, para. 175.

⁶⁶⁶*Ibid.*, para. 479.

⁶⁶⁷Panel Report, *US – Continued Suspension*, para. 8.3; Panel Report, *Canada – Continued Suspension*, para. 8.3.

⁶⁶⁸European Communities' appellant's submission, para. 480.

⁶⁶⁹United States' appellee's submission, para. 126.

⁶⁷⁰*Ibid.*, para. 127.

⁶⁷¹*Ibid.*, para. 99.

⁶⁷²*Ibid.*, paras. 120 and 121.

⁶⁷³*Ibid.*, para. 140. The United States points out that "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."

288. Canada submits that, contrary to the European Communities' contentions, the Panel correctly found that "recourse to dispute settlement" within the meaning of Article 23.2(a) is not limited to Article 21.5 panel proceedings. Canada maintains that the European Communities' unilateral assertion of compliance regarding Directive 2003/74/EC does not compel Canada to initiate Article 21.5 proceedings, and does not require Canada to lift the suspension of concessions.⁶⁷⁴ Canada alleges that the European Communities, as the original respondent, is not legally precluded from initiating Article 21.5 proceedings⁶⁷⁵, and that other procedural avenues are also available to the European Communities, including new panel proceedings.⁶⁷⁶ Canada further claims that the Panel correctly interpreted Article 22.8 by concluding that the phrase "until such time as the measure found to be inconsistent with a covered agreement has been removed" means that the inconsistency itself, and not only the originally impugned measure, has been removed.⁶⁷⁷ Finally, Canada maintains that the Panel did not exceed its terms of reference in examining the consistency of Directive 2003/74/EC with the *SPS Agreement*. Rather, Canada asserts that, because the European Communities' claim that Canada breached Article 22.8 is premised on actual compliance by the European Communities, the Panel was required to review the consistency of Directive 2003/74/EC with the *SPS Agreement* to resolve the dispute.⁶⁷⁸

2. Other Appeals by the United States and Canada

289. The United States claims that the Panel erred in finding that the United States was "seeking the redress of a violation" within the meaning of Article 23.1 of the DSU through the continued suspension of concessions. The United States maintains that it "had extensive and lengthy recourse to multiple procedures under the DSU"⁶⁷⁹ before obtaining the authorization of the DSB to suspend concessions on 26 July 1999, and this authorization to suspend concessions has never been revoked.⁶⁸⁰ By finding that the United States was seeking the redress of a violation, the Panel "re-characteriz[ed]"⁶⁸¹, without any legal basis, the United States' suspension of concessions as directed against Directive 2003/74/EC. Furthermore, the United States takes issue with the Panel's finding that the United States' statements regarding Directive 2003/74/EC at DSB meetings constituted a "determination" within the meaning of Article 23.2(a) of the DSU. The United States maintains that such a "determination" cannot be inferred or implied, and the Panel erred in drawing such an

⁶⁷⁴Canada's appellee's submission, para. 8.

⁶⁷⁵*Ibid.*, para. 11.

⁶⁷⁶*Ibid.*, paras. 14 and 15.

⁶⁷⁷*Ibid.*, paras. 25 and 26.

⁶⁷⁸*Ibid.*, para. 41.

⁶⁷⁹United States' other appellant's submission, para. 29.

⁶⁸⁰*Ibid.*, para. 18.

⁶⁸¹*Ibid.*, para. 31.

inference from the United States' "inaction"⁶⁸² regarding the suspension of concessions. In the event that the Appellate Body upholds the Panel's findings under Articles 23.2(a) and 23.1, the United States requests reversal of the Panel's "erroneous suggestion"⁶⁸³ that the United States "must have recourse to the rules and procedures of the DSU without delay". The United States contends that "recourse to the rules and procedures" of the DSU has already been achieved by the United States' participation in this dispute initiated by the European Communities.⁶⁸⁴ The United States further submits that the Panel erred in concluding that it had no jurisdiction to rule on the compatibility of Directive 2003/74/EC with the *SPS Agreement*. Consequently, the Panel's findings regarding the inconsistency of Directive 2003/74/EC with the *SPS Agreement* should be considered "direct" findings and the conclusion that the United States needs to bring its measure into conformity with the DSU should be reversed.⁶⁸⁵

290. Canada alleges that the Panel erred by examining the European Communities' claim under Articles 23.2(a) and 23.1 in isolation from its analysis under Article 22.8 of the DSU. According to Canada, the Panel should have first applied the requirements of Article 22.8 to determine whether the suspension of concessions had to be terminated, and the Panel's failure to do so resulted in "contradictory findings"⁶⁸⁶ concerning the first and second sets of claims of the European Communities. Canada conditionally appeals two other issues, in case the Appellate Body were to find that the Panel was correct in making findings in respect of Articles 23.1 and 23.2(a) without taking into account its finding in respect of Article 22.8. First, Canada contends that, even if the Panel were correct to consider Article 23 in isolation, the Panel erred in finding that Canada was "seeking the redress" of a WTO violation by continuing the suspension of concessions. Canada maintains that it has "sought and obtained"⁶⁸⁷ the DSB's authorization to suspend concessions and that, contrary to the Panel's finding, simply because Directive 2003/74/EC is a new measure does not imply that the legal basis for Canada's suspension of concessions has changed.⁶⁸⁸ Secondly, Canada alleges that the Panel erred in finding that Canada made a unilateral determination of non-compliance regarding Directive 2003/74/EC, within the meaning of Article 23.2(a), on the basis of Canada's statements at the DSB meetings, as well as the fact that Canada continued to suspend concessions.⁶⁸⁹ In the alternative, should the Appellate Body uphold the Panel's findings under Articles 23.2(a) and 23.1,

⁶⁸²United States' other appellant's submission, para. 98.

⁶⁸³*Ibid.*, para. 108.

⁶⁸⁴*Ibid.*, para. 112.

⁶⁸⁵*Ibid.*, para. 119. The United States clarifies that the Appellate Body need not address these last two points should it reverse the Panel's findings and conclusions concerning Articles 23.1 and 23.2(a) of the DSU. (*Ibid.*, para. 9)

⁶⁸⁶Canada's other appellant's submission, para. 43.

⁶⁸⁷*Ibid.*, para. 80.

⁶⁸⁸*Ibid.*, para. 82.

⁶⁸⁹*Ibid.*, para. 87.

Canada requests the Appellate Body to reverse the Panel's conclusion that it did not have jurisdiction to determine the compatibility of Directive 2003/74/EC with the *SPS Agreement*.⁶⁹⁰ Finally, Canada claims that the Panel erred in making the suggestion that "Canada should have recourse to the rules and procedures of the DSU without delay"⁶⁹¹ because this conclusion, according to Canada, contradicts the Panel's own finding that Canada had not breached Article 22.8.⁶⁹²

291. The European Communities responds that Article 23 of the DSU is fully applicable in the implementation and post-suspension stage of a dispute⁶⁹³, because the multilateral dispute settlement system relies on good faith compliance and the presumption of conformity with the covered agreements of measures taken by WTO Members.⁶⁹⁴ The European Communities further contends that the adoption of a measure taken to comply, which must be presumed to be consistent with the WTO agreements, triggers the following duties on the original complainant: (i) to form a view on whether the measure that has been found to be inconsistent has been removed; (ii) to have recourse to Article 21.5 proceedings if it considers that the measure taken to comply is not consistent with the covered agreements; and (iii) to cease the suspension of concessions.⁶⁹⁵ The European Communities disagrees with the argument of the United States and Canada that they are not seeking the redress of a violation within the meaning of Article 23.1 by maintaining the suspension of concessions, because the notification of Directive 2003/74/EC does not change the legal basis for the suspension of concessions.⁶⁹⁶ The European Communities submits that Article 22.8 of the DSU does not specify that it is for the original respondent to show that it has removed the original measure⁶⁹⁷, and that, in any event, the European Communities has effectively shown that the inconsistent measure, namely Directive 96/22/EC, has been removed.⁶⁹⁸ Thus, the United States and Canada could no longer maintain their suspension of concessions once the European Communities had adopted Directive 2003/74/EC.⁶⁹⁹

292. The European Communities further argues that the Panel correctly found that the United States and Canada made a determination to the effect that a violation has occurred within the meaning of Article 23.2(a) of the DSU. The European Communities maintains that the statements by the United States and Canada at the DSB meetings, together with the fact that the United States and Canada have maintained their suspension of concessions, indicate that they made a "definitive"

⁶⁹⁰Canada's other appellant's submission, para. 92.

⁶⁹¹*Ibid.*, para. 96.

⁶⁹²*Ibid.*, para. 95.

⁶⁹³European Communities' appellee's submission, para. 47.

⁶⁹⁴*Ibid.*, para. 40.

⁶⁹⁵*Ibid.*, para. 62.

⁶⁹⁶*Ibid.*, paras. 103, 104, and 113.

⁶⁹⁷*Ibid.*, para. 114.

⁶⁹⁸*Ibid.*, para. 115.

⁶⁹⁹*Ibid.*, paras. 105 and 115.

determination with sufficient "firmness or immutability" regarding the inconsistency of Directive 2003/74/EC with the covered agreements.⁷⁰⁰ Furthermore, the European Communities disagrees with the United States' view that the Panel inferred the existence of a "determination" from inaction. According to the European Communities, the United States "actively considered" that Directive 2003/74/EC is not consistent with the covered agreements and "actively continued" the suspension of concessions.⁷⁰¹

3. Arguments of the Third Participants

293. Australia agrees with the European Communities that the disagreement as to whether Directive 2003/74/EC has removed the measure found to be inconsistent with the WTO agreements should have been resolved through recourse to panel proceedings under Article 21.5.⁷⁰² However, Australia believes that it is open to a Member to continue the suspension of concessions pending the outcome of the Article 21.5 panel proceedings.⁷⁰³ Finally, Australia underscores that no provision of the *SPS Agreement* is included in the Panel's terms of reference, and that to include claims under the *SPS Agreement* within the scope of this dispute effectively reverses the burden of proof between the parties. This "is inconsistent with a fundamental principle ... that the party asserting non-compliance with a covered agreement bears the burden of establishing a *prima facie* case."⁷⁰⁴

294. Brazil contends that none of the three conditions set out in Article 22.8 regarding the termination of the suspension of concessions has been fulfilled, and thus the DSB's authorization granted to the United States and Canada to suspend concessions remains in place.⁷⁰⁵ Brazil agrees with the Panel that the removal of the measure found to be inconsistent, within the meaning of Article 22.8, must be interpreted as requiring substantive compliance. Furthermore, Brazil asserts that, in the post-suspension stage of a dispute, the original responding Member bears the burden of proving that its implementing measure is WTO-consistent.⁷⁰⁶

295. New Zealand submits that the Panel failed to interpret Articles 23.1 and 23.2(a) in the context of Article 22.8 of the DSU. According to New Zealand, Article 22.8 refers to situations where the original inconsistent measure has actually been removed, and not where the measure is merely claimed to have been removed.⁷⁰⁷ Therefore, New Zealand considers that the Panel erred in finding

⁷⁰⁰European Communities' appellee's submission, paras. 126 and 136-138.

⁷⁰¹*Ibid.*, para. 133.

⁷⁰²Australia's third participant's submission, para. 15.

⁷⁰³*Ibid.*, para. 21.

⁷⁰⁴*Ibid.*, para. 25.

⁷⁰⁵Brazil's third participant's submission, para. 10.

⁷⁰⁶*Ibid.*, para. 33.

⁷⁰⁷New Zealand's third participant's submission, para. 3.17.

that the European Communities' claims under Articles 23.1 and 23.2(a) were completely unrelated to whether the European Communities had implemented the DSB's recommendations and rulings in *EC – Hormones*.⁷⁰⁸

296. Norway maintains that Article 22.8 requires that the suspension of concessions be temporary and conditional. Thus, once compliance is achieved, be it through a simple revocation of the inconsistent measure or its replacement with another measure that ensures compliance, the right to suspend concessions "*automatically lapses*"⁷⁰⁹ without a need for formal revocation of the authorization by the DSB. Where the parties disagree as to whether the measure taken to comply actually achieves compliance, as is the case in this dispute, both the original complainant and the original respondent can resort to Article 21.5 panel proceedings.⁷¹⁰

D. *Cessation of the Suspension of Concessions – Article 22.8 of the DSU*

1. Preliminary Comments

297. The European Communities alleges that the Panel erred by failing to find that Article 23.2(a), read together with Articles 21.5 and 23.1 of the DSU, required the United States and Canada to initiate Article 21.5 proceedings if they considered that Directive 2003/74/EC did not bring the European Communities into compliance with the DSB's recommendations and rulings in *EC – Hormones*.⁷¹¹ The European Communities further asserts that the Panel erred in finding that Article 22.8 of the DSU requires actual compliance with the DSB's recommendations and rulings in *EC – Hormones* before the suspension of concessions has to be terminated⁷¹², and that the Panel exceeded its terms of reference by examining such compliance when analyzing the European Communities' claims under Articles 23.1, 22.8, and 3.7 of the DSU.⁷¹³

298. For the sake of simplicity, we refer to the Member applying the suspension of concessions pursuant to the DSB's authorization as the "suspending Member". We refer to the Member against whom the suspension of concessions is applied as the "implementing Member".

299. The European Communities' claims raise several questions concerning the position of the suspending Member in circumstances where a measure is taken by the implementing Member to comply with the DSB's recommendations and rulings. The first question concerns whether the

⁷⁰⁸New Zealand's third participant's submission, para. 3.18.

⁷⁰⁹Norway's third participant's submission, para. 6. (original emphasis)

⁷¹⁰*Ibid.*, para. 9.

⁷¹¹European Communities' appellant's submission, para. 94.

⁷¹²*Ibid.*, para. 152.

⁷¹³*Ibid.*, para. 175.

suspending Member is required to initiate Article 21.5 proceedings, if it considers that the implementing measure fails to bring about compliance. The second question concerns the substantive issue as to whether an obligation to lift the suspension of concessions, pursuant to Article 22.8, arises when an implementing measure replaces the impugned measure. We recall that this dispute concerns the legality of the suspension of concessions maintained by the United States and Canada subsequent to the adoption and notification of the European Communities' implementing measure. The suspension of concessions that is authorized by the DSB must be applied consistently with Article 22.8 of the DSU. Therefore, we first examine whether the Panel erred in finding that Article 22.8 requires actual compliance by the European Communities with the DSB's recommendations and rulings before the suspension of concessions must be terminated by the United States and Canada. We will then turn, in section E, to the issue of whether Article 21.5 proceedings are the proper procedures to follow and which party must initiate such proceedings.

2. When Must a WTO Member Cease to Suspend Concessions Pursuant to Article 22.8 of the DSU?

300. The European Communities submits that its claims under Article 23.1, read together with Articles 22.8 and 3.7 of the DSU, are based on its "*interpretation* of Article 22.8, according to which the words 'the measure found to be inconsistent with a covered agreement' refer to the measure identified in the recommendations of the DSB".⁷¹⁴ The European Communities submits that the "measure found to be inconsistent with a covered agreement" in *EC – Hormones* was Directive 96/22/EC.⁷¹⁵ The European Communities maintains that Directive 96/22/EC "was removed"⁷¹⁶, within the meaning of Article 22.8, after being replaced by Directive 2003/74/EC. Thus, by continuing the suspension of concessions, the United States and Canada made a unilateral determination that Directive 2003/74/EC was not consistent with the *SPS Agreement*, in violation of Article 23.1 "read in the light of Article 22.8".⁷¹⁷ Therefore, the European Communities asserts that, contrary to the Panel's finding, it "never argued" that the claim under Article 23.1, read together with Articles 22.8 and 3.7 of the DSU, was premised on a violation of Article 22.8 by the United States and Canada and "never argued" that this claim was premised on the conformity of the implementing measure with the *SPS Agreement*.⁷¹⁸

301. The European Communities' arguments are premised on its interpretation of Article 22.8 as requiring the termination of suspension of concessions whenever an implementing measure is adopted

⁷¹⁴European Communities' appellant's submission, para. 102. (original emphasis)

⁷¹⁵*Ibid.*, para. 129.

⁷¹⁶*Ibid.*, para. 146.

⁷¹⁷*Ibid.*, para. 102.

⁷¹⁸*Ibid.*, paras. 99 and 100 (referring to Panel Report, *US – Continued Suspension*, para. 7.272; and Panel Report, *Canada – Continued Suspension*, para. 7.288).

to replace the measure found to be inconsistent in proceedings that led to the DSB's recommendations and rulings. According to this interpretation, termination is required irrespective of the content of the implementing measure. Therefore, we proceed to examine the proper interpretation of Article 22.8 and, in particular, the phrase "the measure found to be inconsistent with a covered agreement has been removed" in that provision.

302. Article 3.7 of the DSU states that "the first objective of the dispute settlement mechanism is usually to secure the withdrawal of the measures concerned if these are found to be inconsistent with ... the covered agreements." If this cannot be achieved, the "last resort" provided under the DSU "to the Member invoking the dispute settlement procedures is the possibility of suspending the application of concessions ... on a discriminatory basis vis-à-vis the other Member, subject to authorization by the DSB". Accordingly, in the event that the DSB's recommendations and rulings are not implemented within a reasonable period of time, Article 22.1 provides for the suspension of concessions as a "temporary measure" available to the Member that originally initiated the dispute settlement procedures.⁷¹⁹

303. The suspension of concessions may not be maintained indefinitely. The authorization to suspend concessions is contingent and limited in time. Article 22.8 of the DSU provides that the suspension of concessions shall be "temporary" and shall only be applied until one of the three resolute conditions set out in that provision obtains, namely, when:

... 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.

304. The participants agree that this dispute concerns the first condition listed in Article 22.8, that is, when "the measure found to be inconsistent with a covered agreement has been removed". In most cases, the first condition in Article 22.8 will be met where the implementing Member repeals the inconsistent measure without adopting any new measure in its place. The issue that arises in this dispute, however, is whether an inconsistent measure should be considered "removed" when it is replaced by a new implementing measure. Taken literally, removal of the inconsistent measure could mean that the implementing Member has adopted an act that formally repeals the inconsistent measure and replaces it with another measure, regardless of the content of the new measure and, in

⁷¹⁹Article 22.6 specifies that the DSB, upon a request made within 30 days of the expiry of the reasonable period of time by the Member invoking the dispute settlement procedures, shall grant authorization to suspend concessions, or decide by consensus to reject the request. In addition, an arbitration procedure is envisaged under Article 22.6 in order to determine the proper level of the suspension of concessions and/or the sectors with respect to which the suspension is authorized. As regards the level of the suspension of concessions, Article 22.4 requires that it be "equivalent to the level of the nullification or impairment".

particular, of its compliance with the DSB's recommendations and rulings. Such a literal interpretation of the first condition in Article 22.8, however, does not comport with the other two conditions provided in that provision. The second condition in Article 22.8 requires termination of the suspension of concessions if "the Member that must implement recommendations or rulings provides a solution to the nullification or impairment of benefits", while the third condition refers to a situation where "a mutually agreed solution is reached". The reference to "a solution to the nullification or impairment of benefits" indicates that it is the inconsistency resulting from the measure, rather than the mere existence of the measure, that must be remedied before the obligation to cease the suspension of concessions arises. Moreover, by predicating the termination of the suspension of concessions on a "solution" either provided unilaterally (in the second condition) or reached by agreement (in the third condition), the two conditions require substantive resolution of the dispute. Under these two conditions, termination of the suspension of concessions is the final step in a dispute to which there is substantive resolution of the inconsistency found by the DSB. To achieve a similar result under the first condition, Article 22.8 cannot be understood as requiring the termination of the suspension of concessions merely on the basis of a formal repeal of the measure that has been found to be inconsistent by the DSB. All three conditions in Article 22.8 concern the circumstances under which the suspension of concessions must be terminated because there has been a final and substantive resolution to the dispute.

305. Reading the first sentence of Article 22.8 as a whole, the "removal" of "the measure found to be inconsistent" should be properly understood to require nothing less than substantive removal of the inconsistent measure. Substantive removal may be achieved by repealing the inconsistent measure. Where a WTO Member adopts an implementing measure that replaces the inconsistent measure, the implementing measure must bring about substantive compliance, that is, compliance with the DSB's recommendations and rulings and consistency with the covered agreements. We recognize that the first condition in Article 22.8 may be understood more narrowly as referring only to compliance with the DSB's recommendations and rulings. However, a dispute could not be brought to its finality unless the implementing measure rectifies the inconsistencies found in the DSB's recommendations and rulings and is not in other ways inconsistent with the covered agreements. Interpreting the first condition as requiring substantive compliance, therefore, will ensure that the first condition in Article 22.8 achieves the result obtained under the other two conditions in the same provision, that is, the final and substantive resolution of a dispute. Such an interpretation is also congruent with the scope of compliance proceedings under Article 21.5 of the DSU. Pursuant to the first sentence of that provision, compliance proceedings cover the existence and consistency with the covered agreements of a measure taken to comply with the DSB's recommendations and rulings. As further discussed in

section E, proceedings under Article 21.5 is the proper procedure to follow in determining whether the inconsistent measure has been removed within the meaning of Article 22.8.

306. In terms of the first condition in Article 22.8, therefore, the application of the suspension of concessions may continue until the removal of the measure found by the DSB to be inconsistent results in substantive compliance. If a disagreement arises as to whether substantive compliance is achieved, the fulfilment of the first condition in Article 22.8 cannot be confirmed unless the disagreement is resolved through multilateral dispute settlement. Thus, the suspension of concessions continues to apply pending the outcome of the dispute settlement proceedings concerning the first resolutive condition in Article 22.8. If, by recourse to a multilateral dispute settlement process, the implementing measure is found to bring about substantive compliance, the suspension of concessions may no longer be applied pursuant to the first condition in Article 22.8 and cessation of the suspension is required.

307. This interpretation is supported by the second sentence of Article 22.8, which 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 ... concessions or other obligations have been suspended *but the recommendations to bring a measure into conformity with the covered agreements have not been implemented*.

The second sentence of Article 22.8 requires surveillance by the DSB until its recommendations to bring a measure into conformity with the covered agreements have been implemented. In other words, DSB surveillance is required until substantive compliance is achieved.

308. Moreover, this interpretation of Article 22.8 is consistent with the broader context provided by other provisions of the DSU relating to implementation of the DSB's recommendations and rulings and with the object and purpose of the DSU. Article 22.1 of the DSU provides that the suspension of concessions is not to be "preferred to *full* implementation of a recommendation to bring a measure into conformity with the covered agreements".⁷²⁰ The requirements in Article 21.5 to examine whether compliance measures exist and whether the measures taken to comply are consistent with the covered agreements also suggest that substantive compliance is required, rather than formal removal of the inconsistent measure. Furthermore, pursuant to Article 3.7, the suspension of concessions is the "last resort" available to the Member invoking the dispute settlement procedures when compliance with the DSB's recommendations and rulings has not been achieved within a reasonable period of

⁷²⁰Moreover, pursuant to Article 3.3, the "prompt settlement" of disputes "is essential to the effective functioning of the WTO and the maintenance of a proper balance between the rights and obligations of Members".

time. To require the termination of suspension of concessions before substantive compliance is achieved would significantly weaken the effectiveness of the WTO dispute settlement mechanism. A Member authorized by the DSB to suspend concessions enjoys the assurance under Article 22.8 that, until substantive compliance is achieved or, in case of disagreement, multilaterally-confirmed, the suspension of concessions continues to be permitted under the DSU.

309. The European Communities contends that the three conditions in Article 22.8 concerning the termination of the suspension of concessions are alternatives to each other and that it is sufficient to only look at one condition without considering the others when determining whether the suspension of concessions must cease.⁷²¹ We agree that the three conditions in Article 22.8 are alternatives to each other. However, they are alternatives leading to the same result, that is, the termination of the suspension of concessions and final resolution of a dispute. It is difficult to envisage how a dispute could be finally resolved merely because the inconsistent measure is formally removed, regardless of whether substantive compliance has been achieved. The European Communities further submits that the second sentence of Article 22.8 contemplates that there may be situations in which "a measure has been removed" but "the matter remains under surveillance of the DSB".⁷²² The second sentence of Article 22.8 specifically requires surveillance by the DSB where "*concessions ... have been suspended but the recommendations to bring a measure into conformity with the covered agreement has not been implemented*". Thus, this provision clearly situates the ongoing surveillance within the context of the continued suspension of concessions, indicating that the authorization to suspend concessions does not lapse under Article 22.8 until substantive compliance is achieved. Moreover, the European Communities' position, which requires the termination of the suspension of concessions whenever an implementing measure is notified, undermines the effectiveness of the suspension of concessions in inducing full compliance. Such a position is difficult to reconcile with the DSU's objective of providing security and predictability to the multilateral trading system.

310. Although Article 22.8 sets forth the resolute conditions under which the suspension of concessions must cease to apply, it does not identify the procedures to be followed should a dispute arise as to whether one of the conditions has been satisfied. This does not mean that Members can remain passive once concessions have been suspended pursuant to the DSB's authorization. The requirement that the suspension of concessions must be temporary indicates that the suspension of concessions, as the last resort available under the DSU when compliance is not achieved, is an abnormal state of affairs that is not meant to remain indefinitely. Members must act in a cooperative manner so that the normal state of affairs, that is, compliance with the covered agreements and

⁷²¹European Communities' statement at the oral hearing.

⁷²²*Ibid.*

absence of the suspension of concessions, may be restored as quickly as possible. Thus, both the suspending Member and the implementing Member share the responsibility to ensure that the application of the suspension of concessions is "temporary". Moreover, the fulfilment of the first resolutive condition in Article 22.8 requires certain actions from both Members. The implementing Member is required to remove the measure found to be inconsistent with a covered agreement. At the same time, the suspending Member is required to ensure that the suspension of concessions is only applied within the limits of Article 22.8. Where, as in this dispute, an implementing measure is taken and Members disagree as to whether this measure achieves substantive compliance, both Members have a duty to engage in WTO dispute settlement in order to establish whether the conditions in Article 22.8 have been met and whether, as a consequence, the suspension of concessions must be terminated. Once substantive compliance has been confirmed through WTO dispute settlement procedures, the authorization to suspend concessions lapses by operation of law (*ipso jure*), because it has been determined that one of the resolutive conditions pursuant to Article 22.8 is fulfilled.⁷²³ We examine in section E the procedural avenues that would be available should a disagreement arise as to whether the conditions in Article 22.8 have been satisfied.

3. The Panel's Analysis Concerning Article 22.8 of the DSU

311. The Panel found that "the phrase 'until such time as the measure found to be inconsistent with a covered agreement has been removed' [in Article 22.8] means the illegality itself, and not only the measure, has been removed."⁷²⁴ The Panel considered that this interpretation is confirmed by the second sentence of Article 22.8, which refers to the DSB keeping under surveillance the situations in which concessions have been suspended but the recommendations and rulings of the DSB have not been implemented. In the Panel's view, the second sentence implied that "what is to be achieved is not the removal of the measure but the actual compliance with the recommendations and rulings of the DSB."⁷²⁵ Therefore, according to the Panel, "Article 22.8 may be breached only if the European Communities has complied with the recommendations and rulings of the DSB and [the United States and Canada have] failed to immediately remove its suspension of concessions or other obligations."⁷²⁶ We consider that the Panel was correct in reaching this finding. In subsection 2, we found that the

⁷²³In contrast, where an inconsistent measure is removed without being replaced by a new measure, the objective condition in Article 22.8 would, in most cases, be met and the authority to suspend concessions would automatically lapse.

⁷²⁴Panel Report, *US – Continued Suspension*, para. 7.283; Panel Report, *Canada – Continued Suspension*, para. 7.299.

⁷²⁵Panel Report, *US – Continued Suspension*, para. 7.284; Panel Report, *Canada – Continued Suspension*, para. 7.300.

⁷²⁶Panel Report, *US – Continued Suspension*, para. 7.285; Panel Report, *Canada – Continued Suspension*, para. 7.301.

terms "until such time as the inconsistent measure has been removed" in Article 22.8 require substantive compliance and that, until it is achieved, the suspension of concessions may continue.

312. The European Communities highlights the Panel's statements, made in the context of its findings of procedural violations under Articles 23.2(a) and 23.1, that Directive 2003/74/EC "shows all the signs of an implementing measure ... adopted in good faith".⁷²⁷ The European Communities maintains that once a Member has adopted an implementing measure which it believes in good faith to bring about compliance, the suspension of concessions can no longer be applied.⁷²⁸ The question raised by this claim, therefore, is whether the "removal" of an inconsistent measure within the meaning of Article 22.8 may be established on the sole basis of a presumption of good faith compliance by the European Communities.

313. The DSU makes reference to "good faith" in two provisions, namely, Article 4.3, which relates to consultations, and Article 3.10, which provides that, "if a dispute arises, all Members will engage in these procedures in good faith in an effort to resolve the dispute." These provisions require Members to act in good faith with respect to the initiation of a dispute and in their conduct during a dispute settlement proceedings. Neither provision specifically addresses the question of whether a Member enjoys a presumption of good faith compliance in respect of measures taken to implement the DSB's recommendations and rulings.

314. The Appellate Body has recognized that the principle of good faith, a principle well-recognized in international law, applies in WTO dispute settlement. As the Appellate Body stated in *EC – Sardines*:

We must assume that Members of the WTO will abide by their treaty obligations in good faith, as required by the principle of *pacta sunt servanda* articulated in Article 26 of the *Vienna Convention*. *And, always in dispute settlement, every Member of the WTO must assume the good faith of every other Member.*⁷²⁹ (emphasis added)

315. The Member required to implement the DSB's recommendations and rulings may be presumed to have acted in good faith when adopting the implementing measure. However, the presumption of good faith attaches to the actor, but not to the action itself. Thus, whilst the presumption of good faith concerns the reasons for which a Member acts, such a presumption does not answer the question whether the measure taken by the implementing Member has indeed brought about substantive compliance. Similarly, the suspending Member can also be presumed to act in good

⁷²⁷Panel Report, *US – Continued Suspension*, para. 7.238; Panel Report, *Canada – Continued Suspension*, para. 7.231.

⁷²⁸European Communities' appellant's submission, para. 141.

⁷²⁹Appellate Body Report, *EC – Sardines*, para. 278.

faith in maintaining the suspension of concessions, but that does not entail that the suspension of concessions is necessarily consistent with Article 22.8. When a disagreement arises as to whether the implementing measure achieves substantive compliance and whether the suspension of concessions may continue, it should be submitted for adjudication in dispute settlement proceedings. In sum, a presumption of good faith, which can be claimed by both parties, does not offer a clear answer to the question of when inconsistencies arising from the original measure should be considered to have been removed within the meaning of Article 22.8 of the DSU.

316. In the light of our understanding of the presumption of good faith, we do not agree with the European Communities that there is a contradiction between the proposition that Directive 2003/74/EC is a measure adopted in good faith and the interpretation of Article 22.8 that substantive compliance is required for the first resolutive condition to be met. Even if the European Communities should be presumed to have acted in good faith when adopting the implementing measure, that does not mean that the measure has achieved substantive compliance.

317. If the removal of a measure found to be inconsistent were to be established on the sole basis of a presumption of good faith compliance, the DSB's authorization to suspend concessions would expire upon the adoption of an implementing measure and a mere unilateral declaration of the implementing Member that it removed the inconsistent measure. As described above, the suspension of concession is the last resort available to a Member who has successfully challenged the consistency with the covered agreements of another Member's measure. The DSB's authorization to suspend concessions is necessarily preceded by a multi-stage dispute settlement process. This process may encompass: (i) consultations, (ii) panel proceedings, (iii) appellate review, (iv) the adoption of the panel and Appellate Body reports, (v) an arbitration to determine the reasonable period of time for implementation, (vi) compliance panel proceedings, (vii) compliance appellate review, and (viii) an arbitration to determine the level of suspension of concessions. The authorization to suspend concessions is thus granted following a long process of multilateral dispute settlement in which relevant adjudicative bodies, as well as the DSB, render multilateral decisions at key stages of the process. To allow the suspension of concessions to expire as a result of the application of a presumption of good faith with respect to a unilateral declaration of compliance would create an imbalance between the rights and obligations of the complainants and the respondents enshrined in the DSU and would undermine the effectiveness of the dispute settlement mechanism in providing security and predictability. Rather, if the original respondent considers that it has implemented the DSB's recommendations and rulings such that it has achieved substantive compliance, and the complainant who has been authorized to suspend concessions disagrees, that disagreement must be resolved multilaterally through WTO dispute settlement. Thus, we share Canada's view that the

interpretation proposed by the European Communities is an "overly narrow and formalistic interpretation that fails to situate Article 22.8 in its proper context within the terms of the DSU."⁷³⁰

318. Consequently, we disagree with the European Communities' assertion that "the mere *existence* of an implementing measure adopted in good faith and its subsequent notification to the DSB" requires the United States and Canada to cease the application of the suspension of concessions authorized by the DSB.⁷³¹

319. The European Communities additionally alleges that the Panel "fundamentally erred" in the manner in which it identified the "measure found to be inconsistent with a covered agreement" in order to determine whether "it has been removed" within the meaning of Article 22.8.⁷³² The European Communities claims that the Panel found that Directive 96/22/EC, that is, the measure found to be inconsistent with the *SPS Agreement* in *EC – Hormones*, "was removed". Nonetheless, the Panel also held that considering Directive 96/22/EC as the measure found to be inconsistent with a covered agreement within the meaning of Article 22.8 is "unsatisfactory, as Directive 96/22/EC was replaced by Directive 2003/74/EC which also imposes an import ban".⁷³³

320. We recall that, in *EC – Hormones*, Directive 96/22/EC was found to be inconsistent with Article 5.1 of the *SPS Agreement* because the import ban imposed by that Directive on meat from cattle treated with the six hormones at issue was not based on a risk assessment that conformed to the requirements of the *SPS Agreement*.⁷³⁴ In order to comply with the DSB's recommendations and rulings, the European Communities had to remove the import ban or ensure that the import ban had a proper justification under the *SPS Agreement* by being based on a risk assessment under Article 5.1 or as a provisional measure under Article 5.7. Thus, the replacement of Directive 96/22/EC with Directive 2003/74/EC is insufficient for the measure found to be inconsistent in *EC – Hormones* to be considered removed for purposes of Article 22.8 of the DSU.

321. The European Communities also asserts that "interpreting Article 22.8 as referring to 'actual compliance' allows the original complaining Member to make a unilateral determination of the substantive merits of the 'measure taken to comply', without recourse to the procedures of the DSU and without respecting Article 23.1 of the DSU."⁷³⁵ In our view, this argument conflates the proper interpretation of Article 22.8 with the issue as to the proper procedure for resolving a dispute

⁷³⁰Canada's appellee's submission, para. 21.

⁷³¹European Communities' appellant's submission, para. 101. (original emphasis)

⁷³²*Ibid.*, para. 145.

⁷³³Panel Report, *US – Continued Suspension*, para. 7.283; Panel Report, *Canada – Continued Suspension*, para. 7.299.

⁷³⁴Appellate Body Report, *EC – Hormones*, paras. 6 and 253.

⁷³⁵European Communities' appellant's submission, para. 152.

involving Article 22.8. As discussed, Article 22.8 sets forth the resolute conditions under which the suspension of concessions must cease, including the condition that the suspension of concessions shall only apply until the measure found to be inconsistent has been removed. The correct interpretation of Article 22.8 is that once substantive compliance is achieved, the suspending Member is required to cease the application of the suspension of concessions. This, however, does not answer the question regarding the procedures to be followed in the event a disagreement arises as to whether substantive compliance has been achieved and the resolute condition in Article 22.8 has been met. We address the available procedural avenues in section E.

4. Did the Panel Exceed Its Mandate by Addressing the Conformity of Directive 2003/74/EC with the *SPS Agreement*?

322. The European Communities claims that, in the context of reviewing the European Communities' second set of main claims under Article 23.1, read together with Articles 22.8 and 3.7 of the DSU, the Panel exceeded the scope of its mandate by examining the conformity of Directive 2003/74/EC with the *SPS Agreement*. The European Communities maintains that it made a claim under Article 22.8 of the DSU in the alternative, that is, only in the event that the Panel did not find any violation under Articles 23.1, 23.2(a), 3.7, 22.8, and 21.5 of the DSU.⁷³⁶ In the alternative claim, the European Communities alleges that the United States and Canada were required to terminate the suspension of concessions pursuant to Article 22.8 because Directive 2003/74/EC achieved actual (rather than presumed) compliance with the DSB's recommendations and rulings.⁷³⁷ The European Communities explains that it made the alternative claim because "it was confident that, in any event, ... Directive 2003/74/EC was fully consistent with its WTO obligations."⁷³⁸ Therefore, the European Communities asserts, the Panel exceeded its terms of reference by "ignoring the sequencing order of the legal claims made by the European Communities" and by addressing the issue of actual compliance in order to determine whether the United States and Canada breached Article 22.8 of the DSU.⁷³⁹

323. We recall that, in support of its claim under Article 23.1, read together with Articles 22.8 and 3.7, the European Communities maintains that Directive 96/22/EC "was removed"⁷⁴⁰ within the meaning of Article 22.8 after being replaced by Directive 2003/74/EC and that "the mere *existence* of an implementing measure adopted in good faith and its subsequent notification to the DSB"

⁷³⁶European Communities' appellant's submission, para. 166.

⁷³⁷Panel Report, *US – Continued Suspension*, para. 7.156; Panel Report, *Canada – Continued Suspension*, para. 7.143.

⁷³⁸European Communities' appellant's submission, para. 103.

⁷³⁹*Ibid.*, para. 175.

⁷⁴⁰*Ibid.*, para. 146.

required the United States and Canada to cease the application of the suspension of concessions.⁷⁴¹ The European Communities adds that the continuation of the suspension of concessions by the United States and Canada and their failure to initiate Article 21.5 proceedings necessarily implies that they have made a unilateral determination on the inconsistency of the implementing measure with the DSB's recommendations and rulings, "in breach of Article 23.1 read together with Articles 22.8 and 3.7 of the DSU".⁷⁴² Therefore, the European Communities' assertion that the United States and Canada breached Article 23.1 in making "a unilateral determination" is premised on their alleged failure to terminate the suspension of concessions pursuant to Article 22.8 after the removal of Directive 96/22/EC, as well as their alleged failure to initiate Article 21.5 proceedings.

324. As we concluded in the previous sections, the inconsistent measure will not be considered removed within the meaning of Article 22.8 unless substantive compliance is achieved. Therefore, whether Directive 2003/74/EC brings the European Communities into compliance with the DSB's recommendations and rulings in *EC – Hormones* was an issue the Panel had to resolve in order to determine whether the United States and Canada were required to terminate the suspension of concessions pursuant to Article 22.8 and whether failing to do so constituted a violation of Article 23.1, read together with Articles 22.8, and 3.7 of the DSU. Before the Panel, the European Communities maintained that it did not have to demonstrate actual compliance with the DSB's recommendations and rulings because it should benefit from a presumption of good faith compliance with respect to Directive 2003/74/EC.⁷⁴³ We concluded, however, that a presumption that the European Communities acted in good faith when adopting Directive 2003/74/EC is insufficient for establishing removal, within the meaning of Article 22.8, of the measure found to be inconsistent in *EC – Hormones*.

325. On appeal, the European Communities emphasizes that Directive 96/22/EC was replaced by Directive 2003/74/EC and thus the inconsistent measure has been removed. In the previous sections, we rejected the European Communities' formalistic understanding of the phrase "the measure found to be inconsistent has been removed" according to which the repeal of the original measure and its replacement with a new measure would require cessation of suspension, regardless of the content of the new measure. Therefore, the distinction drawn by the European Communities between its second set of main claims and its alternative claim is, in our view, based on an incorrect interpretation of Article 22.8. The fact that the European Communities described the question of actual compliance of Directive 2003/74/EC as an alternative claim did not preclude the Panel from evaluating whether

⁷⁴¹European Communities' appellant's submission, para. 101. (original emphasis)

⁷⁴²*Ibid.*, para. 101.

⁷⁴³Panel Report, *US – Continued Suspension*, para. 7.286; Panel Report, *Canada – Continued Suspension*, para. 7.302.

there is substantive compliance, if doing so was necessary to adjudicate the second main claim of the European Communities under Articles 23.1, 22.8, and 3.7. On the contrary, the Panel would have failed to correctly interpret and apply Article 22.8 if it had followed the approach of the European Communities and had refrained from addressing the issue of whether the repeal of Directive 96/22/EC and its replacement by Directive 2003/74/EC resulted in substantive compliance.

326. In *EC – Hormones*, the European Communities' import ban on meat from cattle treated with oestradiol-17 β , progesterone, testosterone, trenbolone acetate, zeranol, or MGA was found to be inconsistent with Article 5.1 of the *SPS Agreement* because it was not based on a proper risk assessment.⁷⁴⁴ To implement the DSB's recommendations and rulings, the European Communities adopted Directive 2003/74/EC, which repealed Directive 96/22/EC. Directive 2003/74/EC applies a ban on the importation of meat from cattle treated with oestradiol-17 β for growth-promotion purposes, while the importation of meat from cattle treated with the other five hormones is provisionally forbidden. According to the European Communities, Directive 2003/74/EC is based on a comprehensive risk assessment that "sufficiently warrants"⁷⁴⁵ the permanent import prohibition regarding oestradiol-17 β and is therefore consistent with Article 5.1 of the *SPS Agreement*. The European Communities also contends that the risk assessment provides the "available pertinent information" on the basis of which the provisional prohibition regarding the other five hormones has been enacted. Thus, in the European Communities' view, the provisional import ban is consistent with Article 5.7 of the *SPS Agreement*, which allows Members to adopt provisional SPS measures on the basis of available pertinent information in cases where "relevant scientific evidence is insufficient". On this basis, the European Communities argues that it has implemented the DSB's recommendations and rulings in *EC – Hormones*.⁷⁴⁶

327. The Panel addressed the consistency with Articles 5.1 and 5.7 of the *SPS Agreement* of the import ban imposed by Directive 2003/74/EC.⁷⁴⁷ We have found that the European Communities was required to bring about substantive compliance for the United States and Canada to be under an obligation to terminate the suspension of concessions pursuant to Article 22.8 of the DSU. The DSB's

⁷⁴⁴Appellate Body Report, *EC – Hormones*, para. 208.

⁷⁴⁵European Communities' first written submission to the Panel, para. 17 (quoting Appellate Body Report, *EC – Hormones*, para. 253(1)).

⁷⁴⁶*Ibid.*, para. 17.

⁷⁴⁷We note that the Panel reviewed, and rejected, the United States' claim that Directive 2003/74/EC was inconsistent with Article 5.2 of the *SPS Agreement*. (Panel Report, *US – Continued Suspension*, para. 7.573) Moreover, both the United States and Canada claimed before the Panel that Directive 2003/74/EC was inconsistent with Article 3.3 of the *SPS Agreement*. The Panel found it unnecessary to examine the claims under Article 3.3, having already concluded that Directive 2003/74/EC was not consistent with Articles 5.1 and 5.7 of the *SPS Agreement*. (*Ibid.*, para. 7.846; Panel Report, *Canada – Continued Suspension*, para. 7.831) The Panel's findings with respect to Articles 5.2 and 3.3 of the *SPS Agreement* were not appealed. We therefore find it unnecessary to examine whether these two provisions were properly before the Panel.

recommendations and rulings from *EC – Hormones* included a finding that the import ban on meat from cattle treated with oestradiol-17 β was inconsistent with Article 5.1 of the *SPS Agreement* because it was not based on a proper risk assessment. Thus, in order to determine whether the European Communities had complied with the DSB's recommendations and rulings, the Panel had to examine whether the European Communities had brought its import ban relating to oestradiol-17 β into conformity with Article 5.1 of the *SPS Agreement* by basing the import ban in Directive 2003/74/EC relating to the same substance on a proper risk assessment.

328. We face a somewhat different situation in relation to Article 5.7 of the *SPS Agreement*. The European Communities did not invoke that provision in *EC – Hormones* to justify its import ban on meat from cattle treated with the other five hormones. Thus, the DSB's recommendations and rulings in *EC – Hormones* did not include findings under Article 5.7 of the *SPS Agreement*. Instead, the import ban relating to the other five hormones was found to be inconsistent with Article 5.1 because it was not based on a proper risk assessment. This raises the question as to whether the European Communities' changed justification precluded the Panel from examining its consistency with the *SPS Agreement*, and particularly with Article 5.7, a provision that was not part of the DSB's recommendations and rulings in *EC – Hormones*. In our view, the Panel was not precluded from assessing the consistency of Directive 2003/74/EC with Article 5.7 for the following reasons. The definitive import ban that was the subject of *EC – Hormones* and found to be inconsistent with Article 5.1 has been replaced, under Directive 2003/74/EC, by a provisional ban relating to the five other hormones. The import ban applies to the same products: meat from cattle treated with progesterone, testosterone, trenbolone acetate, zeranol, and MGA. The European Communities replaced the original definitive ban with a provisional ban and invoked Article 5.7 as an alternative justification to Article 5.1. The European Communities has characterized the import ban as a provisional one and has sought to justify it under Article 5.7 of the *SPS Agreement*:

The new Directive provides that the use for animal growth promotion of one of the six hormones in dispute is permanently prohibited while the use of the other five is provisionally forbidden. It is based on a comprehensive risk assessment and, thus, is fully compliant with the DSB recommendations and rulings. In particular, as stipulated by the Appellate Body, the results of the risk assessment "sufficiently warrant" the definite import prohibition regarding one of the hormones (Article 5.1 of the *SPS Agreement*), and provide the "available pertinent information" on the basis of which the provisional prohibition regarding the other five hormones has been enacted (Article 5.7 of the *SPS Agreement*). Consequently, through Directive 2003/74/EC the European Communities has implemented

the rulings and recommendations in the *Hormones* case.⁷⁴⁸ (footnote omitted)

Article 22.8 demands substantive compliance with the DSB's recommendations and rulings. A change in justification, by itself, cannot be said to achieve substantive compliance. Compliance with the DSB's recommendations and rulings concerning Article 5.1 and the definitive ban on the five hormones cannot be established without reviewing the alternative justification for the provisional ban under Article 5.7. If the new justification for the ban is not consistent with the *SPS Agreement*, substantive compliance has not been achieved.

329. We recall that the Appellate Body has stated that, "pursuant to Article 7 of the DSU, the panel's terms of reference are governed by the request for the establishment of a panel."⁷⁴⁹ We recognize that the European Communities' requests for the establishment of a panel do not list Articles 5.1 and 5.7.⁷⁵⁰ Also, we are mindful that a panel request submitted by an original respondent in the post-suspension stage is different from a panel request in original and compliance proceedings in the pre-suspension stage. In the requests for establishment of a panel, the European Communities asserts that it has brought itself into compliance with the DSB's recommendations and rulings which included a violation of Article 5.1. It gives the following reason why the suspensions of concessions could no longer be justified:

In the same communication [in which Directive 2003/74/EC was notified to the DSB], the European Communities explained that it considers itself to have fully implemented the recommendations and rulings of the DSB in the *EC – Hormones* dispute and that, as a consequence, it considers [the United States' and Canada's] suspension of concessions vis-à-vis the European Communities to be no longer justified.⁷⁵¹ (footnote omitted)

330. Directive 2003/74/EC specifies that the original definitive import ban that had been found to be inconsistent with the covered agreements was replaced by a permanent ban in respect of oestradiol-17 β and a provisional ban in relation to the other five hormones. Such a provisional ban implicates Article 5.7 as explained above. Moreover, the requests for establishment of a panel acknowledge that the United States and Canada did not consider that Directive 2003/74/EC complied with the *SPS Agreement*:

The [United States and Canada] disagreed and denied that the new Directive was based on science and that it implemented the DSB's recommendations and rulings. The [United States and Canada] formally stated in the DSB that [they] considered the new Directive

⁷⁴⁸European Communities' first written submission to the Panel, para. 17.

⁷⁴⁹Appellate Body Report, *US – Carbon Steel*, para. 124.

⁷⁵⁰WT/DS320/6; WT/DS321/6.

⁷⁵¹*Ibid.*

to be inconsistent with the European Communities obligations under the *SPS Agreement* and that [they] would continue to impose retaliatory duties on certain products from the European Communities.⁷⁵² (footnotes omitted)

331. Finally, the European Communities claims in its request that the United States' and Canada's conduct is inconsistent with Article 22.8 of the DSU. It is evident from the panel requests that the consistency of the United States' and Canada's continued suspension with Article 22.8 was linked to the European Communities' implementation of the DSB's recommendations and rulings in *EC – Hormones*. We fail to see how the claims explicitly listed in the panel requests by the European Communities could be resolved in isolation from the question of whether Directive 2003/74/EC has brought the European Communities into compliance with these DSB's recommendations and rulings.

332. Taken together, these elements support the conclusion that the consistency of Directive 2003/74/EC with Articles 5.1 and 5.7 of the *SPS Agreement* was part of the matter to be examined by the Panel. In these circumstances, we reject the European Communities' claim that the Panel exceeded its terms of reference by addressing the consistency of Directive 2003/74/EC with Articles 5.1 and 5.7 of the *SPS Agreement*. We uphold the Panel's finding that "it has jurisdiction to consider the compatibility of the [European Communities'] implementing measure with the *SPS Agreement* as part of its review of the claim raised by the European Communities with respect to Article 22.8 of the DSU."⁷⁵³

E. *Procedural Avenues for Resolving Disagreements as to Whether the Inconsistent Measure Has Been Removed under Article 22.8 of the DSU*

1. What Is the Appropriate Procedural Avenue to Resolve a Disagreement as to Whether the Inconsistent Measure Has Been Removed?

333. The European Communities argues that, where a WTO Member continues to suspend concessions because it considers that the implementing measure does not achieve compliance with the DSB's recommendations and rulings or is otherwise inconsistent with the covered agreements, the Member has an obligation to initiate Article 21.5 proceedings.

334. Article 21.5 provides that:

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

⁷⁵²WT/DS320/6; WT/DS321/6.

⁷⁵³Panel Report, *US – Continued Suspension*, para. 7.379; Panel Report, *Canada – Continued Suspension*, para. 7.376.

possible resort to the original panel. The panel shall circulate its report within 90 days after the date of referral of the matter to it. When the panel considers that it cannot provide its report within the time frame, it shall inform the DSB in writing of the reasons for the delay together with an estimate of the period within which it will submit its report.

335. The European Communities reads the words "shall be decided" and "including" as indicating an obligation to have recourse to an Article 21.5 panel in the sense that it constitutes a mandatory step in the process of adjudicating disagreements over the existence or consistency of measures taken to comply, even though additional procedural steps may also be available under the DSU. However, the United States and Canada read the phrase "shall be decided through recourse to these dispute settlement procedures" to mean that recourse could encompass any of the procedures available under the DSU, and not just an Article 21.5 panel procedure. The phrase "including wherever possible ... the original panel" would then be read as one of several options. This seems to be the view taken by the Panel when it read the phrase to mean resort "to the panelists that reviewed the original case, rather than to other individuals."⁷⁵⁴ The Panel further found that several procedural means are available to the European Communities for obtaining the termination of the suspension of concessions, including good offices and consultations, arbitration under Article 25 of the DSU, panel proceedings under Article 21.5 of the DSU, and new panel proceedings involving a challenge against the continued suspension of concessions.⁷⁵⁵

336. The opening clause of Article 21.5 specifies the types of disputes that fall within the scope of this provision, that is, those involving a disagreement as to the existence or consistency with a covered agreement of measures taken to comply with the recommendations and rulings of the DSB. The word "shall" in Article 21.5 indicates that such disagreements must be resolved through recourse to "these dispute settlement procedures". Read together with the second sentence of Article 21.5, "these dispute settlement procedures" do not refer generally to all proceedings under the DSU, but specifically to the panel proceedings envisaged in Article 21.5, in which the original panelists are preferred for the composition of the panel and in which the time frame of the proceedings is shortened. In other words, Article 21.5 dictates that panel proceedings pursuant to this provision are the procedures that must be followed for adjudicating the cause of action as framed in its opening clause.

337. As we see it, at the core of this dispute is a disagreement as to whether Directive 2003/74/EC, the measure taken by the European Communities to comply with the DSB's recommendations and

⁷⁵⁴Panel Report, *US – Continued Suspension*, para. 7.351; Panel Report, *Canada – Continued Suspension*, para. 7.349.

⁷⁵⁵Panel Report, *US – Continued Suspension*, para. 7.350; Panel Report, *Canada – Continued Suspension*, para. 7.348.

rulings in *EC – Hormones*, achieves substantive compliance. Before the Panel, the European Communities claimed that it had removed Directive 96/22/EC, which had been found to be inconsistent in *EC – Hormones*, and that the United States and Canada breached Article 23.1, read together with Articles 22.8 and 3.7, by failing to terminate the suspension of concessions.⁷⁵⁶ The United States and Canada disagreed that they were in breach of Article 22.8 and argued that it has not been demonstrated that the European Communities has in fact removed its WTO-inconsistent measure.⁷⁵⁷ Because the phrase "until such time as the measure found to be inconsistent with a covered agreement has been removed" in Article 22.8 must be properly interpreted as referring to substantive compliance, the disagreement as to whether such compliance has been achieved is the central issue that must be resolved in order to assess the legality of the continued suspension.

338. Article 21.5 provides for specific procedures for adjudicating a disagreement as to the consistency with the covered agreements of measures taken by a Member to implement the DSB's recommendations and rulings. Thus, panel proceedings under Article 21.5 is the proper procedure for resolving the disagreement as to whether Directive 2003/74/EC has achieved substantive compliance and whether, consequently, the resolute condition in Article 22.8 that requires the termination of the suspension of concessions has been met. Indeed, as the Panel pointed out, "the option naturally coming to mind when it comes to reviewing compliance is the procedure provided under Article 21.5 of the DSU."⁷⁵⁸ The Panel also recognized that it "performed functions similar to that of an Article 21.5 panel" by addressing the consistency with the covered agreements of Directive 2003/74/EC.⁷⁵⁹

339. The Panel nonetheless found that Article 21.5 panel proceedings were not "the only avenue available to address a claim of compliance by a Member alleging to have complied with recommendations and rulings of the DSB".⁷⁶⁰ Rather, as described above, the Panel found that good offices, consultations, and arbitration under Article 25 of the DSU were other procedures available to the European Communities for obtaining the termination of the suspension of concessions.

340. Certainly, parties to a dispute are not precluded from pursuing consensual or alternative means of dispute settlement foreseen in the DSU. Article 3.7 of the DSU provides that "[a] solution

⁷⁵⁶Panel Report, *US – Continued Suspension*, para. 7.252; Panel Report, *Canada – Continued Suspension*, para. 7.245.

⁷⁵⁷Panel Report, *US – Continued Suspension*, para. 7.264; Panel Report, *Canada – Continued Suspension*, para. 7.261.

⁷⁵⁸Panel Report, *US – Continued Suspension*, para. 7.351; Panel Report, *Canada – Continued Suspension*, para. 7.349.

⁷⁵⁹Panel Report, *US – Continued Suspension*, para. 8.3; Panel Report, *Canada – Continued Suspension*, para. 8.3.

⁷⁶⁰Panel Report, *US – Continued Suspension*, para. 7.355; Panel Report, *Canada – Continued Suspension*, para. 7.353.

mutually acceptable to the parties to a dispute and consistent with the covered agreements is clearly to be preferred." To reach a mutually acceptable solution, Members can engage in consultations or resort to mediation and good offices. Moreover, Article 25 provides for arbitration as an alternative to panel proceedings for dispute resolution. Consultations, mediation, good offices, and arbitration are, however, alternatives to compulsory adjudication and require the consent of the parties. In the absence of such consent, they cannot lead to a binding decision. Thus, it is important to distinguish between these consensual means of dispute resolution, which are always at the Members' disposal, and adjudication through panel proceedings, which are compulsory. It is in this sense that Article 21.5 is cast in obligatory language. In this dispute, it is clear that a mutually acceptable solution was not reached and the European Communities decided to resort to adjudication. In addition, the parties to this dispute were unable to agree on an arbitration procedure pursuant to Article 25 of the DSU.⁷⁶¹ The issue before us, therefore, is which procedure must be followed when parties do not avail themselves of the consensual and alternative means of dispute resolution provided in the DSU, and the dispute must proceed to the adjudication phase.

341. Another possibility the Panel identified are new panel proceedings involving a challenge against the legality of the continued suspension of concessions, such as the European Communities' initiation of the current proceedings.⁷⁶² As discussed, the legality of the continued suspension of concessions in this dispute hinges on whether Directive 2003/74/EC achieves substantive compliance, an issue that should be properly adjudicated in Article 21.5 proceedings. The Panel itself recognized that it had to "perform functions similar to that of an Article 21.5 panel".⁷⁶³ By contrast, the cause of action in new panel proceedings normally does not involve the issue of whether a measure taken to comply with the DSB's recommendations and rulings is consistent with the covered agreements. The European Communities initiated the current proceedings, in part, on account of its belief that an original respondent is precluded from initiating Article 21.5 panel proceedings. We address this issue in subsection 2 below.

342. Furthermore, a disagreement under Article 22.8 concerning the removal of "a measure found to be inconsistent" in an original proceeding does not exist in the abstract but, rather, occurs in the context of a pre-existing dispute that gave rise to the DSB's recommendations and rulings. Recourse

⁷⁶¹The European Communities alleges that it proposed to the United States to submit the dispute to arbitration under Article 25 of the DSU, but the United States refused. (European Communities' appellant's submission, para. 62)

⁷⁶²Panel Report, *US – Continued Suspension*, para. 7.350; Panel Report, *Canada – Continued Suspension*, para. 7.348.

⁷⁶³Panel Report, *US – Continued Suspension*, para. 8.3; Panel Report, *Canada – Continued Suspension*, para. 8.3.

to Article 21.5 proceedings keeps the successive proceedings relating to the same dispute within "a continuum of events"⁷⁶⁴, and is conducive to reaching a final resolution of the dispute.

343. Finally, in contrast to new panel proceedings, recourse to Article 21.5 is a more efficient use of the dispute settlement system. As the Appellate Body observed:

First, the composition of an Article 21.5 panel is, in principle, already determined—wherever possible, it is the original panel. These individuals will be familiar with the contours of the dispute, and the experience gained from the original proceedings should enable them to deal more efficiently with matters arising in an Article 21.5 proceeding "against the background of the original proceedings". Secondly, the time-frames are shorter—an Article 21.5 panel has, in principle, 90 days in which to issue its report, as compared to the six to nine months afforded original panels.⁷⁶⁵

344. As discussed, underlying this dispute concerning the continued suspension of concessions lies a disagreement over the consistency with the covered agreements of Directive 2003/74/EC, a measure taken by the European Communities to comply with the DSB's recommendations and rulings in *EC – Hormones*. The individuals who served in the panel in *EC – Hormones* were familiar with the background of the dispute and the inconsistencies with the covered agreements they had found with respect to Directive 96/22/EC. Recourse to Article 21.5 panel proceedings would allow these individuals to examine whether the inconsistencies found in *EC – Hormones* have been rectified by Directive 2003/74/EC. Such proceedings would benefit from their knowledge and expertise gained from serving as panelists in *EC – Hormones*, and would be adjudicated within a shorter time frame than regular panel proceedings. Recourse to Article 21.5 proceedings under such circumstances is therefore also consistent with the objective of the dispute settlement system of achieving prompt settlement of disputes.

345. In sum, we consider that recourse to Article 21.5 panel proceedings is the proper course of action within the procedural structure of the DSU in cases where, as in this dispute, a Member subject to the suspension of concessions has taken an implementing measure and a disagreement arises as to whether "the measure found to be inconsistent with a covered agreement has been removed" within the meaning of Article 22.8. Therefore, we share the European Communities' view that Article 21.5 panel proceedings are the procedures to be followed where there is disagreement as to whether Directive 2003/74/EC has achieved substantive compliance. We turn now to examine which party may initiate the Article 21.5 panel proceedings.

⁷⁶⁴ Appellate Body Report, *Mexico – Corn Syrup (Article 21.5 – US)*, para. 121.

⁷⁶⁵ Appellate Body Report, *US – Softwood Lumber IV (Article 21.5 – Canada)*, para. 71.

2. Is the European Communities Precluded from Initiating Article 21.5 Panel Proceedings Regarding Whether Directive 2003/74/EC Has Brought It into Compliance?

346. The European Communities argues that the Panel erred in finding that proceedings under Article 21.5 could have been initiated by the European Communities as the original responding party in *EC – Hormones*.⁷⁶⁶ According to the European Communities, "it is inherent in the wording, context and object and purpose of the provision that it is the obligation of the complaining party to have recourse to Article 21.5."⁷⁶⁷

347. A "disagreement" as to the consistency with the WTO agreements of a measure taken to comply arises from the existence of conflicting views: the original complainant's view that such a measure is inconsistent with the WTO agreements or brings about only partial compliance, and the original respondent's view that a measure is consistent with the WTO agreements and brings about full compliance with the DSB's recommendations and rulings. Article 21.5 does not indicate which party may initiate proceedings under this provision. Rather, the language of the provision is neutral on this matter, and it is open to either party to refer the matter to an Article 21.5 panel to resolve this disagreement. The text of Article 21.5, therefore, leaves open the possibility that either party to the original dispute may initiate the proceedings. Thus, contrary to the European Communities' argument, the text of Article 21.5 does not preclude an original respondent from initiating proceedings under that provision to obtain confirmation of the consistency with the WTO agreements of its implementing measure.

348. Moreover, we recall that the suspension of concessions is an abnormal state of affairs because it is the last resort available under the DSU when compliance is not achieved. Pursuant to Article 22.8, this abnormal state of affairs must be "temporary" and must be brought back to normality as soon as possible. Consequently, both the suspending Member and the implementing Member share the responsibility to ensure that the suspension of concessions is not applied indefinitely. Thus, initiation of Article 21.5 proceedings by either Member, as soon as possible, to examine the consistency with the covered agreements of Directive 2003/74/EC would contribute to a prompt resolution of the disagreement as to whether the inconsistent measure has been removed and whether the suspension of concessions must be terminated pursuant to Article 22.8.

349. The European Communities advances several reasons why initiation of Article 21.5 panel proceedings by the original respondent is not permissible, including: (i) the adversarial nature of the

⁷⁶⁶Panel Report, *US – Continued Suspension*, para. 7.355; Panel Report, *Canada – Continued Suspension*, para. 7.353.

⁷⁶⁷European Communities' appellant's submission, para. 75.

WTO dispute settlement system and its inapplicability to a Member's request for an "abstract confirmation" of the consistency of a measure; (ii) the difficulty in defining the Article 21.5 panel's terms of reference; (iii) the possibility that the original complainants would refuse to participate; and (iv) the lack of recommendations and rulings directly addressing the illegality of the continued suspension of concessions should the measure taken to comply be found to be consistent with the WTO agreements. We address below each of the objections raised by the European Communities.

(a) The "Adversarial" Nature of the WTO Dispute Settlement System

350. According to the European Communities, an implementing Member cannot have recourse to Article 21.5 of the DSU to confirm the consistency with the WTO agreements of its own measures, because the dispute settlement system is based on adversarial proceedings and is not applicable to "requests for an abstract confirmation of the consistency of a measure".⁷⁶⁸ The European Communities adds that its understanding of Article 21.5 is confirmed by the concept of a "dispute" as reflected in Article 3.3 of the DSU, which, according to the European Communities, "assumes a situation where one Member challenges the measure of another Member" because the former considers that its rights are being affected.⁷⁶⁹ The European Communities also refers to the text of Article XXIII:1 of the GATT 1994 which contains language similar to that in Article 3.3 of the DSU.

351. Article 3.3 provides that:

The prompt settlement of situations in which a Member considers that any benefits accruing to it directly or indirectly under the covered agreements are being impaired by measures taken by another Member is essential to the effective functioning of the WTO and the maintenance of a proper balance between the rights and obligations of Members.

352. It is evident that the implementing Member would not normally consider its benefits to have been impaired by the measure it has itself taken to comply with the DSB's recommendations and rulings. In the post-suspension stage of a dispute, however, an original respondent would initiate Article 21.5 panel proceedings for a specific reason: to obtain a multilateral confirmation that its implementing measure has achieved substantive compliance, so as to render the continued application of the suspension of concessions unlawful pursuant to Article 22.8. The situation is thus one of those envisaged under Article 3.3, in that the original respondent considers that its benefits under the covered agreement are being impaired by the suspension of concessions maintained by the original complainant, which is denied by the suspending Member. The task of an Article 21.5 panel,

⁷⁶⁸European Communities' appellant's submission, para. 78. (emphasis omitted)

⁷⁶⁹*Ibid.*, para. 85.

established at the request of the original respondent, is to determine whether the implementing measure brings about substantive compliance. There is nothing "abstract" about such a determination; it results in an adjudication with real consequences, including, in particular, whether the application of the suspension of concessions may continue.

(b) The Terms of Reference of an Article 21.5 Panel Requested by the Original Respondent

353. The European Communities submits that "[i]t would be manifestly impossible for the European Communities to fulfil the very basic requirements of Article 6 for the purposes of seeking confirmation of the consistency with the WTO agreements of its implementing measure since it would not be in a position to identify the provisions of the *SPS Agreement* that are violated."⁷⁷⁰ We agree that the original respondent that has taken a measure to comply cannot be expected to speculate as to the violations that could possibly be raised against its measure by other Members, and this is not what the original respondent is expected to do if it initiates Article 21.5 panel proceedings. Rather, the original respondent will be able to identify in its panel request the measure it has taken to comply and the specific inconsistencies found in the DSB's recommendations and rulings in the original proceedings, and claim before the Article 21.5 panel that it has complied with the DSB's recommendations and rulings by rectifying those inconsistencies. It would then be for the Article 21.5 panel to determine if the measure taken to comply does, in fact, rectify the inconsistencies identified in the DSB's recommendations and rulings.

354. The original complainant may respond to the allegations of compliance made by the original respondent. If, however, the original complainant considers that the implementing measure is inconsistent with provisions of the WTO agreements not covered in the request for the establishment of a panel by the implementing Member, it may file its own request for the establishment of a panel under Article 21.5 identifying those provisions that it considers should be examined by the Article 21.5 panel. It would be for the Article 21.5 panel to determine if the implementing measure violates the WTO agreements in ways different from the original measure or whether certain claims fall outside the scope of Article 21.5 proceedings.⁷⁷¹ The original complainant would be expected to

⁷⁷⁰European Communities' appellant's submission, para. 88.

⁷⁷¹As the Appellate Body has explained, a complainant who had failed to make out a *prima facie* case in the original proceedings regarding an element of the measure that remains unchanged since the original proceedings may not re-litigate the same claim with respect to the unchanged element of the measure in the Article 21.5 proceedings. (Appellate Body Report, *EC – Bed Linen (Article 21.5 – India)*, paras. 87 and 96) Similarly, a complainant may not reassert the same claim against an unchanged aspect of the measure that was found to be *WTO-consistent* in the original proceedings. (Appellate Body Report, *US – Shrimp (Article 21.5 – Malaysia)*, para. 96) Moreover, a complaining Member ordinarily would not be allowed to raise claims in the Article 21.5 proceedings that it could have pursued in the original proceedings, but did not. (Appellate Body Report, *US – Upland Cotton (Article 21.5 – Brazil)*, para. 211)

do so as soon as possible after adoption of an implementation measure or after the filing of the original respondent's panel request, so that both Article 21.5 panel requests may be referred to the original panel wherever possible, allowing review of all the issues relating to substantive compliance in the same Article 21.5 proceedings.⁷⁷²

355. Such an approach is consistent with the requirements of Article 22.8 of the DSU. As noted above, Article 22.8 provides certain resolute conditions which, if met, render the suspension of concessions without legal basis. The suspending Member and the implementing Member share the responsibility to ensure that the suspension of concessions is applied only insofar as none of the conditions laid down in Article 22.8 are met. Thus, both Members have an obligation to engage in a cooperative manner in WTO dispute settlement to establish whether the suspension of concessions can continue or must be discontinued pursuant to Article 22.8. Irrespective of who initiates the Article 21.5 panel proceedings, a finding of an Article 21.5 panel that the implementing Member has removed the inconsistent measure means that one of the resolute conditions in Article 22.8 is met. This finding, once adopted by the DSB—the same body that authorized the suspension of concessions—signifies that the inconsistency against which the suspension of concessions was authorized has now been remedied. Thus, by operation of law (*ipso jure*), the suspension of concessions may no longer be applied.

(c) The Original Complainants' Incentive to Participate in Article 21.5 Panel Proceedings Initiated by the Original Respondent

356. The European Communities further submits that it "appears that the United States and Canada as 'defending parties' would not be obliged to participate"⁷⁷³ in Article 21.5 panel proceedings initiated by the European Communities. In support of this argument, the European Communities referred to the fact that in *EC – Bananas III (Article 21.5 – EC)*, one of the original complainants (the United States) refused to participate in the Article 21.5 panel proceedings that the original respondent (the European Communities) had initiated. The European Communities therefore takes issue with the Panel's reference to that dispute in finding that Article 21.5 panel proceedings may be initiated by the original respondent.

357. We note that the panel in *EC – Bananas III (Article 21.5 – EC)* did not find that it was precluded from examining the European Communities' claims because the European Communities

⁷⁷²Even if delays between the original respondent's and original complainant's panel requests do not allow for harmonization pursuant to Article 9 of the accelerated working schedules under Article 21.5, the matter raised by the original respondent and the original complainant would nevertheless, wherever possible, be referred to the same individuals that served on the original panel.

⁷⁷³European Communities' appellant's submission, para. 90.

had been the respondent in the original proceedings.⁷⁷⁴ Moreover, the exceptional circumstances in *EC – Bananas III (Article 21.5 – EC)*, including the particular request made by the European Communities in those proceedings, could explain the lack of participation of certain original complainants and that panel's decision not to make a ruling on the consistency of the European Communities' first implementing measure. In *EC – Bananas III (Article 21.5 – EC)*, an Article 21.5 panel was established at the request of one of the original complainants, Ecuador, in which the European Communities' first implementing measure was found to be inconsistent with the WTO agreements. There was also an ongoing arbitration pursuant to Article 22.6 of the DSU between the European Communities and the United States.⁷⁷⁵ That dispute, on its unusual facts, does not lead to the conclusion that an Article 21.5 panel would be precluded from making an objective assessment of the matter referred to it by the original respondent.

358. We recognize that it is theoretically possible for the original complainant to refuse to participate in Article 21.5 proceedings initiated by the original respondent.⁷⁷⁶ Yet, this is not a feature that may only occur in Article 21.5 proceedings initiated by the original respondent, because the DSU does not provide the means to compel any party to participate in any dispute settlement proceedings. A defending party who refuses to participate in dispute settlement proceedings will lose the opportunity to defend its position and will risk a finding in favour of the complaining party that has established a *prima facie* case.⁷⁷⁷ Similarly, in Article 21.5 panel proceedings initiated by the original respondent, the original complainant who refuses to participate forgoes the opportunity to explain to the Article 21.5 panel why the measure taken to comply fails to rectify the inconsistencies found in the original proceeding and, consequently, why the suspension of concessions remains justified under Article 22.8 despite the measure taken to comply. Absent any rebuttal by the original complainant, the Article 21.5 panel will make its determination on the basis of a *prima facie* case presented by the original respondent that its implementing measure has brought it into compliance with the DSB's recommendations and rulings. Therefore, where the original complainant has suspended concessions according to the DSB's authorization, the original complainant would have a strong incentive to participate lest the authorization to suspend concessions lapses as a result of the adoption by the DSB of the Article 21.5 panel's finding that the original respondent has brought itself into compliance.

359. Like any other panel, an Article 21.5 panel established in the post-suspension stage, at the request of the original respondent, would be bound to make an objective assessment of the matter.

⁷⁷⁴Panel Report, *EC – Bananas III (Article 21.5 – EC)*, para. 4.18.

⁷⁷⁵We do not need to express a view here on whether the consistency of the implementation measure could or should have been addressed by the arbitrators acting pursuant to Article 22.6 of the DSU.

⁷⁷⁶European Communities' appellant's submission, para. 89.

⁷⁷⁷For the appellate stage, see Rule 29 of the *Working Procedures*.

The ultimate issue before such a panel is whether the measure found to be inconsistent with a covered agreement has been removed. We have interpreted "removed" to mean substantive compliance. The question is which party bears the burden of proof in respect of the issues of substantive compliance. Is the burden to be allocated according to a mechanistic rule that it is for the party initiating the proceedings to prove substantive compliance or is it the case that the burden of proof is allocated according to different principles? Much of the reluctance of the parties to secure a definitive determination in respect of Article 22.8 is the apprehension that, upon initiation, a party will attract the full burden of proof.

360. In our view, the allocation of the burden of proof, in the context of Article 22.8, should not be determined simply on the basis of a mechanistic rule that the party who initiates the proceedings bears the burden of proof. As we have indicated, in case of a disagreement, both parties are under an obligation to secure a definitive multilateral determination as to whether the suspension of concessions must be terminated. The burden of proof does not attach to a party simply because such party discharges this obligation. To hold otherwise would create a disincentive to act in a manner which we consider to be obligatory and desirable.

361. The allocation of the burden of proof in the context of claims arising under Article 22.8 is a function of the following considerations. First, what is the nature of the cause of action that is framed under Article 22.8. Second, the practical question as to which party may be expected to be in a position to prove a particular issue. Third, consideration must be given to the requirements of procedural fairness.

362. Since the suspension of concessions is a remedy of last resort imposed after an elaborate multilateral dispute settlement process, in our view, it is appropriate that the Member whose measure has brought about the suspension of concessions should make some showing that it has removed the measure found to be inconsistent by the DSB in the original proceedings, so that normality can be lawfully restored. This requires that the original respondent will have an onus to show that its implementing measure has cured the defects identified in the DSB's recommendations and rulings. The quantum of proof entailed by this is a clear description of its implementing measure, and an adequate explanation regarding how this measure rectifies the inconsistencies found in the original proceedings, so as to place the Article 21.5 panel in a position to make an objective assessment of the matter and, in the absence of rebuttal, to rule in favour of the original respondent.

363. If the original respondent initiates Article 21.5 proceedings to determine that the first resolute condition in Article 22.8 has been fulfilled, and, consequently, that the suspension of concessions must end, and the original complainant fails to appear and answer the case, what would

the original respondent need to establish to satisfy a panel that the resolute condition has been fulfilled? The original respondent, in this situation, would be required to place evidence before the Article 21.5 panel sufficient to permit the panel, in carrying out its duty, to make an objective assessment of the matter. The quantum of evidence necessary for this purpose is the burden of proof, described above, that attaches to the original respondent.

364. In respect of all other issues, the burden of proof rests upon the original complainant. Such issues may include a claim that the implementing measure is otherwise inconsistent with the covered agreements or that the implementing measure remains wanting for reasons not traversed by the original respondent in discharging its burden of proof.

365. This allocation of the burden of proof is also consistent with the parties' shared responsibility to ensure that the suspension of concessions is "temporary", and that the normal state of affairs, that is, conformity with the covered agreements and absence of the suspension of concessions, is restored as quickly as possible.

(d) The Lack of Recommendations and Rulings Regarding the Legality of the Continued Suspension of Concessions

366. The European Communities further states that, if it had initiated Article 21.5 panel proceedings in this case, the Article 21.5 panel could not have made recommendations addressed to the United States and Canada to cease the suspension of concessions, because an Article 21.5 panel would only have had jurisdiction to rule on the compliance of the implementing measure.⁷⁷⁸

367. A finding that the implementing Member has achieved substantive compliance means that the first resolute condition in Article 22.8 has been met. Such a finding, adopted by the DSB as part of the Article 21.5 panel (and Appellate Body) report(s), would, by operation of law (*ipso jure*), result in the termination of the DSB's authorization to suspend concessions. This result obtains irrespective of whether the Article 21.5 panel was initiated by the original respondent or by the original complainant. It does not depend on which party initiates the Article 21.5 panel proceedings. Rather, the result depends on whether the Article 21.5 panel confirms that the implementing Member has brought itself into substantive compliance, thereby triggering the obligation to cease applying the suspension of concessions, as required by Article 22.8 of the DSU.

368. In sum, we are not persuaded by the European Communities' argument that an original respondent in the post-suspension stage of a dispute would be precluded from initiating Article 21.5 proceedings. Therefore, we find that the Panel did not err in stating that proceedings under

⁷⁷⁸European Communities' appellant's submission, para. 92.

Article 21.5 of the DSU may be initiated not only by the complainant, but also by the respondent in the original proceedings.

F. *Analysis of the Panel's Findings of "Procedural Violations"*

369. The United States and Canada allege that the Panel erred in finding that they breached Articles 23.2(a) and 23.1 of the DSU by continuing the suspension of concessions after the notification of Directive 2003/74/EC⁷⁷⁹, and request the Appellate Body to reverse these findings. In particular, the United States and Canada assert that the Panel erred in finding that: (i) through the maintenance of the suspension of concessions against the European Communities, they are seeking the redress of a violation with respect to Directive 2003/74/74/EC; and (ii) they made a unilateral determination to the effect that a violation has occurred without recourse to dispute settlement under the DSU, in contravention of Article 23.2(a).

1. The Prohibition on Certain Unilateral Actions – Article 23 of the DSU

370. We begin our analysis with the interpretation of the terms of Article 23 that are relevant to this dispute. Entitled "Strengthening of the Multilateral System", Article 23 provides that:

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

2. In such cases, Members shall:

(a) not make a determination to the effect that a violation has occurred, that benefits have been nullified or impaired or that the attainment of any objective of the covered agreements has been impeded, except through recourse to dispute settlement in accordance with the rules and procedures of this Understanding, and shall make any such determination consistent with the findings contained in the panel or Appellate Body report adopted by the DSB or an arbitration award rendered under this Understanding;

(b) follow the procedures set forth in Article 21 to determine the reasonable period of time for the Member concerned to implement the recommendations and rulings; and

(c) follow the procedures set forth in Article 22 to determine the level of suspension of concessions or other obligations and obtain DSB authorization in accordance with those procedures before suspending concessions or other obligations under the covered

⁷⁷⁹Panel Report, *US – Continued Suspension*, paras. 7.251 and 7.856; Panel Report, *Canada – Continued Suspension*, paras. 7.244 and 7.841.

agreements in response to the failure of the Member concerned to implement the recommendations and rulings within that reasonable period of time.

371. As the Appellate Body has explained, Article 23.1 lays down the fundamental obligation of WTO Members to have recourse to the rules and procedures of the DSU when seeking redress of a violation of the covered agreements.⁷⁸⁰ Article 23 restricts WTO Members' conduct in two respects. First, Article 23.1 establishes the WTO dispute settlement system as the exclusive forum for the resolution of such disputes and requires adherence to the rules of the DSU. Secondly, Article 23.2 prohibits certain unilateral action by a WTO Member. Thus, a Member cannot unilaterally: (i) determine that a violation has occurred, benefits have been nullified or impaired, or that the attainment of any objective of the covered agreements has been impeded; (ii) determine the duration of the reasonable period of time for implementation; or (iii) decide to suspend concessions and determine the level thereof.

372. The phrase "[i]n such cases, Members shall" with which Article 23.2 begins refers back to the situation described in Article 23.1, namely, when a Member is seeking the redress of, *inter alia*, a violation of obligations under the covered agreements. We share the view of the panel in *US – Section 301 Trade Act* that the terms "[i]n such cases, Members shall" used in the chapeau of Article 23.2 make clear that Article 23.2 is "explicitly linked to, and has to be read together with and subject to, Article 23.1".⁷⁸¹ Therefore, the specific prohibitions of unilateral actions in Article 23.2 must be understood in the context of the overarching provision of Article 23.1. In other words, the unilateral actions prohibited by Article 23.2 are those taken by a Member with a view to seeking redress of a violation. Moreover, the phrase "[i]n such cases, Members shall" at the beginning of Article 23.2 indicates that the specific obligations set forth in its subparagraphs clarify and illustrate the scope of the general and ongoing obligation in Article 23.1. This does not mean, however, that the scope of Article 23.1 is exhausted by the situations described in Article 23.2.⁷⁸²

373. Seeking the redress of a violation is of course not by itself prohibited by Article 23.1 of the DSU. Rather, to be in breach of Article 23.1, a Member must be seeking redress without having recourse to, or abiding by, the rules of the DSU.

⁷⁸⁰ Appellate Body Report, *US – Certain EC Products*, para. 111.

⁷⁸¹ Panel Report, *US – Section 301 Trade Act*, para. 7.44.

⁷⁸² As the panel in *US – Section 301 Trade Act* pointed out, the prohibitions mentioned in Article 23.2 are examples of conduct that contradicts the rules and procedures of the DSU which, under the obligation in Article 23.1 to "abide by the rules and procedures" of the DSU, Members are obligated to follow. These rules and procedures cover more than those specifically mentioned in Article 23.2 and "[t]here is a great deal more State conduct which can violate the general obligation in Article 23.1 to have recourse to, and abide by, the rules and procedures of the DSU than the instances especially singled out in Article 23.2." (Panel Report, *US – Section 301 Trade Act*, para. 7.45) (footnote omitted)

374. An initial question that arises in this case is whether the continued application of a previously authorized suspension of concessions can be said to constitute the seeking of redress. On the one hand, the authorization to suspend concessions can be said to be the result of a previous act of seeking redress that involved initiating a dispute. On the other hand, the continued application of the suspension of concessions can be said to reflect a continuous act of seeking redress for a violation found by the DSB that has not yet been rectified. In any event, the suspension of concessions that has been duly authorized by the DSB will not constitute a violation of Article 23.1, as long as it is consistent with other rules of the DSU, including paragraphs 2 through 8 of Article 22, even if the continued application of the suspension of concessions is regarded as an action or part of a process of "seeking the redress". This is because, before obtaining the DSB's authorization to suspend concessions, a Member must initiate a dispute settlement process in which it challenges the consistency with the covered agreements of a measure taken by another Member. The Member initiating the process will only be authorized to suspend concessions when the measure is found by the panel (and the Appellate Body, if appealed) to be inconsistent with the covered agreements and the Member taking the measure fails to implement the panel's (or Appellate Body's) findings within a reasonable period of time or, if it takes a measure to comply, that measure is found by the panel (and the Appellate Body) in compliance proceedings not to have brought the Member concerned into compliance. In other words, the Member will only be able to suspend concessions pursuant to the DSB's authorization after having had extensive recourse to, and abided by, the rules and procedures of the DSU, consistent with the requirements of Article 23.1.

375. This does not mean that Article 23.1 ceases to apply once the suspension of concessions has been authorized by the DSB. Article 23.2(c) specifically refers to Article 22 of the DSU. Paragraph 8 of this provision states that the suspension of concessions shall only be applied until the inconsistent measure has been removed or one of the other two conditions in Article 22.8 is met. Thus, if the Member subject to the suspension of concessions takes an implementing measure and that measure is found in WTO dispute settlement proceedings to bring this Member into substantive compliance, the suspension of concessions would no longer be consistent with Article 22.8 of the DSU, and, as a result, would become a unilateral action prohibited by Articles 23.1 and 23.2. In other words, the requirements in Article 22.8 and Article 23 apply and must be read together in the post-suspension stage of a dispute. Therefore, Article 23 must be seen as containing an ongoing obligation and continues to apply even after the suspension of concessions has been duly authorized by the DSB.

376. With this in mind, we turn to examine the issues raised by the United States and Canada on appeal.

2. The Panel's Alleged Examination of Articles 23.2(a) and 23.1 in Isolation from the Requirements in Article 22.8 of the DSU

377. The United States and Canada submit that the Panel erred by examining the European Communities' claims under Articles 23.2(a), 23.1, and 21.5 independently from the question of whether Article 22.8 required the termination of the suspension of concessions. The United States argues that the Panel ignored the fact that none of the conditions requiring the cessation of the suspension of concessions under Article 22.8 of the DSU had occurred. Thus, the United States maintains, the Panel's findings that the suspension of concessions by the United States is "without recourse to the procedures under the DSU"⁷⁸³ would effectively undermine the DSB's authorization to suspend concessions, rendering it "meaningless".⁷⁸⁴ Canada claims that the "[k]ey to this case is Article 22.8 of the DSU"⁷⁸⁵ which, as *lex specialis* in the post-suspension phase of a dispute, sets out the three conditions that must be met in order to have the suspension of concessions terminated, one of the conditions being actual compliance with the DSB's recommendations and rulings. Canada adds that "the continuous involvement of the DSB", pursuant to the second sentence of Article 22.8, "suggests that [the DSB] retains jurisdiction over the matter until its recommendations and rulings have been fully implemented."⁷⁸⁶ Thus, in Canada's view, the Panel should have first considered whether Canada was required to discontinue the suspension of concessions pursuant to Article 22.8.⁷⁸⁷

378. We note that the suspension of concessions maintained by the United States and Canada were duly authorized by the DSB subsequent to its adoption of the recommendations and rulings in *EC – Hormones* and an arbitration award resulting from proceedings under Article 22.6 regarding the level of the suspension of concessions.⁷⁸⁸ As discussed above, where the suspension of concessions has been duly authorized by the DSB and is applied consistently with the rules of the DSU, including Article 22.8, it does not constitute a violation of Article 23.1, because it is not imposed without recourse to or without abiding by the DSU. The requirements in Article 22 and those in Article 23 must be read together, in the post-suspension stage of the dispute, to determine the legality of the continued suspension when an implementing measure has been taken. Thus, we share the view of the United States and Canada that, in order to determine whether they acted inconsistently with Article 23 by continuing the suspension of concessions subsequent to the notification of Directive 2003/74/EC, the Panel had to first determine whether the suspension of concessions was being applied consistently with Article 22.8 of the DSU.

⁷⁸³United States' other appellant's submission, para. 29.

⁷⁸⁴*Ibid.*, para. 30.

⁷⁸⁵Canada's other appellant's submission, para. 35.

⁷⁸⁶*Ibid.*, para. 36.

⁷⁸⁷*Ibid.*, paras. 60 and 61.

⁷⁸⁸Article 22.4 provides that "[t]he level of the suspension of concessions or other obligations authorized by the DSB shall be equivalent to the level of the nullification or impairment."

379. The European Communities asserts that the United States and Canada "entirely ignore"⁷⁸⁹ the fact that the European Communities' first series of main claims, alleging violations of Articles 23.1, 23.2(a), and 21.5, did not include Article 22.8 of the DSU. The European Communities further contends that the Panel's approach in examining the claims under Articles 23.1 and 23.2(a) was correct, because Directive 2003/74/EC, as a measure taken to comply, must be presumed to be compliant with the covered agreements until shown otherwise in Article 21.5 proceedings.

380. In section D above, we found that the presumption that an implementing Member acts in good faith is insufficient to establish substantive compliance. The European Communities should be presumed to have acted in good faith when adopting the implementing measure; however, this did not mean that the taking of such measure in itself establishes that the measure achieves substantive compliance. We also rejected the formalistic interpretation of Article 22.8 advanced by the European Communities that the adoption, and notification to the DSB, of a measure taken to comply replacing the original measure is sufficient to establish the removal of the measure found to be inconsistent with a covered agreement within the meaning of Article 22.8. Rather, a proper interpretation of Article 22.8, in its context and in the light of the object and purpose of the DSU, indicates that substantive compliance is required before the suspension of concessions must be terminated. Where parties disagree as to whether there is substantive compliance, the duty to cease the suspension of concessions is not triggered until substantive compliance is determined through multilateral dispute settlement proceedings. A unilateral declaration of compliance cannot have the same effect. We note that, as the original respondent, the European Communities has the option to initiate Article 21.5 panel proceedings for purposes of determining whether the DSB's recommendations and rulings have been implemented through the adoption of Directive 2003/74/EC.

381. The European Communities further submits that, upon the adoption of Directive 2003/74/EC in good faith, the suspension of concessions would have achieved its objective and would do nothing to induce compliance. Article 22.1 of the DSU provides that the suspension of concessions is not to be "preferred to *full* implementation of a recommendation to bring a measure into conformity with the covered agreements".⁷⁹⁰ Requiring termination of the suspension of concessions simply because a Member declares that it has removed the inconsistent measure, without a multilateral determination that substantive compliance has indeed been achieved, would undermine the important function of the suspension of concessions in inducing compliance. This would significantly weaken the effectiveness

⁷⁸⁹European Communities' appellee's submission, para. 29.

⁷⁹⁰Moreover, pursuant to Article 3.3, the "prompt settlement" of disputes "is essential to the effective functioning of the WTO and the maintenance of a proper balance between the rights and obligations of Members".

of the WTO dispute settlement system and its ability to provide security and predictability to the multilateral trading system.

382. The European Communities additionally submits that its position is consistent with the approach taken in the Articles on Responsibility of States for Internationally Wrongful Acts⁷⁹¹ (the "Articles on State Responsibility"), which require that countermeasures be suspended if the internationally wrongful act has ceased and the dispute is pending before a tribunal that has the authority to make decisions binding upon the parties.⁷⁹² Yet, the Articles on State Responsibility do not lend support to the European Communities' position. For example, Article 53 provides that countermeasures must be terminated as soon as the State "has complied with its obligations" in relation to the internationally wrongful act. Thus, relevant principles under international law, as reflected in the Articles on State Responsibility, support the proposition that countermeasures may continue until such time as the responsible State has ceased the wrongful act by fully complying with its obligations.

383. In sum, the suspension of concessions maintained by the United States and Canada has been duly authorized by the DSB and was obtained through recourse to the relevant rules and procedures of the DSU, consistently with Article 23.1 of the DSU. Pursuant to Article 22.8, the legality of the continued suspension of concessions depends on whether the measure found to be inconsistent in *EC – Hormones* has been removed, and this requires substantive compliance. We therefore find that the Panel erred in considering that the European Communities' claims under Articles 23.2(a), 23.1, and 21.5 may be examined "completely separately" from whether the European Communities implemented the DSB's recommendations and rulings in *EC – Hormones*.⁷⁹³

384. The DSB's authorization does not mean that Article 23 becomes irrelevant. Rather, as Article 23.2(c) specifies, the suspension of concessions is subject to Article 22, including the requirement in Article 22.8 that it shall only be applied until such time as the measure found to be inconsistent with the covered agreements has been removed. Therefore, the suspension of concessions by the United States and Canada would be in breach of Article 23.2(c), and consequently Article 23.1, if it were established in WTO dispute settlement that the inconsistent measure has indeed been removed within the meaning of Article 22.8 and the suspension is not immediately terminated. Article 22.8 thus provides relevant context for the analysis of the issues appealed under Article 23. Moreover, the application of DSB-authorized suspension of concessions is temporary and subject to the objective conditions laid down in Article 22.8. The United States, Canada, as well as the

⁷⁹¹See *supra*, footnote 481.

⁷⁹²See European Communities' appellee's submission, paras. 94-96.

⁷⁹³Panel Report, *US – Continued Suspension*, para. 7.182; Panel Report, *Canada – Continued Suspension*, para. 7.164.

European Communities, have the shared responsibility to ensure that the suspension of concessions is not applied beyond the time foreseen in Article 22.8. Consequently, the United States and Canada have a duty to engage actively in dispute settlement proceedings concerning whether the suspension of concessions is applied consistently with such conditions. Failing to do so could be contrary to the overarching principle in Article 23.1 prohibiting Members from seeking redress without having recourse to, or abiding by the rules of, the DSU. Nonetheless, this is not currently the case, because both the United States and Canada are actively engaged in these proceedings initiated by the European Communities to determine whether the measure found to be inconsistent with a covered agreement in *EC – Hormones* has been removed within the meaning of Article 22.8.

3. Whether the Panel Erred in Finding that the United States and Canada Are "Seeking the Redress of a Violation" with Respect to Directive 2003/74/EC

385. We turn to examine the claim by the United States and Canada that the Panel erred in finding that, by continuing the suspension of concessions subsequent to the notification of Directive 2003/74/EC, they were seeking the redress of a violation without having recourse to, or abiding by, the rules and procedures of the DSU within the meaning of Article 23.1 of the DSU.

386. The Panel found that Directive 2003/74/EC, which the European Communities adopted to implement the DSB's recommendations and rulings in *EC – Hormones*, is a new measure that "has never been as such subject to recourse to the rules and procedures of the DSU".⁷⁹⁴ The Panel stated that, although Directive 2003/74/EC, like Directive 96/22/EC (which was found to be WTO-inconsistent in *EC – Hormones*), also imposed an import ban, "it is not the ban ... but the justification for this ban which was found insufficient" in *EC – Hormones*.⁷⁹⁵ According to the Panel, therefore, the fact that the ban remains in place does not mean that no new measure has been adopted. The Panel thus found that, through the continued suspension of concessions, the United States and Canada are seeking redress of a violation caused by Directive 2003/74/EC, a measure they had not challenged by having recourse to the DSU.⁷⁹⁶

387. We recall that the suspension of concessions maintained by the United States and Canada was authorized by the DSB as a result of the finding in *EC – Hormones* that Directive 96/22/EC was inconsistent with the *SPS Agreement*. The Panel correctly noted that the existence of an import ban in Directive 2003/74/EC (which replaced Directive 96/22/EC) does not mean that no implementing

⁷⁹⁴Panel Report, *US – Continued Suspension*, para. 7.206; Panel Report, *Canada – Continued Suspension*, para. 7.198.

⁷⁹⁵Panel Report, *US – Continued Suspension*, para. 7.207; Panel Report, *Canada – Continued Suspension*, para. 7.199.

⁷⁹⁶Panel Report, *US – Continued Suspension*, para. 7.215; Panel Report, *Canada – Continued Suspension*, para. 7.207.

measure has been adopted. Yet, the Panel's analysis under Article 23 stopped short of considering whether the European Communities' implementing measure resulted in substantive compliance. As we explained earlier, such analysis is necessary to determine whether the suspension of concessions was required to be terminated pursuant to Article 22.8 of the DSU. Even if the United States and Canada could be said to continue to seek redress of the violation resulting from Directive 96/22/EC by maintaining the suspension of concessions, they are not prevented from doing so as long as the removal of the inconsistent measure has not been established in WTO dispute settlement. In obtaining DSB authorization for that suspension, the United States and Canada abided by the DSU as required by Article 23.1. The Panel's finding that, by maintaining the suspension of concessions, the United States and Canada are seeking the redress of a violation without abiding by the rules of the DSU thus appears to presuppose what is yet to be established, that is, that the inconsistent measure against which the suspension of concessions was authorized (Directive 96/22/EC) has actually been "removed" within the meaning of Article 22.8 by Directive 2003/74/EC.⁷⁹⁷ This finding of the Panel flows from its erroneous approach of considering Articles 23.1 and 23.2(a) completely separately from the requirements of Article 22.8, which we discussed and rejected earlier.

388. The Panel rejected the arguments by the United States and Canada that they were authorized to suspend concessions and that this authorization has not been revoked.⁷⁹⁸ The Panel stated that the DSB's authorization to suspend concessions is "only an *authorization*, not an *obligation*".⁷⁹⁹ According to the Panel, this meant that the United States and Canada were "free to apply" the suspension of concessions or not, and the fact that they did not lift the suspension after the notification of Directive 2003/74/EC indicated their intention to seek redress of a violation arising from Directive 2003/74/EC.⁸⁰⁰ We fail to see the relevance of the distinction between an authorization and an obligation to suspend concessions for purposes of analyzing whether the United States and Canada are seeking the redress of a violation concerning Directive 2003/74/EC. The relevant question before the Panel was whether the authorization to suspend concessions had lapsed because one of three conditions in Article 22.8 has been met. In the absence of a finding in WTO dispute settlement that

⁷⁹⁷In the context of addressing the European Communities' claim that the United States and Canada also breached Article 22.8, the Panel found that "it has not been established that the European Communities has removed the measure found to be inconsistent with a covered agreement." (Panel Report, *US – Continued Suspension*, para. 7.847; and Panel Report, *Canada – Continued Suspension*, para. 7.832) For this reason, the Panel concluded that the European Communities "did not demonstrate a breach of Article 22.8 of the DSU" by the United States and Canada. (Panel Report, *US – Continued Suspension*, para. 7.850; Panel Report, *Canada – Continued Suspension*, para. 7.835)

⁷⁹⁸Panel Report, *US – Continued Suspension*, para. 7.208; Panel Report, *Canada – Continued Suspension*, para. 7.200.

⁷⁹⁹Panel Report, *US – Continued Suspension*, para. 7.209; Panel Report, *Canada – Continued Suspension*, para. 7.201. (original emphasis)

⁸⁰⁰Panel Report, *US – Continued Suspension*, paras. 7.209 and 7.210; Panel Report, *Canada – Continued Suspension*, paras. 7.201 and 7.202.

the first condition in Article 22.8 had been met, the authorization to suspend concessions did not cease to be legally valid.

389. In addition, the Panel observed that "[i]n none of the circumstances foreseen by [the first sentence of] Article 22.8 does this provision require a decision of the DSB".⁸⁰¹ We agree that, under the first sentence of Article 22.8, a decision of the DSB is not required if Members reach a mutually agreed solution. Similarly, a DSB decision is not required if the suspending Member does not dispute that the measure found to be inconsistent with a covered agreement has been removed. However, where a disagreement arises as to whether the measure found to be inconsistent has indeed been removed, this disagreement must be resolved through Article 21.5 proceedings to determine whether the suspension of concessions is still applied consistently with the objective conditions under Article 22.8 or must be terminated. Under such circumstances, DSB decisions are required for the dispute to proceed pursuant to the rules of the DSU, including the decision to establish a panel and the adoption of the panel or Appellate Body reports examining the implementing measure. Moreover, the second sentence of Article 22.8 requires the DSB to keep under surveillance the implementation of adopted recommendations and rulings in cases where concessions have been suspended. Article 22.8 therefore clearly contemplates an ongoing role of the DSB in reviewing the implementation of recommendation and rulings, thus confirming that a dispute concerning implementation should be subject to multilateral resolution and not be decided on the basis of a unilateral declaration of compliance or non-compliance.

390. We also note the Panel's statement that, "pursuant to Article XVI:4 of the [*WTO Agreement*], Members must ensure the conformity of their laws, regulations and administrative procedures with their obligations as provided" in the covered agreements, "including the DSU".⁸⁰² According to the Panel, this obligation also applies to the suspension of concessions. Article XVI:4 applies equally to all WTO Members. The European Communities was required to ensure the conformity of its implementing measure, just as it is the obligation of the United States and Canada to ensure the conformity of their continued application of suspension of concessions.⁸⁰³ We do not see the relevance of this provision in the Panel's analysis under Article 23.1 of the DSU, as long as the conditions for the cessation of suspension under Article 22.8 have not been established.

⁸⁰¹Panel Report, *US – Continued Suspension*, para. 7.211; Panel Report, *Canada – Continued Suspension*, para. 7.203.

⁸⁰²Panel Report, *US – Continued Suspension*, para. 7.212; Panel Report, *Canada – Continued Suspension*, para. 7.204.

⁸⁰³As the United States argues, this provision "militates equally in favor of a finding that the continued suspension of concessions by the United States" after the European Communities' notification of Directive 2003/74/EC "did *not* demonstrate that the United States was 'seeking redress of a violation' within the meaning of Article 23.1 with respect to" this Directive. (United States other appellant's submission, para. 58) (original emphasis)

391. On appeal, the European Communities submits that "the *adoption* of a measure taken to comply" that is "*different* from the original [measure] *triggers* the presumption of good faith compliance" and, consequently, the "obligation to remove the suspension of concessions".⁸⁰⁴ The European Communities' argument is again premised on the proposition that the implementing measure should be presumed to bring about full compliance as a result of the application of the presumption of good faith, as well as its understanding of the phrase "the measure found to be inconsistent with a covered agreement has been removed" in Article 22.8 as requiring merely the formal removal of the original measure, both of which we rejected in section D.

392. The European Communities further asserts that "even the United States acknowledged that it was maintaining its suspension of concessions against the new measure", as demonstrated by the United States' statements at the DSB meetings subsequent to the notification of Directive 2003/74/EC and in its Trade Policy Agenda in 2005.⁸⁰⁵ As will be discussed in subsection 4 below, the DSB statements referred to by the European Communities do not, in themselves, have the legal effects that the Panel attributed to them. Moreover, the Trade Policy Agenda document referred to by the European Communities states that the United States "maintains its WTO-authorized sanctions on [European Communities'] products because the United States fails to see how the revised [European Communities'] measure could be considered to implement the recommendations and rulings of the DSB in this matter".⁸⁰⁶ Thus, contrary to the European Communities' arguments, the statements make clear that the legal basis for maintaining the suspension of concessions was not the new measure. Rather, the basis for maintaining the suspension of concessions was that the United States considered that the European Communities had failed to implement the DSB's recommendations and rulings in *EC – Hormones* flowing from the inconsistency of Directive 96/22/EC.

393. Accordingly, we find that the Panel erred in concluding that, "by maintaining the suspension of concessions even after the notification of [Directive 2003/74/EC]", the United States and Canada are "seeking redress of a violation with respect to [this Directive], within the meaning of Article 23.1 of the DSU".⁸⁰⁷

⁸⁰⁴European Communities' appellee's submission, para. 104. (original emphasis)

⁸⁰⁵*Ibid.*, para. 106 (referring to Panel Report, *US – Continued Suspension*, paras. 7.219-7.221).

⁸⁰⁶*Ibid.*

⁸⁰⁷Panel Report, *US – Continued Suspension*, para. 7.215; Panel Report, *Canada – Continued Suspension*, para. 7.207.

4. Whether the Panel Erred in Finding that the United States and Canada Made a Determination of Violation Without Recourse to the DSU, Within the Meaning of Article 23.2(a)

394. We turn now to review the claims by the United States and Canada that the Panel erred in finding that they made a determination of violation regarding Directive 2003/74/EC without having recourse to dispute settlement in accordance with the rules and procedures of the DSU, contrary to Article 23.2(a) of the DSU.

395. We recall that, on the basis of the statements made by Canadian and United States delegates at two DSB meetings⁸⁰⁸ concerning Directive 2003/74/EC, the Panel concluded that the United States and Canada had reached "a more or less final decision"⁸⁰⁹ that this Directive is inconsistent with the *SPS Agreement* and fails to implement the DSB's recommendations and rulings in *EC – Hormones*. Such statements, in the Panel's view, constitute a "determination" under Article 23.2(a) of the DSU and, because the determination was made unilaterally without recourse to the DSU, it breached Article 23.2(a).⁸¹⁰

396. We share the view of the panel in *US – Section 301 Trade Act* that a "determination" within the meaning of Article 23.2(a) "implies a high degree of firmness or immutability, i.e. a more or less final decision by a Member in respect of the WTO consistency of a measure taken by another Member".⁸¹¹ Moreover, preliminary opinions or views expressed without a clear intention to seek redress are not covered by Article 23.2(a).⁸¹² The statements made by delegates of the United States and Canada, on which the Panel focused its attention, were made shortly after the European Communities notified Directive 2003/74/EC to the DSB. The statements were made at the two DSB meetings held, respectively, two weeks and five weeks from the DSB meeting at which Directive 2003/74/EC was notified by the European Communities.⁸¹³ These statements, therefore, seem no more than initial reactions to the European Communities' self-proclaimed compliance with the DSB's recommendations and rulings in *EC – Hormones*. Considering the complexity of the issues

⁸⁰⁸See Panel Report, *US – Continued Suspension*, paras. 7.219 and 7.220 (quoting Minutes of the DSB Meetings held on 7 November and 1 December 2003, WT/DSB/M/157, paras. 29 and 30, and WT/DSB/M/159, para. 25, respectively); and Panel Report, *Canada – Continued Suspension*, paras. 7.211-7.213 (quoting Minutes of the DSB Meetings held on 7 November and 1 December 2003, WT/DSB/M/157, para. 31, and WT/DSB/M/159, para. 24, respectively).

⁸⁰⁹Panel Report, *US – Continued Suspension*, para. 7.222; Panel Report, *Canada – Continued Suspension*, para. 7.215 (quoting Panel Report, *US – Section 301 Trade Act*, footnote 657 to para. 750).

⁸¹⁰Panel Report, *US – Continued Suspension*, paras. 7.225 and 7.226; Panel Report, *Canada – Continued Suspension*, paras. 7.219, 7.222, and 7.223.

⁸¹¹Panel Report, *US – Section 301 Trade Act*, footnote 657 to para. 7.50.

⁸¹²See *ibid.*. See also Panel Report, *US – Certain EC Products*, para. 6.18.

⁸¹³The European Communities notified the DSB of the adoption of Directive 2003/74/EC on 27 October 2003. See Panel Report, *US – Continued Suspension*, para. 7.219; and Panel Report, *Canada – Continued Suspension*, para. 7.211.

that arise with respect to the consistency of Directive 2003/74/EC (as demonstrated in sections VI and VII of the Report), it is reasonable to assume that the United States and Canada needed some time before forming a definitive view regarding whether the European Communities had brought itself into compliance. We thus share the United States' and Canada's view that the statements at the DSB meetings lack sufficient amount of "firmness or immutability" for them to constitute a determination within the meaning of Article 23.2(a).⁸¹⁴

397. In their statements, the United States and Canada indicated that they would be willing to engage in further bilateral discussions regarding the alleged scientific justification for Directive 2003/74/EC.⁸¹⁵ This readiness to discuss Directive 2003/74/EC is difficult to reconcile with a finding that the DSB statements constituted a "determination" with the type of firmness and immutability required by its ordinary meaning and the relevant context of Article 23, as interpreted by the panel in *US – Section 301 Trade Act*. The Panel recognized this intention to engage in bilateral discussions evidenced in the DSB statements, but found that the consultations that took place after the notification of Directive 2003/74/EC "largely related to procedural issues".⁸¹⁶ Simply because subsequent consultations related largely to procedural issues does not mean that, *at the time the DSB statements were made*, the United States and Canada had made a unilateral determination without recourse to the DSU within the meaning of Article 23.2(a).

398. Moreover, DSB statements are not intended to have legal effects and do not have the legal status of a definitive determination in themselves. Rather, they are views expressed by Members and should not be considered to prejudice Members' position in the context of a dispute. As the United States rightly points out, "[s]tatements made by Members at DSB meetings, especially those

⁸¹⁴United States' other appellant's submission, paras. 79-81; Canada's other appellant's submission, para. 89. Canada adds that the statements made at the two DSB meetings were "the equivalent of Canada reserving its rights while not acquiescing to the [European Communities'] assertions of compliance". (*Ibid.*) We consider this a proper characterization of these statements.

⁸¹⁵Panel Report, *US – Continued Suspension*, para. 7.220; Panel Report, *Canada – Continued Suspension*, para. 7.212. The United States indicated at the meeting of 1 December 2003 that "[t]he United States would be pleased to discuss with [European Communities'] officials any outstanding issues regarding the [European Communities'] ban on certain beef produced in the United States, including their reactions to the detailed points that the United States had raised in its statement at the 7 November DSB meeting. With regard to the suggestion made by the [European Communities] at the present meeting that multilateral proceedings be initiated, the United States would be happy to discuss this suggestion with the [European Communities] along with other procedural options." (Panel Report, *US – Continued Suspension*, para. 7.220) Canada indicated at the meeting of 7 November 2003 that "Canada did not see any reason for WTO procedures at this time, but would welcome the opportunity for further discussion with the [European Communities] concerning the justification for its measures." (Panel Report, *Canada – Continued Suspension*, para. 7.211)

⁸¹⁶Panel Report, *US – Continued Suspension*, para. 7.224; Panel Report, *Canada – Continued Suspension*, para. 7.222.

expressing a view as to the WTO consistency of another Member's measures or actions, are generally diplomatic or political in nature" and "generally have no legal effect or status in and of themselves".⁸¹⁷

399. The Panel's finding that DSB statements could constitute a definitive determination concerning the WTO-inconsistency of a Member's measure could adversely affect WTO Members' ability to freely express their views on the potential compatibility with the covered agreements of measures adopted by other Members.⁸¹⁸ This would result in a "chilling" effect on those statements⁸¹⁹, because Members would refrain from expressing their views at DSB meetings regarding the WTO-inconsistency of other Members' measures lest such statements be found to constitute a violation of Article 23. If this were the case, the DSB would be inhibited from properly carrying out its function, pursuant to Article 21.6 of the DSU, to keep under surveillance the implementation of its recommendations and rulings.

400. The European Communities disagrees with the United States' argument that statements made at DSB meetings have no legal effect in themselves, arguing, instead, that "those statements can be used as *evidence* of a particular position, view or determination taken by a Member."⁸²⁰ The European Communities refers to the Appellate Body's observation in *US – Upland Cotton (Article 21.5 – Brazil)* that certain statements in a United States Government press release indicated that it was taking a measure to comply with the DSB's recommendations and rulings.⁸²¹ The European Communities' reliance on the Appellate Body's findings in *US – Upland Cotton (Article 21.5 – Brazil)* is misplaced. In that dispute, the Appellate Body did not rely on the press release of the United States Government in making a finding on the scope of the "measure taken to comply", but only referred to the statements of the United States' officials as providing confirmation of its earlier conclusion, reached on the basis of an examination of the measure itself and the DSB's recommendations and rulings in the original dispute. In contrast, the Panel in this dispute based its finding that the United States and Canada made a determination of violation directly on the statements they made at the DSB.

⁸¹⁷United States' other appellant's submission, para. 93.

⁸¹⁸We note the United States' concern that "[t]he Panel has thereby made the bold and novel move of transforming the minutes of DSB, other WTO committee meetings, and even Trade Policy Review meetings into a fertile source of comments that ... could constitute 'determinations' actionable under Article 23.2(a)." (*Ibid.*, para. 94)

⁸¹⁹*Ibid.*, para. 95.

⁸²⁰European Communities' appellee's submission, para. 131. (original emphasis)

⁸²¹*Ibid.* (referring to Appellate Body Report, *US – Upland Cotton (Article 21.5 – Brazil)*, para. 204).

401. We agree therefore with the United States and Canada that their statements at the DSB meetings did not involve the degree of firmness or immutability necessary in order to constitute a "determination" within the meaning of Article 23 of the DSU.⁸²²

402. The Panel went on to find that, even if the DSB statements were considered to be provisional, "the subsequent continuation of the suspension of concessions by [the United States and Canada] without alteration and without saying that [they were] still studying [Directive 2003/74/EC]" confirmed that they made such a "determination".⁸²³ The United States and Canada submit that the Panel "inferred"⁸²⁴, or "construed"⁸²⁵ the existence of a determination on the basis of the mere continuation of the suspension of concessions. They argue that the Panel's reasoning is flawed because it draws an inference from the "inaction"⁸²⁶, or "non-feasance"⁸²⁷, of the United States and Canada in failing to terminate the suspension of concessions.

403. As we stated earlier, the DSB authorization of the suspension of concessions by the United States and Canada flowed from the inconsistency of Directive 96/22/EC and continued to be legally valid until the measure found to be inconsistent with a covered agreement in *EC – Hormones* was removed within the meaning of Article 22.8. Although the European Communities may have claimed to have removed the inconsistent measure and declared compliance, the United States and Canada disagreed that this was in fact the case. Thus, until the removal of the European Communities' inconsistent measure was determined through WTO dispute settlement, the United States' and Canada's authorization to suspend concessions did not lapse. Under these circumstances, the suspension of concessions applied pursuant to the DSB's authorization in respect of Directive 96/22/EC was maintained through recourse to, and abiding by, the rules and procedures of the DSU. Its continuation thus did not "confirm" that the United States and Canada made a unilateral determination regarding Directive 2003/74/EC, as the Panel found, in violation of Article 23.2(a) of the DSU.⁸²⁸

⁸²²United States' other appellant's submission, para. 96; Canada's other appellant's submission, para. 89.

⁸²³Panel Report, *US – Continued Suspension*, para. 7.230; Panel Report, *Canada – Continued Suspension*, para. 7.224.

⁸²⁴United States' other appellant's submission, para. 98.

⁸²⁵Canada's other appellant's submission, para. 81.

⁸²⁶United States' other appellant's submission, para. 98.

⁸²⁷Canada's other appellant's submission, para. 81.

⁸²⁸Nonetheless, we do not share the view of the United States and Canada that the continued suspension of concessions should be properly characterized as inaction. Upon the authorization to suspend concessions in 1999, the United States and Canada respectively took the measures to impose tariffs on all imports of certain European Communities products at rates substantially exceeding the bound tariff rates and have continuously collected the additional tariffs since then. Thus, the continued suspension of concessions by the United States and Canada is more properly characterized as an ongoing action.

404. The United States further asserts that, by inferring the existence of a "determination" within the meaning of Article 23.2(a) on the basis of the continued suspension of concessions, the Panel effectively read into Article 23 a deadline by which a unilateral determination inconsistent with Article 23.2(a) will be imputed to a Member, even though Article 23 contains no such deadline.⁸²⁹ The European Communities contends that the Panel correctly observed that the deadline by which a Member shall have recourse to the DSU pursuant to Articles 23.1 and 23.2(a) "was not an issue before the Panel".⁸³⁰ However, without a proper identification of the time at which the continued suspension of concessions would be found to constitute a unilateral determination inconsistent with the DSU, WTO Members would be unsure as to when or for how long they could properly rely on a DSB authorization to suspend concessions. Such an outcome is contrary to the DSU's objective of providing security and predictability.⁸³¹ In any event, given that we have found above that an original respondent may initiate Article 21.5 proceedings, and that the authority to suspend concessions lapses once one of the three conditions in Article 22.8 is met, we feel no need to further explore this question.

405. Thus, we conclude that the Panel erred in finding that the United States and Canada "made a 'determination' within the meaning of Article 23.2(a) in relation to Directive 2003/74/EC" on the basis of statements made at DSB meetings and the fact that the suspension of concessions continued subsequent to the notification of Directive 2003/74/EC.⁸³²

406. Having found that the United States and Canada made a determination of violation in relation to Directive 2003/74/EC, the Panel went on to find that, because "the authorization to suspend concessions" does not amount to "a multilateral determination of inconsistency"⁸³³ of Directive 2003/74/EC, the United States and Canada had not made the determination through recourse to dispute settlement in accordance with the rules and procedures of the DSU.⁸³⁴ However, whether Directive 2003/74/EC "removed" the inconsistencies within the meaning of Article 22.8 was disputed and had not yet been determined through WTO dispute settlement. Therefore, the DSB's authorization remained valid. The Panel's finding also contradicts its own approach, correctly taken in the context of its examination of Article 22.8, that the suspension of concessions is not required to

⁸²⁹United States' other appellant's submission, para. 105.

⁸³⁰European Communities' appellee's submission, para. 134 (referring to Panel Report, *US – Continued Suspension*, para. 7.232).

⁸³¹See Canada's other appellant's submission, para. 81.

⁸³²Panel Report, *US – Continued Suspension*, para. 7.239; Panel Report, *Canada – Continued Suspension*, para. 7.232.

⁸³³Panel Report, *US – Continued Suspension*, para. 7.242; Panel Report, *Canada – Continued Suspension*, para. 7.235.

⁸³⁴Panel Report, *US – Continued Suspension*, para. 7.243; Panel Report, *Canada – Continued Suspension*, para. 7.236.

be terminated merely on the basis of a formal removal of the inconsistent measure but, rather, is required once there is substantive compliance.

407. Because we have found that the Panel erred in concluding that the United States and Canada made a determination that a violation has occurred within the meaning of Article 23.2(a), the Panel's finding that the United States and Canada had "failed to make any such determination consistent with the findings contained in the panel or Appellate Body report adopted by the DSB or an arbitration award rendered under the DSU", in breach of Article 23.2(a)⁸³⁵, also fails.

5. Conclusion

408. We concluded in the preceding sections that the Panel erred in finding that the United States and Canada were seeking the redress of a violation with respect to Directive 2003/74/EC, within the meaning of Article 23.1 of the DSU, and made a determination in relation to that Directive to the effect that a violation has occurred, within the meaning of Article 23.2(a) of the DSU. Therefore, we reverse the Panel's finding that the United States and Canada have "violated Article[s] 23.1 and 23.2(a) of the DSU by seeking redress of violation of the WTO Agreement through a determination that the [European Communities'] implementing measure did not comply with the DSB recommendations and rulings in the *EC – Hormones* case without having recourse to dispute settlement in accordance with the rules and procedures of the DSU."⁸³⁶

409. The European Communities claims that, in order to fulfil their obligations under Articles 23.1 and 23.2(a) of the DSU to have recourse to dispute settlement in accordance with the DSU, the United States and Canada were required to initiate Article 21.5 panel proceedings if they considered that Directive 2003/74/EC fails to bring the European Communities into compliance. The European Communities submits that, upon finding that the United States and Canada breached Articles 23.2(a) and 23.1 by seeking the redress of a violation without recourse to the DSU, the Panel should have also found that the United States and Canada breached Article 21.5 by failing to initiate panel proceedings under that provision. We have reversed the Panel's finding that the United States and Canada breached Articles 23.2(a) and 23.1 by seeking the redress of a violation without recourse to the DSU. We also recall our earlier finding that the original respondent is not precluded under Article 21.5 from initiating Article 21.5 compliance proceedings. Consequently, we dismiss the European Communities' claim. This does not mean that the United States and Canada do not have an obligation to engage in the dispute settlement procedures in an cooperative manner. Rather, the United States,

⁸³⁵Panel Report, *US – Continued Suspension*, para. 7.244; Panel Report, *Canada – Continued Suspension*, para. 7.237.

⁸³⁶Panel Report, *US – Continued Suspension*, para. 7.251; Panel Report, *Canada – Continued Suspension*, para. 7.244.

Canada, and the European Communities have an obligation to engage in Article 21.5 proceedings in order to obtain objective ascertainment of whether substantive compliance has been achieved in this case and whether the resolute condition in Article 22.8 has been met.

G. *The Panel's Finding that It Had No Jurisdiction to Make Findings under the SPS Agreement*

410. The United States and Canada request that, should the Appellate Body uphold the Panel's findings that they breached Articles 23.2(a) and 23.1 of the DSU, it reverse the Panel's statement, in the last paragraph of its Report, that it had no jurisdiction to determine the compatibility of Directive 2003/74/EC with the *SPS Agreement*.⁸³⁷ Because we have reversed the Panel's finding that the United States and Canada breached Articles 23.2(a) and 23.1 of the DSU, the condition upon which the United States' and Canada's requests rest is not met. We note, however, that in section D.4 above we upheld the Panel's finding that "it has jurisdiction to consider the compatibility of the [European Communities'] implementing measure with the *SPS Agreement* as part of its review of the claim raised by the European Communities with respect to Article 22.8 of the DSU."⁸³⁸ In any event, in sections VI and VII below, we reverse the Panel's findings under Articles 5.1 and 5.7 of the *SPS Agreement*.

H. *The Panel's Suggestion*

411. In addition to finding that the United States and Canada committed procedural violations under Article 23 of the DSU, the Panel suggested, pursuant to Article 19.1 of the DSU, that the United States and Canada "should have recourse to the rules and procedures of the DSU without delay".⁸³⁹ The European Communities, the United States, and Canada all take issue with this suggestion.

412. The United States and Canada request that, in the event that the Appellate Body upholds the Panel's finding that the United States and Canada committed procedural violations under Articles 23.2(a) and 23.1 of the DSU, the Appellate Body reverse the Panel's suggestion that they should have recourse to the DSU without delay.⁸⁴⁰

413. The European Communities contends that the Panel's suggestion, that the United States and Canada should have recourse to dispute settlement without delay, is "too vague to be of much

⁸³⁷United States' other appellant's submission, paras. 108 and 120; Canada's other appellant's submission, para. 92.

⁸³⁸Panel Report, *US – Continued Suspension*, para. 7.379; Panel Report, *Canada – Continued Suspension*, para. 7.376.

⁸³⁹Panel Report, *US – Continued Suspension*, para. 8.3; Panel Report, *Canada – Continued Suspension*, para. 8.3.

⁸⁴⁰United States' other appellant's submission, paras. 108 and 116; Canada's other appellant's submission, paras. 92 and 98.

assistance", because it is unclear to "which rules and procedures of the DSU" the United States and Canada should have recourse.⁸⁴¹ Therefore, the European Communities requests the Appellate Body to "improve the Panel's suggestion in order to bring it into a clear form that is also more in line with the Panel's own findings".⁸⁴² More specifically, the European Communities requests the Appellate Body to "modify" the suggestion so as to make clear that the United States and Canada should: (i) cease applying the suspension of concessions; and (ii) seek resolution of any disagreement regarding the consistency of Directive 2003/74/EC through recourse to panel proceedings under Article 21.5 of the DSU, or any other dispute settlement proceedings that the parties may agree.⁸⁴³

414. The Panel's suggestion that the United States and Canada "should have recourse to the rules and procedures of the DSU without delay" rests on its findings that the United States and Canada breached Articles 23.2(a) and 23.1 of the DSU by seeking redress of a violation of the covered agreement without having recourse to dispute settlement under the DSU. We have reversed these findings of the Panel. Thus, the Panel's suggestion cannot stand.

V. Due Process in the Panel's Consultations with the Scientific Experts

415. We now turn to the European Communities' claims that the Panel failed to respect the principle of due process and, consequently, also failed to make an objective assessment of the matter under Article 11 of the DSU, in selecting and relying upon two of the scientific experts consulted by the Panel.

A. The Panel's Findings

416. On 25 November 2005, following consultation with the parties, the Panel adopted Working Procedures for Consultations with Scientific and/or Technical Experts (the "Experts Working Procedures").⁸⁴⁴ The Panel decided not to establish an expert review group as had been suggested by the European Communities, but to consult experts on an individual basis.⁸⁴⁵ Moreover, the Panel "sought information not only from selected experts but also from three relevant international entities,

⁸⁴¹European Communities' appellant's submission, para. 479.

⁸⁴²*Ibid.*

⁸⁴³*Ibid.*, para. 480.

⁸⁴⁴Panel Report, *US – Continued Suspension*, para. 7.71; Panel Report, *Canada – Continued Suspension*, para. 7.69. The Experts Working Procedures are reproduced in Annex A-5 of the Panel Reports. A single expert selection process was carried out for both disputes. (Panel Report, *US – Continued Suspension*, para. 7.76; Panel Report, *Canada – Continued Suspension*, para. 7.74)

⁸⁴⁵Panel Report, *US – Continued Suspension*, para. 7.71; Panel Report, *Canada – Continued Suspension*, para. 7.69. The European Communities initially indicated that the Panel did not have to consult experts. (Panel Report, *US – Continued Suspension*, para. 7.56; Panel Report, *Canada – Continued Suspension*, para. 7.54)

the Codex Alimentarius Commission (Codex), the Joint FAO/WHO Expert Committee on Food Additives (JECFA), and the International Agency for Research on Cancer (IARC)."⁸⁴⁶

417. In accordance with paragraph 3 of the Experts Working Procedures, the Panel solicited suggestions for experts from the Secretariats of Codex, JECFA, and the IARC.⁸⁴⁷ From these suggestions, the Panel provided to the parties all the information received from the 11 experts that were interested and available, and asked them to indicate any "compelling reasons" why particular experts should not be chosen.⁸⁴⁸ The European Communities objected to the inclusion of experts that had participated in JECFA's risk assessment work, explaining that "the scientific controversy over the JECFA reports is at the heart of this case and is the reason why the Panel is now seeking advice from outside experts."⁸⁴⁹ The European Communities added that such experts "cannot be considered to be objective and impartial in these circumstances, because this would amount to asking them to review and criticise their proper work".⁸⁵⁰

418. Because the parties' positions with respect to the experts "differed significantly", the Panel sought additional names of experts from the parties pursuant to paragraph 6 of the Experts Working Procedures.⁸⁵¹ Of the 71 experts suggested by the international organizations and the parties, 40 experts indicated that they were available, and 35 responded to the request for their *curriculum vitae* and information regarding potential conflicts of interest.⁸⁵² This information was provided to the parties for comments and objections.⁸⁵³ As the Panel explained:

One party or another submitted objections with regard to all but one of the experts by arguing either that an expert lacked sufficient expertise in the areas of the dispute identified as needing scientific or technical expertise, or was affiliated with the government of a party to this dispute; or was affiliated with JECFA; or had received

⁸⁴⁶Panel Report, *US – Continued Suspension*, para. 7.78; Panel Report, *Canada – Continued Suspension*, para. 7.76. (footnotes omitted)

⁸⁴⁷Panel Report, *US – Continued Suspension*, para. 7.79; Panel Report, *Canada – Continued Suspension*, para. 7.77.

⁸⁴⁸Panel Report, *US – Continued Suspension*, para. 7.79; Panel Report, *Canada – Continued Suspension*, para. 7.77.

⁸⁴⁹Letter from the European Communities to the Panel dated 16 January 2006 (quoted in European Communities' appellant's submission, para. 193).

⁸⁵⁰*Ibid.*

⁸⁵¹Panel Report, *US – Continued Suspension*, para. 7.80; Panel Report, *Canada – Continued Suspension*, para. 7.78.

⁸⁵²Panel Report, *US – Continued Suspension*, para. 7.82; Panel Report, *Canada – Continued Suspension*, para. 7.80.

⁸⁵³Panel Report, *US – Continued Suspension*, para. 7.83; Panel Report, *Canada – Continued Suspension*, para. 7.81.

funding from the pharmaceutical industry; or had been involved in the regulatory approval of any of the six hormones.⁸⁵⁴

419. On 24 March 2006, the Panel informed the parties of the six experts it had selected. The Panel explained its considerations in the selection process as follows:

The Panel excluded experts with close links with governmental authorities directly involved in policy-making regarding the six hormones and experts with close links to pharmaceutical companies or involved in public advocacy activities. The Panel chose not to exclude *a priori* experts who had participated in the preparation and drafting of JECFA's risk assessments because this would deprive the Panel and the parties of the benefit of the contribution of internationally recognized specialists and because the Panel was of the opinion that experts familiar with the JECFA reports would be well-placed to assist the Panel in understanding the work of JECFA extensively referred to by the parties in their submissions, in particular by the European Communities. Moreover, the Panel, who was fully aware of the fields of competence of these experts, considered that they would be competent to answer questions with respect to risk assessment regarding the hormones at issue. The Panel also decided not to exclude *a priori* all experts who were current or past governmental employees unless a potential conflict of interests could reasonably be assumed from their official functions. In selecting the experts, the Panel also had in mind the need to choose experts with expertise to cover all the fields identified as at issue in the dispute.⁸⁵⁵

420. The European Communities asked the Panel to reconsider its decision with respect to two experts, Dr. Jacques Boisseau⁸⁵⁶ and Dr. Alan Boobis⁸⁵⁷, arguing that "these experts had real or perceived conflicts of interests that should disqualify them from assisting the Panel."⁸⁵⁸ In addition to reiterating concerns about the involvement of the two selected experts "in the drafting and adoption of the JECFA reports concerning the subject matter of this dispute"⁸⁵⁹, the European Communities advanced other reasons to exclude Drs. Boisseau and Boobis. The European Communities argued that Dr. Boisseau should be dismissed because he had not "submitted a statement of conflict of interest to the Panel", had "already taken a position on the issue at stake in this dispute" in a public

⁸⁵⁴Panel Report, *US – Continued Suspension*, para. 7.84; Panel Report, *Canada – Continued Suspension*, para. 7.82.

⁸⁵⁵Panel Report, *US – Continued Suspension*, para. 7.85; Panel Report, *Canada – Continued Suspension*, para. 7.83. (footnote omitted)

⁸⁵⁶Former Director, French Agency for Veterinary Medical Products. (See Panel Report, *US – Continued Suspension*, para. 7.86; and Panel Report, *Canada – Continued Suspension*, para. 7.84)

⁸⁵⁷Director, Experimental Medicine and Toxicology Division of Medicine, Faculty of Medicine, Imperial College, London; Professor of Biochemical Pharmacology at Imperial College, London. (See Panel Report, *US – Continued Suspension*, para. 7.86; and Panel Report, *Canada – Continued Suspension*, para. 7.84)

⁸⁵⁸Panel Report, *US – Continued Suspension*, para. 7.87; Panel Report, *Canada – Continued Suspension*, para. 7.85.

⁸⁵⁹Letter from the European Communities to the Panel dated 28 March 2006 (quoted in European Communities' appellant's submission, para. 196).

hearing before the French Senate, had taken a position in a public debate "that only 'major' risks are relevant in precautionary decision making", and had neither "carried out any real scientific research" nor "written anything on the substances under consideration".⁸⁶⁰ With regard to Dr. Boobis, the European Communities alleged that he had received funding from, and provided consultancy to, several pharmaceutical companies, some of which had not been disclosed in his statement on conflicts of interest.⁸⁶¹ The Panel did not consider that the European Communities' objections were "justified"⁸⁶², adding:

The Panel found in particular that the statement that one expert had made before the French Senate in 1996 had not been made in relation to hormones used for growth promotion purposes. Rather, it had been made with respect to hormones used for medical treatment purposes. The Panel also found that the links of another expert with two companies involved in research and counselling were not in the area of veterinary drugs or hormonal substances. ... In addition, having considered the information available about the various candidates, the Panel found that these two experts were the best choices among the very few individuals available with expertise in the area of risk assessment and would be able to provide the Panel with insight on international standards on the hormones at issue.⁸⁶³

421. At the interim review stage, and upon a request made by the European Communities for clarification of certain passages, the Panel said that it "remain[ed] however puzzled by the [European Communities'] suggestions that a scientist who worked with JECFA could be deemed to be biased in assessing the scientific evidence on which [European Communities'] Directive 2003/74/EC relies and could be assumed to defend JECFA's work".⁸⁶⁴ The Panel explained:

First, scientists would readily admit that science is constantly evolving and the fact that new studies are peer reviewed is evidence that assessing new ideas and findings is part of scientific work. Assuming that scientists may lack objectivity because they

⁸⁶⁰Letter from the European Communities to the Panel dated 28 March 2006 (quoted in European Communities' appellant's submission, para. 196).

⁸⁶¹*Ibid.*

⁸⁶²Panel Report, *US – Continued Suspension*, para. 7.87; Panel Report, *Canada – Continued Suspension*, para. 7.85.

⁸⁶³*Ibid.* The Panel further commented that:

The Panel wishes to highlight the challenges it encountered in selecting experts. There was a limited number of specialists suggested and actually available in each of the fields on which the Panel needed assistance and almost always one or more of the parties objected to that specialist. For example, only six of the identified available experts were deemed to have extensive expertise in risk analysis. All of these experts were objected to by at least one party.

(Panel Report, *US – Continued Suspension*, footnote 382 to para. 7.87; Panel Report, *Canada – Continued Suspension*, footnote 374 to para. 7.85)

⁸⁶⁴Panel Report, *US – Continued Suspension*, para. 6.22; Panel Report, *Canada – Continued Suspension*, para. 6.21.

participated in the preparation and drafting of JECFA's risk assessments on the hormones at issue would call into question the whole principle of peer review. The Panel also notes that JECFA is the body that provides the independent scientific advice on which the work of Codex is based and Codex is expressly recognized by the *SPS Agreement* as having responsibilities for the establishment of "international standards, guidelines and recommendations". The Panel also recalls the role given to international standards, guidelines and recommendations by Article 3.1 and 3.2 of the *SPS Agreement*. It is therefore consistent with this role for the Panel to rely on experts who contributed in the preparation and drafting of JECFA's risk assessments of the substances at issue.⁸⁶⁵

422. The Panel elaborated further that:

... it was necessary for the Panel to be able to rely on the advice of experts intimately knowledgeable about the substance of JECFA's risk assessments. ... Second, the Panel recalls that JECFA is an international, independent entity composed of highly qualified experts selected by the WHO or FAO according to strict procedures. JECFA also regularly reassesses its risk assessments. ... Moreover, JECFA reaches its conclusions by consensus. So the opinions expressed by the two experts were given with regard to the consensual view of JECFA on this matter, not just their own personal positions in the past. This does not mean, however, that JECFA's work is these particular experts' own work: it is a joint work by several experts.

The experts that the European Communities claims were defending their work acknowledge that the state of knowledge can evolve. ... The experts consulted by the Panel are used to considering and peer reviewing studies that go beyond what they have published themselves or perhaps even contradict them. In other words, they are not likely to feel any need to defend their own previous work results in the light of new, convincing evidence or techniques that put such previous work into doubt.⁸⁶⁶

423. The Panel also rejected the European Communities' argument that "the two experts at issue should not be described as 'internationally recognized specialists'"⁸⁶⁷:

The Panel recalls that they have been selected by the FAO and WHO as part of the JECFA selection process. The selection procedure has been described in JECFA's reply to question 14 to JECFA. The Panel fails to understand why the JECFA selection would not be evidence of the international reputation of the scientists at issue. The [European Communities] concerns about JECFA's work and the

⁸⁶⁵Panel Report, *US – Continued Suspension*, para. 6.22; Panel Report, *Canada – Continued Suspension*, para. 6.21.

⁸⁶⁶Panel Report, *US – Continued Suspension*, paras. 6.62 and 6.63; Panel Report, *Canada – Continued Suspension*, paras. 6.57 and 6.58. (footnotes omitted)

⁸⁶⁷Panel Report, *US – Continued Suspension*, para. 6.23; Panel Report, *Canada – Continued Suspension*, para. 6.22.

selection of experts to participate in that work are in contradiction with the role attributed by the *SPS Agreement* to Codex and to international standards, guidelines and recommendations. The Panel was fully aware of the area of expertise of the two scientists at issue, and believed that they would be more at liberty to comment on the content of JECFA's work than officials of the JECFA Secretariat. It also specified the reasons why those experts were selected in spite of not having carried out experiments with the substances at issue and does not see any need for further substantial elaboration.⁸⁶⁸

424. During the Panel proceedings, the experts provided written responses to scientific and technical questions posed by the Panel.⁸⁶⁹ The Panel held a meeting with the scientific experts, which included the participation of the parties. At the meeting, the parties and the Panel had the opportunity "to ask questions to the experts and for the experts to clarify points that they had made in their written responses to the questions".⁸⁷⁰

B. *Claims and Arguments on Appeal*

425. On appeal, the European Communities asserts that "the consultation of experts by the Panel[] for the purposes of scientific and technical advice including their selection must respect general principles of law, and in particular the principle of due process."⁸⁷¹ The European Communities adds that "[i]t is inherent in the principle of due process that the parties to a dispute are given a fair hearing including that the experts a court, tribunal or panel hears or consults are *independent and impartial*."⁸⁷² The European Communities takes issue with the Panel's selection of Dr. Jacques Boisseau and Dr. Alan Boobis. The European Communities claims that "any 'reliance' the Panel[] [has] placed on what these two experts from JECFA said is a violation of the relevant rules on conflict of interest, of its rights of due process and of the requirement for the Panel[] to perform an 'objective assessment' of the matter before [it]"⁸⁷³ as required under Article 11 of the DSU. As a result, the European Communities requests that the Appellate Body "reverse all findings of the Panel[] which depend on the advice [it] received from these experts".⁸⁷⁴

426. The European Communities contends that "the relevant legal test" the Panel should have applied is whether there was "likelihood or justifiable doubts" as to the experts' independence, a test

⁸⁶⁸Panel Report, *US – Continued Suspension*, para. 6.23; Panel Report, *Canada – Continued Suspension*, para. 6.22. (footnotes omitted)

⁸⁶⁹Panel Report, *US – Continued Suspension*, paras. 7.95-7.97; Panel Report, *Canada – Continued Suspension*, paras. 7.92-7.94.

⁸⁷⁰Panel Report, *US – Continued Suspension*, para. 7.98; Panel Report, *Canada – Continued Suspension*, para. 7.95. (footnote omitted) The Panel's meeting with the scientific experts took place immediately before the second substantive meeting of the Panel with the parties.

⁸⁷¹European Communities' appellant's submission, para. 188.

⁸⁷²*Ibid.* (original emphasis)

⁸⁷³*Ibid.*, para. 202.

⁸⁷⁴*Ibid.*, para. 212.

that the European Communities describes as "quite simple and low", and not requiring "certainty or high probability".⁸⁷⁵ The standard applied by the Panel, however, was "based on a very narrow definition of a perceived conflict of interest because it required an actual or almost certain conflict, not a perceived, likelihood or a justifiable doubts test".⁸⁷⁶ The European Communities asserts that Dr. Boisseau took "a position in favour of the safety of these hormones" and that "Dr. Boobis has been receiving funding from the pharmaceutical industry in his research and counselling".⁸⁷⁷ In addition, the European Communities alleges that, since Drs. Boisseau and Boobis were among the authors of the JECFA reports, which are criticized in Directive 2003/74/EC on scientific grounds, they should have been precluded from providing expert advice to the Panel. The European Communities observes that, as co-authors of the JECFA reports, "[t]hey cannot be considered to be independent and impartial in these circumstances, because this would amount to asking them to review and criticise reports that are their own doing."⁸⁷⁸

427. The European Communities also faults the Panel for "relying overwhelmingly"⁸⁷⁹ on the opinions of Drs. Boisseau and Boobis; for failing to ensure that the self-disclosure requirement under the *Rules of Conduct* be complied with before selecting these experts⁸⁸⁰; for failing to "actually examine[] whether all of the experts had a potential conflict of interest"; and for accepting as experts persons whose independence and impartiality was not assured.⁸⁸¹ Finally, the European Communities argues that, "even if one were to take the view that the Panel[] could accept the non-independent experts provided that [it] would constantly bear in mind the potential conflicts when weighing the expert opinions, it is clear that the Panel[] refused to do so, considering the issue of the experts finally resolved when dismissing the European Communities' objections."⁸⁸² Indeed, these experts "dominate[d] the entire scientific examination by the Panel[] both from the point of view of how often they [were] referred to and whether the Panel[] ever question[ed] their opinions and whether their opinions go beyond science and stray into the area of the risk regulator."⁸⁸³

428. The United States argues that the Panel's conduct in the selection of experts was transparent and consultative, providing the parties with notice and opportunities to respond, express their

⁸⁷⁵European Communities' appellant's submission, para. 195.

⁸⁷⁶*Ibid.*, para. 203.

⁸⁷⁷*Ibid.* The European Communities qualifies its charges against both experts. It admits, for instance, that Dr. Boisseau's position on the safety of hormones was taken "in the context of a discussion on therapeutic treatment in animals", and that the funding Dr. Boobis received from the pharmaceutical industry was "not from companies in the area of veterinary drugs or these hormones". (*Ibid.*)

⁸⁷⁸*Ibid.*, para. 205.

⁸⁷⁹*Ibid.*, para. 212.

⁸⁸⁰*Ibid.*, para. 192.

⁸⁸¹*Ibid.*

⁸⁸²*Ibid.*, para. 211. (footnote omitted)

⁸⁸³*Ibid.*, para. 208.

concerns, and be heard before the Panel made its decisions. The United States further asserts that "[t]he fact of the matter is that the Panel and the parties were provided with full disclosure of the experts' professional affiliations and financial interests" and "[t]he record demonstrates that the Panel took the [European Communities'] concerns into account in concluding that the two experts in question were not disqualified from serving."⁸⁸⁴ Moreover, the United States alleges that the European Communities provides no support for the claims regarding due process rights, arguing that the European Communities cited nothing more "than the most general statement" by the Appellate Body in *Thailand – H-Beams* and a judgment by the European Court of Human Rights that the European Communities had already relied upon in its challenge to the panel's expert selection process in *EC – Hormones*.⁸⁸⁵ Finally, in respect of the European Communities' allegation of breach of Article 11 of the DSU, the United States argues that the Panel acted within the proper bounds of its discretion as fact-finder.⁸⁸⁶

429. Canada rejects the position of the European Communities that the relevant legal standard to determine independence or impartiality is "likelihood or justifiable doubt".⁸⁸⁷ Rather, it observes that the only standard governing conflict of interest questions is found in Section II (Governing Principle) of the *Rules of Conduct*. That provision requires that all persons covered under the *Rules of Conduct*, including experts, "shall be independent and impartial" and "shall avoid direct or indirect conflicts of interest".⁸⁸⁸ Moreover, Canada asserts that Drs. Boisseau and Boobis met the disclosure requirement in the Experts Working Procedures, and that, in particular, both complied with the requirements by disclosing their involvement in JECFA. In Canada's view, "it was up to the Panel to evaluate whether this had an impact [on] the independence and impartiality of these candidates in this case."⁸⁸⁹

430. Canada argues that the Panel correctly found that Drs. Boisseau and Boobis were independent and impartial. It notes that the Panel "expressly addressed" the allegation that these two experts were defending their work when it explained that the purpose of consulting them was to obtain advice about the substance of JECFA's risk assessment, and to help identify the extent to which concerns raised by the European Communities had been considered in JECFA's risk assessment.⁸⁹⁰ Canada also points to language in the Panel Report, noting that the Panel was asking the experts about JECFA's consensual view, which may differ from the experts' personal views, and that both experts

⁸⁸⁴United States' appellee's submission, para. 88.

⁸⁸⁵*Ibid.*, para. 89.

⁸⁸⁶*Ibid.*, para. 90.

⁸⁸⁷Canada's appellee's submission, para. 47 (quoting European Communities' appellant's submission, para. 195).

⁸⁸⁸*Ibid.*, para. 47.

⁸⁸⁹*Ibid.*, para. 49.

⁸⁹⁰*Ibid.*, para. 54 (quoting Panel Report, *Canada – Continued Suspension*, para. 6.57).

admitted to the Panel that the state of scientific knowledge can evolve.⁸⁹¹ In Canada's view, it is inaccurate to portray the participation by Drs. Boisseau and Boobis in JECFA panels as "giving them an (almost proprietary) interest in the outcome of the JECFA process that they would have felt compelled to defend when advising the Panel".⁸⁹² Canada cautions that the practical consequence of the Panel excluding Drs. Boisseau and Boobis as experts would have been that "the pool of eligible experts would have been shrunk significantly, such that it would have become very difficult for the Panel to appoint experts in all the areas of expertise that it had identified."⁸⁹³

431. Therefore, the United States and Canada request that the Appellate Body reject the European Communities' claim that the Panel acted inconsistently with the principle of due process, the requirements of the *Rules of Conduct*, and Article 11 of the DSU, in selecting Drs. Boisseau and Boobis, and to reject the request to reverse the Panel's findings that relied on the advice of these two experts.

432. Australia agrees with the European Communities' submission that panels must observe due process in selecting and consulting with experts, and considers that fundamental fairness and due process "permeate[] all aspects of the WTO dispute settlement process, including a panel's use of experts".⁸⁹⁴

C. *Did the Panel Infringe the European Communities' Due Process Rights and Fail to Make an Objective Assessment of the Matter in the Consultations with the Scientific Experts*

433. The Appellate Body has previously found that the obligation to afford due process is "inherent in the WTO dispute settlement system"⁸⁹⁵ and it has described due process requirements as "fundamental to ensuring a fair and orderly conduct of dispute settlement proceedings".⁸⁹⁶ In our view, the protection of due process is an essential feature of a rules-based system of adjudication, such as that established under the DSU. Due process protection guarantees that the proceedings are conducted with fairness and impartiality, and that one party is not unfairly disadvantaged with respect to other parties in a dispute.

434. The Appellate Body has recognized the need for panels to afford due process to the parties with respect to specific procedural issues. For instance, the Appellate Body has recognized due

⁸⁹¹Canada's appellee's submission, para. 54 (quoting Panel Report, *Canada – Continued Suspension*, para. 6.57).

⁸⁹²*Ibid.*, para. 56.

⁸⁹³*Ibid.*, para. 57.

⁸⁹⁴Australia's third participant's submission, para. 48.

⁸⁹⁵Appellate Body Report, *Chile – Price Band System*, para. 176. See also Appellate Body Report, *Mexico – Corn Syrup (Article 21.5 – US)*, para. 107.

⁸⁹⁶Appellate Body Report, *Thailand – H-Beams*, para. 88.

process as requiring that parties to proceedings be afforded an adequate opportunity to respond to claims, arguments, or evidence presented by other parties.⁸⁹⁷ It has also referred to the principle of due process in suggesting the need for panels to have standard working procedures⁸⁹⁸, and for panels to have discretion to allow for the enhanced participation by third parties.⁸⁹⁹ Moreover, the Appellate Body has found that due process is required by Article 11 of the DSU. In *US – Gambling*, the Appellate Body stated:

[A]s part of their duties, under Article 11 of the DSU, to "make an objective assessment of the matter" before them, panels must ensure that the due process rights of parties to a dispute are respected.⁹⁰⁰

435. These due process considerations are reflected in the *Rules of Conduct*. Section II (Governing Principle) of the *Rules of Conduct* provides that all covered persons, such as panelists and experts advising panels:

... shall be independent and impartial, shall avoid direct or indirect conflicts of interest and shall respect the confidentiality of proceedings of bodies pursuant to the dispute settlement mechanism, so that through the observance of such standards of conduct the integrity and impartiality of that mechanism are preserved.

436. Scientific experts and the manner in which their opinions are solicited and evaluated can have a significant bearing on a panel's consideration of the evidence and its review of a domestic measure, especially in cases like this one involving highly complex scientific issues. Fairness and impartiality in the decision-making process are fundamental guarantees of due process. Those guarantees would not be respected where the decision-makers appoint and consult experts who are not independent or impartial. Such appointments and consultations compromise a panel's ability to act as an independent adjudicator. For these reasons, we agree with the view of the European Communities that the protection of due process applies to a panel's consultations with experts. This due process protection applies to the process for selecting experts and to the panel's consultations with the experts, and continues throughout the proceedings.

⁸⁹⁷ Appellate Body Report, *US – Gambling*, paras. 269-273; Appellate Body Report, *Canada – Wheat Exports and Grain Imports*, para. 177; Appellate Body Report, *Mexico – Corn Syrup (Article 21.5 – US)*, para. 47; Appellate Body Report, *Australia – Salmon*, paras. 272 and 278; and Appellate Body Report, *Brazil – Desiccated Coconut*, p. 22, DSR 1997:1, 167, at 186.

⁸⁹⁸ Appellate Body Report, *Argentina – Textiles and Apparel*, footnote 68 to para. 79; Appellate Body Report, *India – Patents (US)*, para. 95.

⁸⁹⁹ Appellate Body Report, *US – FSC (Article 21.5 – EC)*, para. 243; Appellate Body Report, *EC – Hormones*, para. 154.

⁹⁰⁰ Appellate Body Report, *US – Gambling*, para. 273.

(a) Standard for Selection of Experts

437. The authority to seek information from individuals or to consult experts is provided to panels pursuant to Article 13 of the DSU (Right to Seek Information). Article 13.2 provides:

Panels may seek information from any relevant source and may consult experts to obtain their opinion on certain aspects of the matter. With respect to a factual issue concerning a scientific or other technical matter raised by a party to a dispute, a panel may request an advisory report in writing from an expert review group. Rules for the establishment of such a group and its procedures are set forth in Appendix 4.

438. Article 11.2 of the *SPS Agreement* specifically addresses the consultation of experts in disputes under that Agreement.⁹⁰¹ It reads:

In a dispute under this Agreement involving scientific or technical issues, a panel should seek advice from experts chosen by the panel in consultation with the parties to the dispute. To this end, the panel may, when it deems it appropriate, establish an advisory technical experts group, or consult the relevant international organizations, at the request of either party to the dispute or on its own initiative.

439. Panels are understood to have "significant investigative authority"⁹⁰² under Article 13 of the DSU and Article 11.2 of the *SPS Agreement* and broad discretion in exercising this authority. In *US – Shrimp*, the Appellate Body expounded on the comprehensive authority of panels under Article 13:

The comprehensive nature of the authority of a panel to "seek" information and technical advice from "any individual or body" it may consider appropriate, or from "any relevant source", should be underscored. This authority embraces more than merely the choice and evaluation of the *source* of the information or advice which it may seek. A panel's authority includes the authority to decide *not to seek* such information or advice at all. We consider that a panel also has the authority to *accept or reject* any information or advice which it may have sought and received, or to *make some other appropriate disposition* thereof. It is particularly within the province and the authority of a panel to determine *the need for information and advice* in a specific case, to ascertain the *acceptability* and *relevancy* of information or advice received, and to decide *what weight to ascribe*

⁹⁰¹Article 11.2 of the *SPS Agreement* is listed in Appendix 2 of the DSU (Special or Additional Rules and Procedures contained in the covered agreements).

⁹⁰²Appellate Body Report, *Japan – Agricultural Products II*, para. 129.

to that information or advice or to conclude that no weight at all should be given to what has been received.⁹⁰³

440. The European Communities has not challenged on appeal the Panel's decision to consult experts *per se*, nor does it claim that the Panel failed to consult with the parties on expert selection.⁹⁰⁴ The European Communities disagrees with the Panel's decision to consult experts individually, rather than establish an expert review group, but does not raise a claim in this respect on appeal.⁹⁰⁵

441. Paragraph 9 of the Experts Working Procedures adopted by the Panel prescribes that experts will be selected "on the basis of their qualification and the need for specialized scientific or technical expertise". Paragraph 11 additionally provides:

The selected experts shall act in their individual capacities and not as representatives of any entity. They shall be subject to the *Rules of Conduct for the Understanding on Rules and Procedures Governing the Settlement of Disputes* (WT/DSB/RC1), including the self-disclosure requirement set out in Section VI of the *Rules of Conduct*.

442. As we noted earlier, experts advising panels are specifically covered by the *Rules of Conduct* and, pursuant to Section II (Governing Principle), they "shall be independent and impartial, [and] shall avoid direct or indirect conflicts of interest ... , so that through the observance of such standards of conduct the integrity and impartiality of that mechanism are preserved".

443. Selected experts are also subject to certain self-disclosure and confidentiality obligations set out elsewhere in the *Rules of Conduct*, and procedures exist for the referral of a "material violation" of these obligations to the Chairman of the DSB for appropriate action.⁹⁰⁶

444. The European Communities claims that due process requires that the "experts a court, tribunal

⁹⁰³Appellate Body Report, *US – Shrimp*, para. 104. (original emphasis) Given the manner in which the Appellate Body has addressed the scope of a panel's authority under Article 13 of the DSU, this discretion would seem to apply equally to the discretion of panels under Article 11.2 of the *SPS Agreement*.

⁹⁰⁴The Appellate Body has found that panels are free to consult experts as individuals or as part of an expert review group. (Appellate Body Report, *EC – Hormones*, para. 147)

⁹⁰⁵The European Communities notes that the Panel "for no good reason declined to follow the European Communities' suggestion to constitute an expert review group", and that "[i]n retrospect, this has proven disastrous in this case in view of the very different, conflicting and irreconcilable opinions it received on many crucial issues from its experts." (European Communities' appellant's submission, footnote 76 to para. 187) The Panel explained its decision to consult experts on an individual basis with the following reasons: (1) the experts' varying fields of competence would make it important, on relevant subjects, to consult experts individually on their respective field of expertise; and (2) it did not want a consensus text from an expert review group that would reflect a minimum common position, but wished to hear dissenting or minority views among the experts. (Panel Report, *US – Continued Suspension*, para. 7.71; Panel Report, *Canada – Continued Suspension*, para. 7.69)

⁹⁰⁶*Rules of Conduct*, Sections VI (Self-Disclosure Requirements by Covered Persons), VII (Confidentiality), and VIII (Procedures Concerning Possible Material Violations).

or panel hears or consults are *independent and impartial*."⁹⁰⁷ It then asserts that the relevant legal test for evaluating whether an expert is independent and impartial is founded on the self-disclosure obligation in Section VI.2 of the *Rules of Conduct*, which requires that experts "disclose any information ... which is likely to affect or give rise to justifiable doubts as to their independence or impartiality". This is a standard the European Communities asserts is "simple and low" and "does not require certainty or high probability".⁹⁰⁸

445. The requirements under Section VI of the *Rules of Conduct* relate, as the title indicates, to the self-disclosure obligation of covered persons, including experts. The *Rules of Conduct* do not provide for automatic exclusion of a covered person upon the disclosure of information pursuant to Section VI and the Illustrative List of Information to be Disclosed, which is attached to the *Rules of Conduct* as Annex 2. However, we fail to see on what basis a panel, presented with information likely to affect or give rise to justifiable doubts as to the independence or impartiality of an expert, could choose to consult such an expert.

446. We do not agree, however, with the European Communities' characterization of Section VI.2 as setting out a "low" standard. On the contrary, we consider the standard set forth in Section VI.2 to be a strict one. Covered persons should be encouraged to disclose any information that may be relevant for purposes of ascertaining whether there may be justifiable doubts as to their independence or impartiality. Disclosure should not lead to automatic exclusion. Whether the disclosed information is likely to affect or give rise to justifiable doubts as to the person's independence or impartiality must be objectively determined and properly substantiated. In the case of an expert, the panel should assess the disclosed information against information submitted by the parties or other information that may be available. It should then determine whether, on the correct facts, there is a likelihood that the expert's independence and impartiality may be affected, or if justifiable doubts arise as to the expert's independent or impartiality. If this is indeed the case, the panel must not appoint such person as an expert.

(b) Disclosure of Conflicts of Interest

447. The European Communities also argues that the Panel did not enforce compliance with the self-disclosure requirement, and did not adequately explore potential conflicts of interest. The European Communities charges that the Panel "failed to require that the self-disclosure requirement

⁹⁰⁷European Communities' appellant's submission, para. 188. (original emphasis)

⁹⁰⁸*Ibid.*, para. 195.

be complied with"⁹⁰⁹ for Dr. Boisseau and therefore rendered paragraph 4 of the Experts Working Procedures "a dead letter".⁹¹⁰

448. Section VI.2 of the *Rules of Conduct* requires all covered persons, including experts, to "disclose any information that could reasonably be expected to be known to them at the time which, coming within the scope of the Governing Principle of these Rules, is likely to affect or give rise to justifiable doubts as to their independence or impartiality". The Illustrative List of Information to be Disclosed pursuant to Section VI includes the following examples of matters to be disclosed:

(b) professional interests (e.g. a past or present relationship with private clients, or any interests the person may have in domestic or international proceedings, and their implications, where these involve issues similar to those addressed in the dispute in question);

(c) other active interests (e.g. active participation in public interest groups or other organizations which may have a declared agenda relevant to the dispute in question);

(d) considered statements of personal opinion on issues relevant to the dispute in question (e.g. publications, public statements).

449. Paragraph 4 of the Experts Working Procedures adopted by the Panel provides:

The Panel will seek a *curriculum vitae*, including all relevant publications, from each individual suggested. The candidate experts will also be asked to provide information about potential conflicts of interest and indications on whether they have worked for, been funded by or provided advice to the industries concerned, or to domestic or international regulatory bodies involved in issues similar to those addressed in this dispute. A list of eligible experts, including their *curricula vitae* and declarations of interest will be provided to the parties. Parties will have sufficient time to examine them and will be given the opportunity to comment on and to make known any compelling objections to any particular expert.⁹¹¹

450. In his self-disclosure statement, Dr. Boisseau stated that "[h]aving worked as a civil servant, I have no conflict of interest which could prevent me to serve as a scientific expert to these two WTO panels."⁹¹² The purpose of the self-disclosure statement is to reveal relevant facts that would allow the Panel to determine whether the information is likely to affect or give rise to justifiable doubts as to the expert's independence or impartiality. Instead, Dr. Boisseau's statement draws a conclusion on a matter that was for the Panel to decide. Dr. Boisseau's statement does not identify whether he has "worked for, been funded by, or provided advice to, the industries concerned, or to domestic or

⁹⁰⁹European Communities' appellant's submission, para. 192.

⁹¹⁰*Ibid.*, para. 197.

⁹¹¹Panel Reports, Annex A-5, p. A-10.

⁹¹²See Panel record document, "Information on Conflict of Interest by Dr. Jacques Boisseau" (undated).

international regulatory bodies involved in issues similar to those addressed in this dispute". The statement does not mention his affiliation with JECFA, nor the fact that he was the Chairman or Vice-Chairman of JECFA panels that evaluated some of the hormones at issue in this dispute.⁹¹³ Also, Dr. Boisseau's position as a civil servant did not itself shield him from having a conflict of interest. Thus, we agree with the European Communities that Dr. Boisseau's statement would not appear to comply fully with the requirements of Section VI.2 of the *Rules of Conduct* or paragraph 4 of the Experts Working Procedures adopted by the Panel.

451. We note that, in Canada's view, the self-disclosure requirement was satisfied by the information provided on Dr. Boisseau's *curriculum vitae*, which it considers provided full disclosure of Dr. Boisseau's involvement with JECFA.⁹¹⁴ While panels should insist that self-disclosure requirements under the *Rules of Conduct* are observed by potential experts, and while parties are entitled to full self-disclosure by experts, we find that the Panel did not exceed its authority in concluding that Dr. Boisseau's brief statement, when considered together with the information contained in his *curriculum vitae*, provided sufficient disclosure in this case. Dr. Boisseau's *curriculum vitae* provides information about his involvement with JECFA and his other professional activities.⁹¹⁵

452. The European Communities also claims that the Panel "never actually examined whether all of the experts had a potential conflict of interest and whether the experts fulfilled the conditions to be truly independent and impartial".⁹¹⁶ We understand this claim to refer to the objections of the European Communities, also raised in its letter to the Panel dated 28 March 2006, that: (i) Dr. Boisseau stated "in a public hearing in the French Senate, in 1996 ... that the three natural hormones do not present a danger for public health"; (ii) Dr. Boisseau took the position "in a public debate ... that only 'major' risks are relevant in precautionary decision making"; and (iii) Dr. Boobis allegedly received funding from one pharmaceutical company at the time of his disclosure, and did not disclose potential funding and affiliations with two others.⁹¹⁷

⁹¹³See *infra*, para. 458.

⁹¹⁴Canada's appellee's submission, para. 49.

⁹¹⁵Dr. Boisseau's *curriculum vitae* indicates that he was a member of JECFA between 1988-2001, its Chairman in 1994, 1998, 2000, and 2002, and its Vice-Chairman in 1992, 1994, 1995, 1997, and 2001.

⁹¹⁶European Communities' appellant's submission, para. 192.

⁹¹⁷Letter from the European Communities to the Panel dated 28 March 2006 (quoted in European Communities' appellant's submission, para. 196).

453. The Panel stated that it had "carefully considered the European Communities' request, including the information given regarding potential conflicts of interest".⁹¹⁸ Nonetheless, the Panel found that the European Communities' objections "were not justified"⁹¹⁹, adding:

The Panel found in particular that the statement that one expert had made before the French Senate in 1996 had not been made in relation to hormones used for growth promotion purposes. Rather, it had been made with respect to hormones used for medical treatment purposes. The Panel also found that the links of another expert with two companies involved in research and counselling were not in the area of veterinary drugs or hormonal substances.⁹²⁰

454. The European Communities challenges the "narrow" conflict of interest definition applied by the Panel, and reiterates the "undisputed facts" that:

... Dr. Boisseau did take a position in favour of the safety of these hormones, albeit in the context of a discussion on therapeutic treatment in animals, and that Dr. Boobis has been receiving funding from the pharmaceutical industry in his research and counselling, albeit not from companies in the area of veterinary drugs or these hormones (although this has never been specifically verified). ... As regards the industry funding of Dr. Boobis, the Panels refrained from verifying whether there were any actual or possible links of the companies funding him with other companies producing veterinary drugs or these hormones. In fact, as far as the European Communities knows, the Panels refrained from asking any question to Dr. Boobis on this precise issue.⁹²¹

As we have found, the standard to be applied by panels when selecting experts is whether there is an objective basis to conclude that an expert's independence or impartiality is likely to be affected or there are justifiable doubts about that expert's independence or impartiality. In this instance, the Panel explained that it "carefully considered" the objections, "including the information given regarding

⁹¹⁸Panel Report, *US – Continued Suspension*, para. 7.87; Panel Report, *Canada – Continued Suspension*, para. 7.85.

⁹¹⁹Panel Report, *US – Continued Suspension*, para. 7.87; Panel Report, *Canada – Continued Suspension*, para. 7.85.

⁹²⁰Panel Report, *US – Continued Suspension*, para. 7.87; Panel Report, *Canada – Continued Suspension*, para. 7.85. The Panel further commented that:

The Panel wishes to highlight the challenges it encountered in selecting experts. There was a limited number of specialists suggested and actually available in each of the fields on which the Panel needed assistance and almost always one or more of the parties objected to that specialist. For example, only six of the identified available experts were deemed to have extensive expertise in risk analysis. All of these experts were objected to by at least one party.

(Panel Report, *US – Continued Suspension*, footnote 382 to para. 7.87; Panel Report, *Canada – Continued Suspension*, footnote 374 to para. 7.85)

⁹²¹European Communities' appellant's submission, para. 203.

potential conflicts of interest", before concluding that the objections were "not justified".⁹²² Moreover, the Panel provided specific explanations as to why it disagreed with the objections of the European Communities.⁹²³

455. On appeal, the European Communities recognizes that Dr. Boisseau's statement in the French Senate did not refer to the use of the hormones for growth-promotion purposes. The European Communities does not provide argumentation explaining why Dr. Boisseau's statement concerning the use of the hormones for therapeutic purposes signifies that he would not be impartial in his views concerning the use of these hormones for growth-promotion purposes. The European Communities itself regulates the use of the hormones at issue for veterinary purposes differently from the use for growth-promotion purposes in Directive 2003/74/EC.⁹²⁴ In addition, we do not consider that in this case the information about Dr. Boobis' links to certain pharmaceutical companies provided an objective basis to conclude that there were justifiable doubts as to his impartiality or independence. The European Communities did not present evidence indicating that the companies from which Dr. Boobis received funding had links with other companies producing veterinary drugs or the hormones at issue. Thus, we consider that the Panel did not exceed its authority in dismissing the European Communities' objections relating to disclosure statements given by Drs. Boisseau and Boobis pursuant to the *Rules of Conduct* and paragraph 4 of the Experts Working Procedures adopted by the Panel.

(c) Previous Affiliation with JECFA

456. The European Communities claims that the reasons provided by the Panel for declining to exclude Drs. Boisseau and Boobis never addressed the fundamental question of their affiliation with JECFA. In the view of the European Communities, the Panel disregarded its "most important objection"⁹²⁵ that an expert who has participated in the drafting of JECFA reports cannot be independent and impartial because, in this case, the experts were being asked to evaluate new scientific evidence underlying reports that were directly critical of, or in conflict with, their prior contribution to the JECFA reports. The European Communities argues that as "authors of the JECFA reports"⁹²⁶, Drs. Boisseau and Boobis "cannot be considered to be independent and impartial in these

⁹²²Panel Report, *US – Continued Suspension*, para. 7.87; Panel Report, *Canada – Continued Suspension*, para. 7.85.

⁹²³*Ibid.*

⁹²⁴Directive 2003/74/EC states that "the use of certain of the [hormones at issue], where this is necessary, for therapeutic purposes or zootechnical treatment may continue to be authorised as it is not likely to constitute a hazard for public health owing to the nature and the limited duration of the treatments, the limited quantities administered and the strict conditions laid down in Directive 96/22/EC in order to prevent any possible misuse." (Directive 2003/74/EC, Recital 11)

⁹²⁵European Communities' appellant's submission, para. 203.

⁹²⁶*Ibid.*, para. 205.

circumstances, because this would amount to asking them to review and criticise reports that are their own doing".⁹²⁷

457. JECFA, which is administered jointly by the FAO and the WHO, is "an international expert scientific committee" that evaluates the safety of food additives, contaminants, naturally-occurring toxicants and residues of veterinary drugs in food.⁹²⁸ JECFA "performs risk assessments and provides advice to FAO, WHO and the member countries of both organizations".⁹²⁹ Some countries use information from JECFA in their national food safety control programmes.⁹³⁰ Requests for scientific advice "are in general channelled through the Codex Alimentarius Commission (Codex)".⁹³¹ Codex also adopts international standards based on evaluations performed by JECFA.⁹³² Codex has adopted international standards for five of the hormones at issue in this case, that is, oestradiol-17 β , testosterone, progesterone, trenbolone acetate, and zeranol, on the basis of evaluation performed by JECFA.⁹³³ In addition, Codex has initiated a standard-setting process for MGA, also on the basis of JECFA's evaluation, but this process has not yet concluded.⁹³⁴

458. The risk assessments performed by JECFA in relation to oestradiol-17 β , testosterone, progesterone, trenbolone acetate, and zeranol lie at the centre of the dispute between the participants in this case. In the case of oestradiol-17 β , the European Communities argued that "the Codex approach has serious limitations in non-linear situations, such as with regard to these hormones", and explained that "currently available Codex guidance poorly addresses cases such as this where the risks are embedded in changes in exposure to biologically active molecules which may, with minute differences in their bioavailability, have dramatic effects, such as turning on or off complete developmental programmes of the human genome, or inducing pathological conditions."⁹³⁵ The European Communities also argued that JECFA's evaluation was based on "outdated" data.⁹³⁶ As for the four hormones that are subject to the provisional ban and for which there is an international

⁹²⁷European Communities' appellant's submission, para. 205.

⁹²⁸Panel Report, *US – Continued Suspension*, footnote 377 to para. 7.78; Panel Report, *Canada – Continued Suspension*, footnote 369 to para. 7.76.

⁹²⁹*Ibid.*

⁹³⁰*Ibid.*

⁹³¹*Ibid.*

⁹³²*Ibid.*

⁹³³Codex Alimentarius Commission, *Maximum Residue Limits for Veterinary Drugs in Foods*, updated as at the 29th Session of the Codex Alimentarius Commission (July 2006), CAC/MRL 2 (Exhibit CDA-22 submitted by Canada to the Panel in *Canada – Continued Suspension*).

⁹³⁴See Panel Report, *US – Continued Suspension*, para. 7.813; Panel Report, *Canada – Continued Suspension*, para. 7.799.

⁹³⁵Panel Report, *US – Continued Suspension*, para. 7.458; Panel Report, *Canada – Continued Suspension*, para. 7.446 (referring to reply of the European Communities to Question 24 posed by the Panel, Panel Reports, Annex B-1, para. 140).

⁹³⁶Panel Report, *US – Continued Suspension*, para. 7.423; Panel Report, *Canada – Continued Suspension*, para. 7.414.

standard, the European Communities asserted that the conclusions reached by JECFA in 1988 and 1999 are "no longer valid".⁹³⁷ As regards MGA, which is also subject to the provisional ban, the European Communities notes that "nearly all the studies" referred to in the 2000 JECFA report evaluating MGA "date from the 1960s and 1970s".⁹³⁸ The European Communities considered JECFA's assessment of these hormones to be "insufficient"⁹³⁹ for purposes of conducting a risk assessment of the type required by the *SPS Agreement*, in light of the fact that the European Communities had decided to adopt a higher level of protection than that underlying JECFA's international standards.⁹⁴⁰ In these circumstances, the Panel should have closely scrutinized any institutional links the experts may have had with JECFA and objectively determined whether those links were likely to affect or give rise to justifiable doubts as to the experts' independence or impartiality.

459. Both Drs. Boisseau and Boobis had close institutional links with JECFA. Dr. Boisseau was a member of JECFA from 1987 to 2002.⁹⁴¹ Dr. Boobis was a member from 1997 to 2006. Membership of JECFA, in our view, reflects international recognition of the expertise of a particular scientist. The Panel observed, in this regard, that JECFA is an "international, independent entity composed of highly qualified experts selected by the WHO or FAO according to strict procedures".⁹⁴² We agree with the Panel that Drs. Boisseau and Boobis are highly qualified scientists. We do not see the fact that Drs. Boisseau and Boobis are qualified and knowledgeable—and thus experts—as giving rise to

⁹³⁷Panel Report, *US – Continued Suspension*, para. 4.226; Panel Report, *Canada – Continued Suspension*, para. 4.217.

⁹³⁸Panel Report, *US – Continued Suspension*, para. 4.233; Panel Report, *Canada – Continued Suspension*, para. 4.221.

⁹³⁹Panel Report, *US – Continued Suspension*, para. 4.234; Panel Report, *Canada – Continued Suspension*, para. 4.222.

⁹⁴⁰By contrast, as we explain in section VII.E, the Panel considered that the existence of international standards (or, in the case of MGA, of an advanced process that could eventually lead to the adoption of an international standard) established a presumption that there was sufficient scientific evidence to conduct a risk assessment. The Panel explained its view as follows:

The presumption of consistency of measures conforming to international standards, guidelines and recommendations with the relevant provisions of the *SPS Agreement* implies that these standards, guidelines or recommendations, particularly those referred to in this case, are based on risk assessments that meet the requirements of the *SPS Agreement*. This means, therefore, that there was sufficient evidence for JECFA to undertake the appropriate risk assessments.

(Panel Report, *US – Continued Suspension*, para. 7.644; Panel Report, *Canada – Continued Suspension*, para. 7.622) (footnote omitted)

⁹⁴¹Dr. Boisseau's *curriculum vitae* indicates that he was a member of JECFA from 1988-2001. However, he is listed as a member in JECFA's 32nd Report, which corresponds to a session held in Rome on 15-23 June 1987, and also in JECFA's 58th Report, which corresponds to a session held in Rome on 21-27 February 2002. (See Exhibit US-25 submitted by the United States to the Panel; and Exhibits CDA-29 and CDA-34 submitted by Canada to the Panel)

⁹⁴²Panel Report, *US – Continued Suspension*, para. 6.62; Panel Report, *Canada – Continued Suspension*, para. 6.57.

concerns about their impartiality and independence. On the contrary, we would expect a person who is regarded as an expert to hold views, and even very strong views, on his or her particular area of expertise. However, we agree with the European Communities that the qualifications and relevant knowledge of Drs. Boisseau and Boobis are not by themselves sufficient guarantees of their independence and impartiality.⁹⁴³ An expert could be very qualified and knowledgeable and yet his or her appointment could give rise to concerns about his or her impartiality or independence, because of that expert's institutional affiliation or for other reasons. Similarly, the fact that JECFA may select its experts according to strict procedures does not in itself ensure that these experts are independent and impartial in respect of the issues that may arise in a WTO dispute.

460. Not only did Drs. Boisseau and Boobis participate in JECFA, they were directly involved in JECFA's evaluations of the six hormones at issue. Dr. Boisseau was a member of JECFA in 1987 when the Committee evaluated oestradiol-17 β , progesterone, testosterone, trenbolone acetate, and zeranol.⁹⁴⁴ Both Drs. Boisseau and Boobis were members of JECFA in 1999 when it again evaluated oestradiol-17 β , progesterone, and testosterone. During its 1999 session, JECFA adopted recommended Acceptable Daily Intakes ("ADIs") for oestradiol-17 β , testosterone, and progesterone.⁹⁴⁵ The report of the 1999 session lists Dr. Boisseau as the Chairman and Dr. Boobis as one of two Joint Rapporteurs. Drs. Boisseau and Boobis also participated in the evaluation of MGA in 2000.⁹⁴⁶ On this occasion, the relevant JECFA report lists Dr. Boisseau as Vice-Chairman and Dr. Boobis as a Joint Rapporteur.⁹⁴⁷ Thus, Dr. Boisseau was a member of JECFA when it evaluated all six hormones at issue in this dispute, while Dr. Boobis participated in the evaluation of four of the six hormones. As Chairman, Vice-Chairman, and Joint Rapporteur, they would be expected to have played a significant role in the discussions.

461. Rather than being a source of concern, the Panel considered that Drs. Boisseau's and Boobis' participation in JECFA would make them more useful as experts:

⁹⁴³European Communities' appellant's submission, para. 196.

⁹⁴⁴JECFA, "Evaluation of Certain Drug Residues in Food", 32nd Report, 1988 (Exhibit US-25 submitted by the United States to the Panel in *US – Continued Suspension*).

⁹⁴⁵JECFA, "Evaluation of Certain Drug Residues in Food", 52nd Report, 2000. The Committee did not specify MRLs for these three hormones because it found that "available 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 used according to good practice in the use of veterinary drugs". Thus, 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". (JECFA, 52nd Report, p. 101, footnote 1 (Exhibit US-5 submitted by the United States to the Panel in *US – Continued Suspension*))

⁹⁴⁶Dr. Boobis also participated in the evaluation of MGA in 2004 (JECFA, "Evaluation of Certain Drug Residues in Food", 62nd Report, 2004 (Exhibit CDA-20 submitted by Canada to the Panel in *Canada – Continued Suspension*)).

⁹⁴⁷JECFA, "Evaluation of Certain Drug Residues in Food", 54th Report, 2001 (Exhibit US-24 submitted by the United States to the Panel in *US – Continued Suspension*).

The Panel chose not to exclude *a priori* experts who had participated in the preparation and drafting of JECFA's risk assessments because this would deprive the Panel and the parties of the benefit of the contribution of internationally recognized specialists and because the Panel was of the opinion that experts familiar with the JECFA reports would be well-placed to assist the Panel in understanding the work of JECFA extensively referred to by the parties in their submissions, in particular by the European Communities.⁹⁴⁸

462. The Panel also observed that "since JECFA's risk assessments were used as the reference risk assessments for purposes of the analysis under Article 5.7 of the *SPS Agreement*, it was necessary for the Panel to be able to rely on the advice of experts intimately knowledgeable about the substance of JECFA's risk assessments."⁹⁴⁹ We are not persuaded by the Panel's reasoning. It is precisely because JECFA's risk assessments have such a prominent role in this dispute that the Panel should have exercised particular caution before appointing persons with institutional links to JECFA as experts. The Panel gave the experts wide latitude in terms of their examination of the evidence and the advice they provided. Given how the Panel framed its consultations with the experts, it would have been very difficult for it to limit the scope of the advice it received from Drs. Boisseau and Boobis to the "work of JECFA". In fact, our review of the panel record indicates that the Panel did not limit its consultations with Drs. Boisseau and Boobis to the "work of JECFA".⁹⁵⁰ For example, as regards the European Communities' permanent ban on meat from cattle treated with oestradiol-17 β , the Panel asked the experts (including Drs. Boisseau and Boobis):

To what extent, in your view, does the [European Communities'] risk assessment identify the potential for adverse effects on human health, including the carcinogenic or genotoxic potential, of the residues of oestradiol-17 β found in meat derived from cattle to which this hormone had been administered for growth promotion purposes in accordance with good veterinary practice? To what extent does the [European Communities'] risk assessment evaluate the potential occurrence of these adverse effects?⁹⁵¹

⁹⁴⁸Panel Report, *US – Continued Suspension*, para. 7.85; Panel Report, *Canada – Continued Suspension*, para. 7.83. (footnote omitted)

⁹⁴⁹Panel Report, *US – Continued Suspension*, para. 6.62; Panel Report, *Canada – Continued Suspension*, para. 6.57.

⁹⁵⁰The Panel posed 62 written questions to the six scientific experts. Dr. Boisseau provided responses to 59 questions and Dr. Boobis replied to 45. These stand in sharp contrast to the other experts who provided responses to far fewer questions. Dr. Brabander replied to 17 questions, Dr. Cogliano answered 12 questions, Dr. Guttenplan responded to 31 questions, and Dr. Sippel gave responses to 4 questions. (See Panel record document, *Statistics on Replies of the Scientific Experts*) We do not mean to suggest that it is problematic for an expert to answer too many questions. We refer to these numbers merely to illustrate the breadth of the advice provided by Drs. Boisseau and Boobis in this case.

⁹⁵¹Panel Reports, Annex D, p. D-22, Question 13.

463. This question goes directly to the adequacy of the European Communities' risk assessment and does not concern JECFA's work. Both Drs. Boisseau and Boobis responded to this question and their responses were relied on by the Panel in its analysis:

Dr. Boisseau concluded that the European Communities did not demonstrate that a potential for adverse effects on human health arises from the consumption of meat from cattle treated with any of the six hormones in dispute for growth promotion purposes.⁹⁵²

Dr. Boobis stated that, in his view, none of the information provided by the European Communities demonstrates the potential for adverse effects in humans of any of the six hormones in meat from cattle in which they are used for growth promotion purposes at the levels to which those consuming such meat would be exposed. The studies on genotoxicity provide no convincing evidence of potential for harm in consumers. The carcinogenic effects observed are entirely consistent with a hormonal mode of action that exhibits a threshold that would be well above the intake arising from consumption of meat from treated cattle.⁹⁵³

In their replies, Drs. Boisseau and Boobis directly evaluated the appropriateness of the European Communities' risk assessment.

464. The Panel also asked the experts whether the European Communities' risk assessment examined the risks arising specifically from the consumption of meat from cattle treated with the six hormones at issue:

Do the risk assessment of the European Communities or any other scientific materials referred to by the European Communities demonstrate that a potential for adverse effects on human health arises from the consumption of meat from cattle treated with any of the six hormones in dispute for growth-promotion purposes? If yes, why? If not, what kind of evidence would be required to demonstrate such potential adverse effects? Would your response have been different at the time of adoption of the Directive in September 2003?⁹⁵⁴

465. The question concerns the specificity requirement discussed by the Appellate Body in *EC – Hormones*.⁹⁵⁵ Drs. Boisseau and Boobis both volunteered responses, and the Panel again relied on

⁹⁵²Panel Report, *US – Continued Suspension*, para. 7.526; Panel Report, *Canada – Continued Suspension*, para. 7.498 (referring to replies of the scientific experts to questions posed by the Panel, Panel Reports, Annex D, para. 406).

⁹⁵³Panel Report, *US – Continued Suspension*, para. 7.527; Panel Report, *Canada – Continued Suspension*, para. 7.499 (referring to replies of the scientific experts to questions posed by the Panel, Panel Reports, Annex D, para. 408).

⁹⁵⁴Panel Reports, Annex D, p. D-84, Question 52.

⁹⁵⁵Appellate Body Report, *EC – Hormones*, para. 199.

both of their replies in its examination of the consistency with the *SPS Agreement* of the European Communities' risk assessment. The Panel summarizes the response of Dr. Boisseau as follows:

Dr. Boisseau concluded that the European Communities did not demonstrate that a potential for adverse effects on human health arises from the consumption of meat from cattle treated with any of the six hormones in dispute for growth promotion purposes. Additionally, Dr. Boisseau stated that the kind of evidence required to demonstrate such potential adverse effects should be (a) toxicological data indicating that the values of the ADIs established by JECFA are not conservative enough, and (b) data on residues in treated/non-treated cattle and on daily production of hormones in sensitive individuals [such as pre-pubertal children] indicating that the hormonal residue intake associated with the consumption of meat from treated cattle is such that the established ADIs would be exceeded in the case of use of growth promoters.⁹⁵⁶

466. This excerpt is a good illustration of the problems arising from Drs. Boisseau's and Boobis' involvement with JECFA's evaluation of the hormones at issue in this dispute. Dr. Boisseau's response shows that he considered JECFA and, in particular, its approach of using ADIs, as the benchmark against which to evaluate the European Communities' risk assessment.⁹⁵⁷

467. Another illustration of this problem can be seen in Dr. Boisseau's response to the Panel's question regarding whether the scientific evidence in the SCVPH Opinions supported the conclusion that the carcinogenic effects of the hormones at issue are related to a mechanism other than hormonal activity.⁹⁵⁸ For each of the hormones at issue, except for oestradiol-17 β (in respect of which he referred to an earlier response), Dr. Boisseau compared the European Communities' risk assessment with JECFA's conclusions. For example, Dr. Boisseau gave the following response in relation to progesterone:

In its thirty second session, JECFA concluded that "Although equivocal results have been reported for the induction of single-strand DNA breaks and DNA adducts have been seen in vivo and in vitro in some studies, progesterone was not mutagenic ... progesterone has no genotoxic potential". It concluded also that "these effects on tumour production occurred only with doses of progesterone causing obvious hormonal effects ... the effects of progesterone on tumour production was directly related to its hormonal activity".

⁹⁵⁶Panel Report, *US – Continued Suspension*, para. 7.526; Panel Report, *Canada – Continued Suspension*, para. 7.498 (referring to replies of the scientific experts to questions posed by the Panel, Panel Reports, Annex D, para. 406).

⁹⁵⁷This excerpt also shows that there is a problem in the standard applied by the Panel to review the European Communities' risk assessment. We discuss this in section VII.E of this Report.

⁹⁵⁸Panel Reports, Annex D, p. D-27, Question 16.

In its 1999 report, SCVPH concluded, about the carcinogenicity of progesterone, that "At present, the data are insufficient to make any quantitative estimate of the risk arising from the exposure to residues in meat"[.] Therefore, the scientific evidence relied upon in the SCVPH Opinions does not support the conclusion that the carcinogenic effects of progesterone are related to a mechanism other than hormonal activity.⁹⁵⁹

The response in relation to testosterone is similar:

In its thirty second session, JECFA concluded that the increase of the incidence of prostatic and uterine tumours observed in rodents treated with high doses of testosterone ["]resulted from the hormonal activity of testosterone". In its fifty second session held in 1999, JECFA concluded that "In mammalian cells, no chromosomal aberrations, mutations or DNA adducts were found following treatment with testosterone ... testosterone has no genotoxic potential".

In its 1999 report, SCVPH concluded, about the carcinogenicity of testosterone, that, given the limited data on genotoxicity and on carcinogenicity in humans, no conclusive quantitative estimate of the risk arising from the excess intake with meat from treated animals can be made. Therefore, the scientific evidence relied upon in the SCVPH Opinions does not support the conclusion that the carcinogenic effects of testosterone are related to a mechanism other than hormonal activity.⁹⁶⁰

Both of these responses are cited in the Panel's reasoning.⁹⁶¹ Dr. Boisseau also drew a comparison with JECFA at the end of his response, when he summarized his views as follows:

[C]onsidering the conclusions of JECFA and the fact that SCVPH bases always its reservations on the lack of data more than on data establishing the genotoxicity and the capacity of the five other hormones (progesterone, testosterone, melengestrol, trenbolone and zeranol) to act as complete carcinogens, it can be said that the scientific evidence relied upon in the SCVPH Opinions does not support the conclusion that the carcinogenic effects of these five hormones are related to a mechanism other than hormonal activity.⁹⁶²

468. A similar problem can be seen as regards the question of the sufficiency of the evidence under Article 5.7 of the *SPS Agreement*. At the meeting with the Panel and the parties, the United States asked the experts whether they considered that the scientific evidence relied on by the European

⁹⁵⁹Panel Reports, Annex D, paras. 157 and 158.

⁹⁶⁰*Ibid.*, paras. 159 and 160.

⁹⁶¹Panel Report, *US – Continued Suspension*, para. 7.732 and footnote 859 thereto, para. 7.738 and footnote 865 thereto, and para. 7.752 and footnote 878 thereto; Panel Report, *Canada – Continued Suspension*, para. 7.709 and footnote 807 thereto, para. 7.715 and footnote 813 thereto, and para. 7.731 and footnote 828 thereto.

⁹⁶²Panel Reports, Annex D, para. 167.

Communities in the SCVPH Opinions supported the conclusion that it is not possible to complete a risk assessment for the five hormones that are the subject of the provisional ban.⁹⁶³ Dr. Boobis referred to his experience in JECFA, replying:

I cannot speak for the [European Communities], and I think what has just been said is quite correct. I can speak for JECFA in which I participated, and in our view we had enough information to complete a risk assessment. I don't know if that is helpful, but that was the situation when we looked at the available data on those five other hormones.⁹⁶⁴

469. The European Communities, however, based much of its case before the Panel on the limitations of JECFA's approach. Given that in its own risk assessment the European Communities called into question the validity of JECFA's risk assessments, it was improper for the Panel to have asked Drs. Boisseau and Boobis, who participated directly in JECFA's evaluations, to evaluate the European Communities' risk assessment. The natural inclination of someone placed in that situation would be to compare the risk assessments, rather than to assess whether the science relied upon by the European Communities can support the conclusions it reached, and to favour or defend JECFA's approach. The manner in which the Panel used these experts does not ensure impartiality and cannot be said to ensure fairness in the consultations with the experts. Such a result is not compatible with the due process obligations that are inherent in the WTO dispute settlement system.

470. Canada argues that it is "incorrect to portray" the participation in JECFA panels by Drs. Boisseau and Boobis as "giving them an (almost proprietary) interest in the outcome of the JECFA process that they would have felt compelled to defend".⁹⁶⁵ Canada maintains that the JECFA process "is a diffuse one, in which a number of scientists participate" and is "aimed at reaching a consensus out of what may initially be a variety of scientific views".⁹⁶⁶ Therefore, Canada argues, "the process is very different from scientific conclusions arrived at by one individual's scientific efforts that are published under his or her name"⁹⁶⁷, and Drs. Boisseau and Boobis were no more responsible for authoring the JECFA reports than was any other "expert participating in a JECFA meeting and subscribing to a resulting report [which] might be considered part of the collective authorship of the scientists involved."⁹⁶⁸ At the oral hearing, Canada additionally noted that, at JECFA meetings, the experts reviewed previously prepared monographs that, in this case, did not contain the input of Drs. Boisseau and Boobis.

⁹⁶³Panel Reports, Annex G, para. 770.

⁹⁶⁴*Ibid.*, para. 774.

⁹⁶⁵Canada's appellee's submission, para. 56.

⁹⁶⁶*Ibid.*

⁹⁶⁷*Ibid.*

⁹⁶⁸*Ibid.*, para. 52.

471. The Panel also reasoned that Drs. Boisseau and Boobis may have contributed to the development of JECFA reports, but the nature of their participation ensured that they could remain independent and impartial. In response to objections from the European Communities during the interim review, the Panel explained:

Moreover, JECFA reaches its conclusions by consensus. So the opinions expressed by the two experts were given with regard to the consensual view of JECFA on this matter, not just their own personal positions in the past. This does not mean, however, that JECFA's work is these particular experts' own work: it is a joint work by several experts.⁹⁶⁹

472. We recognize that JECFA involves a decision-making process based on consensus and that the outcome of the process need not necessarily reflect the views of its individual members. However, the fact that this process involves several individuals and that the outcome may be the result of a compromise does not mean that the joint outcome of the process can be disconnected from the experts that participated in the process.⁹⁷⁰ On the contrary, one would expect that the views of the experts that participated in the process would be reflected, in various degrees, in the outcome. As noted earlier, Drs. Boisseau's and Boobis' participation was not indirect or marginal. Rather, both would be expected to have had particular influence in the process given their respective roles as Chairman and Vice-Chairman, and Joint Rapporteur. Moreover, irrespective of their degree of influence in the process, both would be expected to have a natural inclination to identify with JECFA's evaluation as participants in the consensus. Therefore, we do not consider that the fact that JECFA reaches its conclusions by consensus dispels our concerns regarding the propriety of the Panel asking Drs. Boisseau and Boobis to evaluate the European Communities' risk assessment.

⁹⁶⁹Panel Report, *US – Continued Suspension*, para. 6.62; Panel Report, *Canada – Continued Suspension*, para. 6.57.

⁹⁷⁰In the meeting with the Panel and the parties, Dr. Boobis suggested that JECFA had been operating since 1997 on the basis of unanimity. Dr. Boobis' description of JECFA decision-making does not support Canada's argument that JECFA reports may not necessarily reflect the views of Drs. Boisseau and Boobis. Dr. Boobis explained:

The JECFA Committee—at least as far back as 1997—have been able to reach an agreed position on all the questions before them. In the event that there was a disagreement, there would be two possible options – one would be not to proceed further and seek further evidence, and the other would be, as has been indicated already by the secretariat, if the majority was of one view and a minority was of another view, to issue a so-called minority opinion or minority report as well, which reflects a contrary view on the interpretation of the data. As I said earlier, this has not happened, there was unanimity. Generally what happens is that there is a discussion, there may be varying interpretations of a dataset, the experts get together over the period of a meeting and explore the various possibilities, bringing new information, or new insights and reach a common position, and that has worked generally very successfully in the evaluation of the compounds over the last 10 years I have been involved in JECFA.

(Panel Reports, Annex G, para. 511)

473. The United States emphasizes the fact that the Panel consulted with the parties when it adopted the Experts Working Procedures and in the expert selection process.⁹⁷¹ We agree with the United States that consultation with the parties in the adoption of working procedures for selecting the experts and in the expert selection process is a means for ensuring that the parties' due process rights are respected. However, as we explained earlier, the obligation to afford the protection of due process to the parties is not circumscribed to the expert selection stage and does not end with the appointment of the experts. Due process protection continues to apply throughout the consultations with the experts. Thus, the fact that the Panel may have consulted with the parties in this case when preparing the Experts Working Procedures and in selecting the experts does not provide a basis for concluding that due process was also respected in the subsequent stages of the proceedings, including the consultations with the experts. Moreover, in the consultations that the Panel held with the parties, the European Communities repeatedly objected to the selection of experts affiliated with JECFA.⁹⁷²

474. The Panel additionally expressed the view that Drs. Boisseau and Boobis, by virtue of their work as scientists, could be relied upon to be objective in their assessment of critiques of their work, as well as of new scientific evidence that might require altering the conclusions of their prior work. During the interim review stage, the Panel responded to objections of the European Communities as follows:

[S]cientists would readily admit that science is constantly evolving and the fact that new studies are peer reviewed is evidence that assessing new ideas and findings is part of scientific work. Assuming that scientists may lack objectivity because they participated in the preparation and drafting of JECFA's risk assessments on the hormones at issue would call into question the whole principle of peer review.⁹⁷³

475. The Panel added:

The experts that the European Communities claims were defending their work acknowledge that the state of knowledge can evolve. ... The experts consulted by the Panel are used to considering and peer reviewing studies that go beyond what they have published themselves or perhaps even contradict them. In other words, they are not likely to feel any need to defend their own previous work results

⁹⁷¹United States' appellee's submission, para. 85.

⁹⁷²Panel Report, *US – Continued Suspension*, para. 7.79; Panel Report, *Canada – Continued Suspension*, para. 7.77 (referring to the European Communities' comments on the proposed experts of 16 January 2006).

⁹⁷³Panel Report, *US – Continued Suspension*, para. 6.22; Panel Report, *Canada – Continued Suspension*, para. 6.21.

in the light of new, convincing evidence or techniques that put such previous work into doubt.⁹⁷⁴

476. The European Communities argues that the principle of peer review is not found in any of the WTO agreements, and that scientific journals "require that new work submitted for publication must not be given for review by the same persons whose theories the submitted articles contest".⁹⁷⁵ The key question, the European Communities maintains, is "whether an expert that has been the author of a given report is impartial and independent to act as a 'peer' in 'reviewing' reports that explicitly criticise the report where the 'peer' is a co-author."⁹⁷⁶

477. We recognize that scientists will often be asked to review studies performed by other scientists and that the scientific community must constantly reassess theories in the light of scientific progress. However, as we pointed out above, the Panel did not simply ask Drs. Boisseau and Boobis about JECFA's work and risk assessments. In the consultations with experts, the Panel asked Drs. Boisseau and Boobis to evaluate the European Communities' risk assessment and they did so using JECFA's evaluations as a benchmark. This is problematic in this case because the European Communities' risk assessment called into question the validity of JECFA's evaluations and explicitly stated that it would not follow them. In the light of this, it was improper for the Panel to consult with Drs. Boisseau and Boobis, who were directly involved in JECFA's evaluations. The concerns raised in this situation are not addressed by the fact that scientists regularly conduct "peer reviews" or may recognize that science evolves. Nor are the concerns addressed by the Panel's explanation that JECFA's work is linked to Codex, which is expressly recognized by the *SPS Agreement* as having responsibilities for the "establishment of international standards, guidelines and recommendations".⁹⁷⁷

478. The Panel also referred to the presumption of consistency that applies to SPS measures based on international standards under Articles 3.1 and 3.2 of the *SPS Agreement* as an additional justification for its appointment of Drs. Boisseau and Boobis because of their involvement in the risk assessments underlying the international standards at issue in this case. However, we fail to see why the appointment of such experts would be justified in a case such as this one where the WTO Member adopts a higher level of protection than that reflected in the international standards, pursuant to Article 3.3. The Panel's view that it is consistent with JECFA's role in setting international standards "for the Panel to rely on experts who contributed in the preparation and drafting of JECFA's risk

⁹⁷⁴Panel Report, *US – Continued Suspension*, paras. 6.62 and 6.63; Panel Report, *Canada – Continued Suspension*, paras. 6.57 and 6.58.

⁹⁷⁵European Communities' appellant's submission, para. 199.

⁹⁷⁶*Ibid.*

⁹⁷⁷Panel Report, *US – Continued Suspension*, para. 6.22; Panel Report, *Canada – Continued Suspension*, para. 6.21.

assessments on the substances at issue"⁹⁷⁸ rather confirms our impression that the Panel improperly relied on Drs. Boisseau and Boobis to evaluate the European Communities' risk assessment against the evaluations conducted by JECFA.⁹⁷⁹

479. Accordingly, we consider that it was improper for the Panel to consult Drs. Boisseau and Boobis. We reiterate that our concerns do not relate to the qualifications of Drs. Boisseau and Boobis, who are highly recognized experts, nor do they relate to the fact that, as experts, they would have been expected to hold views on issues in their area of expertise. Rather, our concerns arise from their direct involvement in the risk assessments performed by JECFA for the hormones at issue in this dispute and from the particular role that JECFA's risk assessments, and the Codex standards adopted on the basis of those risk assessments, had in this case. As we noted earlier⁹⁸⁰, in its case before the Panel, the European Communities argued that there were limitations in JECFA's evaluation of oestradiol-17 β and that the evidence relied upon by JECFA in the evaluation of the other five hormones was outdated. The Panel, for its part, considered that the existence of an international standard established a presumption that the scientific evidence was not "insufficient" to perform a risk assessment within the meaning of Article 5.7 of the *SPS Agreement*.⁹⁸¹

480. We understand that panels often face practical difficulties in selecting experts who have the required level of expertise and whose selection is not objected to by the parties.⁹⁸² We do not wish to make the expert selection process more difficult than it may already be. However, experts consulted by a panel can have a decisive role in a case, especially when it involves highly complex scientific questions such as this one. The Panel in this case said "the role of the experts was to act as an 'interface' between the scientific evidence and the Panel, so as to allow it to perform its task as the trier of fact."⁹⁸³ Experts appointed by a panel can significantly influence the decision-making process. If a panel does not ensure that the requirements of independence and impartiality are respected in its

⁹⁷⁸Panel Report, *US – Continued Suspension*, para. 6.22; Panel Report, *Canada – Continued Suspension*, para. 6.21.

⁹⁷⁹Panel Report, *US – Continued Suspension*, para. 6.63; Panel Report, *Canada – Continued Suspension*, para. 6.58.

⁹⁸⁰See *supra*, para. 458.

⁹⁸¹See *supra*, para. 940.

⁹⁸²The Panel described some of the difficulties it encountered in this case:

The Panel wishes to highlight the challenges it encountered in selecting experts. There was a limited number of specialists suggested and actually available in each of the fields on which the Panel needed assistance and almost always one or more of the parties objected to that specialist. For example, only six of the identified available experts were deemed to have extensive expertise in risk analysis. All of these experts were objected to by at least one party.

(Panel Report, *US – Continued Suspension*, footnote 382 to para. 7.87; Panel Report, *Canada – Continued Suspension*, footnote 374 to para. 7.85)

⁹⁸³Panel Report, *US – Continued Suspension*, para. 6.72; Panel Report, *Canada – Continued Suspension*, para. 6.67.)

consultations with the experts, this can compromise the fairness of the proceedings and the impartiality of the decision-making. In these circumstances, the practical difficulties that a panel may encounter in selecting experts cannot displace the need to ensure that the consultations with the experts respect the parties' due process rights.

481. For these reasons, we consider that there was an objective basis to conclude that the institutional affiliation with JECFA of Drs. Boisseau and Boobis, and their participation in JECFA's evaluations of the six hormones at issue, was likely to affect or give rise to justifiable doubts as to their independence or impartiality given that the evaluations conducted by JECFA lie at the heart of the controversy between the parties. The appointment and consultations with Drs. Boisseau and Boobis compromised the adjudicative independence and impartiality of the Panel. Therefore, we find that the Panel infringed the European Communities' due process rights as a result of the Panel having consulted with Drs. Boisseau and Boobis as scientific experts.

482. Because the appointment and consultations with Drs. Boisseau and Boobis compromised the Panel's ability to act as an independent adjudicator, the Panel cannot be said to have made "an objective assessment of the matter" as required by Article 11 of the DSU. We recall that, in *US – Gambling*, the Appellate Body held that "as part of their duties, under Article 11 of the DSU, to 'make an objective assessment of the matter' before them, panels must ensure that the due process rights of parties to a dispute are respected."⁹⁸⁴ Consequently, we find that the Panel failed to comply with its duties under Article 11 of the DSU, as a result of the appointment and consultations with Drs. Boisseau and Boobis in the circumstances of this case.

483. The European Communities argues that, if we were to find that the Panel erred in relying on the advice of Drs. Boisseau and Boobis, we would have to reverse all of the Panel's findings under the *SPS Agreement*.⁹⁸⁵ At the oral hearing, the United States and Canada disagreed that this would be the necessary consequence of our making the finding requested by the European Communities.

484. Where a panel's ability to act as an independent adjudicator has been compromised, as we have found in this case, this raises serious issues as to whether the panel's findings may be sustained. We recall, moreover, that Drs. Boisseau and Boobis provided responses to the majority of questions posed by the Panel and the Panel relied extensively on their responses in its assessment of the consistency of Directive 2003/74/EC with Articles 5.1 and 5.7 of the *SPS Agreement*.⁹⁸⁶ Thus, the Panel's findings on Articles 5.1 and 5.7 of the *SPS Agreement* would be difficult to sustain upon

⁹⁸⁴ Appellate Body Report, *US – Gambling*, para. 273.

⁹⁸⁵ European Communities' appellant's submission, paras. 181, 182, and 212.

⁹⁸⁶ See *supra*, footnote 950.

exclusion of the testimony of Drs. Boisseau and Boobis, assuming that disentangling their testimony from the other elements of the Panel's analysis was possible. Although our finding on this issue could, by itself, lead to the invalidation of the Panel's findings under Articles 5.1 and 5.7 of the *SPS Agreement*, we nevertheless proceed to examine the other claims of error raised by the European Communities in respect of the Panel's assessment of the consistency of Directive 2003/74/EC with the *SPS Agreement*. The significance to the Panel's analysis of the testimony of Drs. Boisseau and Boobis will become more evident from our review of the Panel's findings under Articles 5.1 and 5.7 of the *SPS Agreement*.

VI. The Consistency with Article 5.1 of the *SPS Agreement* of the European Communities' Import Ban on Meat from Cattle Treated with Oestradiol-17 β for Growth-Promotion Purposes

A. Introduction

485. We turn next to the European Communities' appeal of the Panel's finding that the permanent ban on meat and meat products from cattle treated with oestradiol-17 β for growth-promotion purposes provided for in Directive 2003/74/EC does not meet the requirements of Article 5.1 of the *SPS Agreement*. Section B provides a summary of the European Communities' risk assessment in relation to oestradiol-17 β , which the European Communities contends brought it into compliance with the recommendations and rulings of the DSB in *EC – Hormones*. This is followed by a summary of the Panel's findings under Article 5.1 of the *SPS Agreement* in section C and of the claims and arguments raised on appeal in section D. We then analyze in section E the specific issues raised by the European Communities' appeal against the Panel's assessment of Directive 2003/74/EC under Article 5.1 of the *SPS Agreement*. Finally, our conclusions are set out in section F.

486. We recall that the Panel found that the European Communities' claim under Article 23.1, read together with Articles 22.8 and 3.7 of the DSU, was premised on the "*conformity* (presumed or actual) with the *SPS Agreement*"⁹⁸⁷ of Directive 2003/74/EC. This is because, in the Panel's view, the phrase "until such time as the measure found to be inconsistent ... has been removed" in Article 22.8 implies that what is to be achieved is not the removal of the measure, but actual compliance with the DSB's recommendations and rulings.⁹⁸⁸ For this reason, the Panel considered that it had to address the consistency of Directive 2003/74/EC with Articles 5.1 and 5.7 of the *SPS Agreement*.

⁹⁸⁷Panel Report, *US – Continued Suspension*, para. 7.272; Panel Report, *Canada – Continued Suspension*, para. 7.288. (original emphasis)

⁹⁸⁸Panel Report, *US – Continued Suspension*, para. 7.284; Panel Report, *Canada – Continued Suspension*, para. 7.300.

B. *The European Communities' Risk Assessment for Meat from Cattle Treated with Oestradiol-17 β*

487. We recall that, in *EC – Hormones*, the European Communities' import ban on meat and meat products from cattle treated with six hormones—oestradiol-17 β , testosterone, progesterone, trenbolone acetate, zeranol, and MGA—was found to be inconsistent with Article 5.1 of the *SPS Agreement*. The Appellate Body found that the scientific studies submitted by the European Communities in that dispute were not "sufficiently specific to the case at hand"⁹⁸⁹, because they were "general studies which do indeed show the existence of a general risk of cancer; but they do not focus on and do not address the particular kind of risk here at stake—the carcinogenic or genotoxic potential of the residues of those hormones found in meat derived from cattle to which the hormones had been administered for growth promotion purposes."⁹⁹⁰ For this reason, the Appellate Body concluded that "no risk assessment that reasonably support[ed] or warrant[ed] the import prohibition embodied in the [European Communities'] Directives was furnished to the Panel"⁹⁹¹, and accordingly found that the European Communities' import ban, imposed under Directive 96/22/EC, was not "based on" a risk assessment within the meaning of Article 5.1.

488. Following the adoption by the DSB of the Panel and Appellate Body Reports in *EC – Hormones*, the European Commission initiated and funded 17 scientific studies to evaluate the potential for adverse effects to human health from residues in bovine meat and meat products resulting from the use of oestradiol-17 β , progesterone, testosterone, zeranol, trenbolone acetate, and MGA in cattle for growth-promotion purposes. The results of these studies, as well as other publicly available information and data collected from international organizations such as Codex and JECFA were reviewed by the SCVPH.⁹⁹²

489. On 30 April 1999, the SCVPH published an Opinion entitled "Assessment of Potential Risks to Human Health from Hormone Residues in Bovine Meat and Meat Products"⁹⁹³ (the "1999 Opinion"). The 1999 Opinion found that "consumption of beef from hormone-treated non-pregnant cattle can result in excess exposure to oestrogens"⁹⁹⁴ and that the "toxicological issues of concern" arising from such excess exposure include "endocrine, developmental, immunological,

⁹⁸⁹Appellate Body Report, *EC – Hormones*, para. 200.

⁹⁹⁰*Ibid.*

⁹⁹¹*Ibid.*, para. 208.

⁹⁹²Panel Report, *US – Continued Suspension*, para. 2.3; Panel Report, *Canada – Continued Suspension*, para. 2.3.

⁹⁹³See *supra*, footnote 20.

⁹⁹⁴1999 Opinion, p. 36.

neurobiological, immunotoxic, genotoxic and carcinogenic effects."⁹⁹⁵ The 1999 Opinion reached the following conclusions in relation to the potential risks to human health from residues of oestradiol-17 β in bovine meat:

- In summary, 17 β -oestradiol has genotoxic⁹⁹⁶ potential. Evidence is building that oestrogens, most likely through oxidative metabolism to catechols and beyond to semiquinones and quinones, are DNA reactive and mutagenic.⁹⁹⁷
- ... in consideration of the recent data on the formation of genotoxic metabolites of oestradiol, suggesting that 17 β -oestradiol acts as complete carcinogen, by exerting tumour initiating and promoting effects, it has to be concluded, that no quantitative estimate of the risk related to residues in meat could be presented.⁹⁹⁸
- These observations strongly suggest that environmental 17 β -oestradiol can, even when administered at very low doses, modulate growth of children of both sexes and decrease the age when final height is achieved and puberty is reached.⁹⁹⁹
- ... it is suggested that environmental 17 β -oestradiol could exert deleterious effects on fertility in men and women, by acting through various, direct and indirect, mechanisms.¹⁰⁰⁰
- ... at relatively high doses oestradiol does produce a number of adverse effects on the immune system in humans e.g. allergy to topical oestradiol (Boehnke and Gall, 1996). The above findings while indicating a possible concern are insufficient to identify whether immune effects could occur in consumers from the ingestion of meat or meat products containing 17 β -oestradiol residues.¹⁰⁰¹

⁹⁹⁵1999 Opinion, p. 39.

⁹⁹⁶See *supra*, footnote 156.

⁹⁹⁷1999 Opinion, p. 41. Mutagenicity is the ability of a physical, chemical, or biological agent to induce heritable changes (mutations) in the genetic material in a cell as a consequence of alterations or loss of genes or chromosomes (or parts thereof). Panel Report, *US – Continued Suspension*, footnote 673 to para. 7.549; Panel Report, *Canada – Continued Suspension*, footnote 623 to para. 7.517 (referring to replies of the experts to Question 2 posed by the Panel to the scientific experts, Panel Reports, Annex D, paras. 34 and 55).

⁹⁹⁸1999 Opinion, p. 43.

⁹⁹⁹*Ibid.*

¹⁰⁰⁰*Ibid.*, p. 44.

¹⁰⁰¹*Ibid.*, p. 45.

490. The 1999 Opinion also reached the following conclusions as to the relevant risks to human health posed by the six hormones, and in particular by oestradiol-17 β :

- As concerns excess intake of hormone residues and their metabolites, and in view of the intrinsic properties of hormones and epidemiological findings, a risk to the consumer has been identified with different levels of conclusive evidence for the [six] hormones in question.
- In the case of oestradiol-17 β , there was a substantial body of recent evidence suggesting that it had to be considered as a complete carcinogen, as it exerted both tumour initiating and tumour promoting effects. The data available did not, however, allow a quantitative estimate of the risk.
- ...
- For all six hormones endocrine, developmental, immunological, neurobiological, immunotoxic, genotoxic and carcinogenic effects could be envisaged. Of the various susceptible risk groups, pre-pubertal children was the group of greatest concern. Again the available data did not enable a quantitative estimate of the risk.
- In view of the intrinsic properties of the hormones and in consideration of epidemiological findings, no threshold levels could be defined for any of the six substances.¹⁰⁰²

491. Subsequent to the adoption of the 1999 Opinion, additional scientific information was made available to the European Commission, in the form of a report by the Committee for Veterinary Medicinal Products ("CVMP") of the European Union (a subcommittee of the European Medicines Agency (EMA)), and a report by the United Kingdom's Veterinary Products Committee sub-group on the 1999 Opinion. At the request of the European Commission, the SCVPH examined this scientific information and, on 3 May 2000, issued a review of its 1999 Opinion in which it declined to alter the conclusions contained therein¹⁰⁰³ (the "2000 Opinion"). The SCVPH observed that "particularly in regards to the subject of estrogenic effects during [various stages of] development, there is no compelling evidence suggesting that these effects do not also occur at low doses."¹⁰⁰⁴ The 2000 Opinion concluded that recent scientific information "did not provide convincing data and arguments demanding

¹⁰⁰²Panel Report, *US – Continued Suspension*, para. 7.391; Panel Report, *Canada – Continued Suspension*, para. 7.388 (quoting 1999 Opinion, p. 73).

¹⁰⁰³See *supra*, footnote 21.

¹⁰⁰⁴2000 Opinion, p. 2.

revision of the conclusions drawn in the [1999 Opinion] on the potential risks to human health from hormone residues in bovine meat and meat products".¹⁰⁰⁵

492. On 10 April 2002, a second review of the 1999 Opinion was issued by the SCVPH¹⁰⁰⁶ (the "2002 Opinion"), on the basis of scientific data collected since the previous review. The scientific data reviewed by the SCVPH included the final results of all 17 studies that had been commissioned by the European Commission, as well as scientific data from relevant international organizations and other sources. The SCVPH considered that the data from the 17 scientific studies and recent scientific literature confirmed the validity of the 1999 Opinion, as reviewed in 2000, and that no amendments to those Opinions were justified.¹⁰⁰⁷ The 2002 Opinion also drew the following conclusions about the potential health risks posed by residues of oestradiol-17 β in meat:

- Ultra-sensitive methods to detect residues of hormones in animal tissues have become available, but need further validation.
- Studies on the metabolism of oestradiol-17 β in bovine species indicated the formation of lipoidal esters, disposed particularly in body fat. These lipoidal esters showed a high oral bioavailability¹⁰⁰⁸ in rodent experiments. Thus, the consequence of their consumption needed to be considered in a risk assessment.
- Experiments with heifers, one of the major target animal groups for the use of hormones, indicated a dose-dependent increase in residue levels of all hormones, particularly at the implantation sites. Misplaced implants and repeated implanting, which seemed to occur frequently, represented a considerable risk that highly contaminated meats could enter the food chain. ...
- Convincing data had been published confirming the mutagenic and genotoxic potential of oestradiol-17 β as a consequence of metabolic activation to reactive quinones. *In vitro*¹⁰⁰⁹ experiments indicated that oestrogenic compounds might alter the expression of an array of genes. Considering that endogenous oestrogens also

¹⁰⁰⁵Panel Report, *US – Continued Suspension*, para. 7.392; Panel Report, *Canada – Continued Suspension*, para. 7.389 (quoting 2000 Opinion, p. 4).

¹⁰⁰⁶See *supra*, footnote 22.

¹⁰⁰⁷Panel Report, *US – Continued Suspension*, para. 7.394; and Panel Report, *Canada – Continued Suspension*, para. 7.391 (referring to 2002 Opinion, pp. 21 and 22).

¹⁰⁰⁸Bioavailability refers to the capacity of a substance to enter the general blood circulation and to diffuse into the human or animal body, or the fraction of a dose of a substance that is available for systemic circulation. See Panel Report, *US – Continued Suspension*, footnote 508 to para. 7.393; and Panel Report, *Canada – Continued Suspension*, footnote 499 to para. 7.390 (referring to replies of the experts to Question 43 posed by the Panel to the scientific experts, Panel Reports, Annex D, paras. 344-357).

¹⁰⁰⁹See *supra*, footnote 365.

exert these effects, the data highlighted the diverse biological effects of this class of hormones.

...

- Epidemiological studies with opposite-sexed twins, suggest that the exposure of the female co-twin *in utero* to hormones results in an increased birth weight and consequently an increased adult breast cancer risk.¹⁰¹⁰

493. In light of the conclusions of the 1999, 2000, and 2002 Opinions, the European Communities adopted Directive 2003/74/EC on 22 September 2003¹⁰¹¹, which amended Directive 96/22/EC. Directive 2003/74/EC provides for the *permanent* prohibition on the importation of meat and meat products from animals treated with oestradiol-17 β for growth-promotion purposes, on the basis of the SCVPH assessment that "recent evidence suggests that [oestradiol-17 β] has to be considered as a complete carcinogen, as it exerts both tumour-initiating and tumour-promoting effects and that the data currently available do not make it possible to give a quantitative estimate of the risk."¹⁰¹² Directive 2003/74/EC also provides for a *provisional* ban on meat and meat products from cattle treated with progesterone, testosterone, zeranol, trenbolone acetate and MGA for growth-promoting purposes.

494. Before the Panel, the European Communities argued that the 1999, 2000, and 2002 Opinions, supported by the 17 studies conducted between 1998 and 2001, constitute the risk assessment upon which Directive 2003/74/EC is based.¹⁰¹³

C. *The Panel's Findings*

495. As noted earlier in section IV of this Report, the European Communities has challenged in these proceedings the continued application of the suspension of concessions by the United States and Canada subsequent to the notification of Directive 2003/74/EC. The European Communities argued, *inter alia*, that Article 22.8 of the DSU permits the application of the suspension of concessions and other obligations only until such time as the measure found to be inconsistent with a covered agreement has been removed, a condition that it claims was met with the adoption and notification of

¹⁰¹⁰Panel Report, *US – Continued Suspension*, para. 7.393; Panel Report, *Canada – Continued Suspension*, para. 7.390.

¹⁰¹¹See *supra*, footnote 5.

¹⁰¹²Panel Report, *US – Continued Suspension*, para. 7.395; Panel Report, *Canada – Continued Suspension*, para. 7.392 (referring to Directive 2003/74/EC).

¹⁰¹³Panel Report, *US – Continued Suspension*, para. 7.389; Panel Report, *Canada – Continued Suspension*, para. 7.386.

Directive 2003/74/EC.¹⁰¹⁴ According to the European Communities, the United States and Canada acted inconsistently with Article 23.1, read together with Articles 22.8 and 3.7 of the DSU, by failing to have recourse to, and abide by, the rules and procedures of the DSU subsequent to the adoption and notification to the DSB of Directive 2003/74/EC.

496. The Panel observed that the European Communities' claim under Article 22.8 of the DSU was premised on the European Communities' contention that Directive 2003/74/EC has brought its import ban on meat and meat products from cattle treated with hormones for growth-promotion purposes into compliance with the *SPS Agreement*. For this reason, the Panel considered that it had jurisdiction to "address the compatibility" of Directive 2003/74/EC with the *SPS Agreement* to the extent necessary to determine whether the "'measure found to be inconsistent' in the *EC – Hormones* case has been removed".¹⁰¹⁵

497. Turning to the allocation of the burden of proof, the Panel observed, first, that it was incumbent upon the European Communities as the complaining party to establish a *prima facie* case of a violation of Article 22.8 of the DSU. The Panel found that the European Communities had met this burden because of the presumption of good faith compliance that the Panel had previously found to apply in relation to the European Communities' implementing measure.¹⁰¹⁶ As a result, the burden shifted to the responding parties. The Panel found that the United States and Canada had sufficiently refuted, "in [their] first written submission[s] through positive evidence of breach of the *SPS Agreement*"¹⁰¹⁷ the European Communities' allegation that its implementing measure complied with the *SPS Agreement*. The Panel further stated that, "[i]n its subsequent submissions before the Panel, the European Communities responded to the allegations of violation made by [the United States and Canada]".¹⁰¹⁸ The Panel added that "[w]hile the presumptions based on good faith enjoyed by each party may have played a role in the burden of proof in the early stage of the Panel proceedings, it is the opinion of the Panel that they eventually 'neutralized' each other since each party also submitted evidence in support of its allegations."¹⁰¹⁹ The Panel ultimately concluded that "each party had to

¹⁰¹⁴We discuss the meaning of "removal" *supra*, section IV.D.

¹⁰¹⁵Panel Report, *US – Continued Suspension*, para. 7.375; Panel Report, *Canada – Continued Suspension*, para. 7.372.

¹⁰¹⁶Panel Report, *US – Continued Suspension*, para. 7.385; Panel Report, *Canada – Continued Suspension*, para. 7.382.

¹⁰¹⁷*Ibid.*

¹⁰¹⁸*Ibid.*

¹⁰¹⁹Panel Report, *US – Continued Suspension*, para. 7.386; Panel Report, *Canada – Continued Suspension*, para. 7.383.

prove its specific allegations in response to evidence submitted by the other party", and that it had "weigh[ed] all the evidence before it"¹⁰²⁰ in reaching its findings.

498. The Panel then explained that it needed to review Directive 2003/74/EC against: (a) the recommendations and rulings of the DSB in the *EC – Hormones* case and (b) the provisions with which the European Communities purports to comply as part of its claim of violation of Article 22.8 by the United States and Canada.¹⁰²¹ The Panel acknowledged that in a case such as this it would be difficult for the complainant to identify all the potential problems of incompatibility. At the same time, the Panel recognized that, in this case, where a finding of violation is conditional on the compliance of a measure of the complainant with the WTO agreements, difficulties could arise if the scope of review of that measure is defined only by the complainant. Indeed, the complainant could limit the scope of the panel's review to provisions with which it believes that its measure is most likely to be found compatible.¹⁰²² Under these circumstances, the Panel found it preferable, both from a legal and a practical point of view, to consider *all* the allegations and arguments raised by each party, as long as the other party had the opportunity to comment on those allegations and arguments. Accordingly, the Panel sought to "circumscribe" the scope of its review under the *SPS Agreement*¹⁰²³, on the basis of the claims and arguments raised by each party, and determined that it would review, to the extent necessary for assessing the European Communities' Article 22.8 claim, the "compatibility"¹⁰²⁴ of Directive 2003/74/EC with Articles 5.1, 5.2¹⁰²⁵, 5.7, and 3.3 of the *SPS Agreement*.

499. The Panel next outlined the standard that it would apply in reviewing the compatibility of Directive 2003/74/EC with those provisions. The Panel noted that the standard of review applicable to legal and factual issues regarding measures reviewed under the *SPS Agreement* is found in Article 11 of the DSU and explained that, as regards the assessment of the facts, this standard has been understood as requiring "neither *de novo review* as such, nor 'total deference', but rather the

¹⁰²⁰Panel Report, *US – Continued Suspension*, para. 7.386; Panel Report, *Canada – Continued Suspension*, para. 7.383.

¹⁰²¹Panel Report, *US – Continued Suspension*, para. 7.402; Panel Report, *Canada – Continued Suspension*, para. 7.399.

¹⁰²²Panel Report, *US – Continued Suspension*, para. 7.403; Panel Report, *Canada – Continued Suspension*, para. 7.400.

¹⁰²³Panel Report, *US – Continued Suspension*, para. 7.398; Panel Report, *Canada – Continued Suspension*, para. 7.395.

¹⁰²⁴Panel Report, *US – Continued Suspension*, para. 7.411; Panel Report, *Canada – Continued Suspension*, para. 7.402.

¹⁰²⁵Only the United States argued that Directive 2003/74/EC was inconsistent with Article 5.2 of the *SPS Agreement*. Accordingly, the Panel Report in *Canada – Continued Suspension* does not address the consistency of Directive 2003/74/EC with this provision.

'objective assessment of the facts'".¹⁰²⁶ According to the Panel, this corresponds to a duty to "consider the evidence presented to us and to make factual findings on the basis of that evidence".¹⁰²⁷ However, the Panel retained the discretion to "decide which evidence [it chose] to utilise in making findings"¹⁰²⁸ and to decide "which [experts'] statements [were] useful to refer to explicitly as long as [it did] not deliberately disregard or distort evidence."¹⁰²⁹

500. The Panel recalled that it had consulted six scientific experts individually, "in order to obtain a more complete picture both of mainstream scientific opinion and of any divergent views."¹⁰³⁰ The Panel explained that, while it generally followed the opinion of a majority of experts that had expressed concurrent views on the scientific questions before it, sometimes divergences of views rendered this approach impracticable. In these circumstances, the Panel accepted the position(s) that it considered most specific to the question at issue, or best supported by arguments and evidence. The experts were also made aware of their role—which was, *inter alia*, to present scientific issues to the members of the Panel in a way that could be understood by them—and of the role of the Panel in the WTO dispute settlement system—which includes being the trier of facts. In assessing the scientific advice received from the experts, the Panel said it fully took into account the comments of the parties, when appropriate. The Panel also recalled the approach followed by the Appellate Body in *Japan – Apples*, which required it to address the compatibility of Directive 2003/74/EC with respect to each of the six hormones covered by the measure. Nevertheless, where the evidence was similar for all hormones, or where information was not provided in relation to each hormone, the Panel addressed the hormones collectively.¹⁰³¹

¹⁰²⁶Panel Report, *US – Continued Suspension*, para. 7.414; Panel Report, *Canada – Continued Suspension*, para. 7.405 (quoting Appellate Body Report, *EC – Hormones*, para. 117).

¹⁰²⁷Panel Report, *US – Continued Suspension*, para. 7.416; Panel Report, *Canada – Continued Suspension*, para. 7.407.

¹⁰²⁸*Ibid.* (referring to Appellate Body Report, *EC – Hormones*, para. 135).

¹⁰²⁹*Ibid.* (referring to Appellate Body Report, *EC – Hormones*, para. 138).

¹⁰³⁰Panel Report, *US – Continued Suspension*, para. 7.418; Panel Report, *Canada – Continued Suspension*, para. 7.409. The Panel noted that, in some circumstances, only one or two experts have expressed their views on an issue. Sometimes these views were similar or complemented each other. (Panel Report, *US – Continued Suspension*, para. 7.420; Panel Report, *Canada – Continued Suspension*, para. 7.411) In other circumstances, a larger number of experts expressed opinions and, sometimes, they expressed diverging opinions.

¹⁰³¹Panel Report, *US – Continued Suspension*, paras. 7.420-7.422; Panel Report, *Canada – Continued Suspension*, paras. 7.411-7.413.

501. Next, the Panel found that Directive 2003/74/EC is an SPS measure within the meaning of paragraph 1 of Annex A to the *SPS Agreement*, and particularly item (b).¹⁰³² The Panel then sought to determine whether the permanent ban on meat and meat products treated with oestradiol-17 β for growth-promoting purposes provided by Directive 2003/74/EC was based on a risk assessment within the meaning of Articles 5.1 of the *SPS Agreement*. The European Communities argued that the three Opinions issued by the SCVPH, supported by the 17 studies conducted between 1998-2001, constituted a risk assessment within the meaning of Article 5.1, and that the permanent ban on meat and meat products from cattle treated with oestradiol-17 β was "based on" such risk assessment.

502. At the outset of its analysis, the Panel noted that, in order to determine whether the SCVPH Opinions constituted a risk assessment within the meaning of Article 5.1 of the *SPS Agreement*, it would have to examine whether the SCVPH Opinions: (1) took into account risk assessment techniques of the relevant international organizations; (2) took into account the factors listed in Article 5.2 of the *SPS Agreement*¹⁰³³; (3) satisfied the definition of "risk assessment" contained in Annex A, paragraph 4, of the *SPS Agreement*; and (4) whether the conclusions in the SCVPH Opinions are supported by the scientific evidence evaluated.¹⁰³⁴

503. Relying on the reasoning of the panel in *Japan – Apples*, the Panel found that Article 5.1 of the *SPS Agreement* does not require compliance with the risk assessment techniques developed by international organizations, insofar as it requires that such techniques are "taken into account" by the risk assessor. The Panel observed that, although the SCVPH Opinions did not strictly follow the

¹⁰³²Panel Report, *US – Continued Suspension*, para. 7.434; Panel Report, *Canada – Continued Suspension*, para. 7.425. Annex A(1)(b) of the *SPS Agreement* reads:

1. Sanitary or phytosanitary measure – Any measure applied:

...

(b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs[.]

...

Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including *inter alia* end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety.

None of the parties has argued that Directive 2003/74/EC is not an SPS measure.

¹⁰³³Canada did not allege that Directive 2003/74/EC was inconsistent with Article 5.2 of the *SPS Agreement*, and therefore this element was only examined in the case involving the United States. (See *supra*, footnote 1025)

¹⁰³⁴Panel Report, *US – Continued Suspension*, para. 7.445; Panel Report, *Canada – Continued Suspension*, para. 7.434.

CODEX and JECFA risk assessment guidelines, the European Communities "was aware of" and "considered" such guidelines when preparing the SCVPH Opinions, and therefore had taken them into account within the meaning of Article 5.1.¹⁰³⁵

504. The Panel in the case involving the United States also examined whether the SCVPH Opinions took into account the factors listed in Article 5.2.¹⁰³⁶ The Panel noted that the United States alleged that the European Communities had failed to take into account two of the specific elements listed in Article 5.2, namely: (i) the available scientific information; and (ii) the relevant inspection, sampling, and testing methods.¹⁰³⁷ In relation to the first element, the Panel concluded that the SCVPH Opinions had specifically addressed evidence available with respect to bioavailability, susceptibility of sensitive populations, and DNA adducts and DNA damages, and took into account the very scientific studies that the United States alleged were not considered.¹⁰³⁸ Regarding the second element, the Panel found that the European Communities had compiled a "Working Document"¹⁰³⁹ recording visits to United States' regulatory agencies, on-site inspections, and data concerning failures in the United States' inspection regime. The Panel also observed that a lengthy section of the 1999 Opinion is dedicated to discussing the relevant inspection, sampling, and testing methods. For these reasons, the Panel concluded that the European Communities had taken into account both the available scientific information and the relevant inspection, sampling and testing methods in preparing the SCVPH Opinions, as required by Article 5.2 of the *SPS Agreement*.¹⁰⁴⁰

505. Next, the Panel examined whether the SCVPH Opinions satisfied the definition of "risk assessment" contained in paragraph 4 of Annex A of the *SPS Agreement*.¹⁰⁴¹ Recalling the Appellate Body's jurisprudence from *EC – Hormones* and *Australia – Salmon*, the Panel stated that the definition of a risk assessment in paragraph 4 of Annex A required WTO Members to: (a) identify the additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs; (b) identify any possible adverse effect on human or animal health; and (c) evaluate the potential for that adverse effect to arise from the presence of the identified additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.¹⁰⁴²

¹⁰³⁵Panel Report, *US – Continued Suspension*, para. 7.469; Panel Report, *Canada – Continued Suspension*, para. 7.459.

¹⁰³⁶This section does not appear in the Panel Report in the case against Canada because Canada did not raise Article 5.2. (See *supra*, footnote 1025)

¹⁰³⁷Panel Report, *US – Continued Suspension*, para. 7.479.

¹⁰³⁸*Ibid.*, para. 7.482.

¹⁰³⁹*Ibid.*, para. 7.483.

¹⁰⁴⁰*Ibid.*, paras. 7.483 and 7.484.

¹⁰⁴¹See *infra*, para. 525.

¹⁰⁴²Panel Report, *US – Continued Suspension*, para. 7.507; Panel Report, *Canada – Continued Suspension*, para. 7.479.

506. The Panel found that the SCVPH Opinions satisfied the first and second requirements of the definition of risk assessment because they sufficiently identified both the contaminant (oestradiol-17 β) and the food (meat and meat products) at issue, as well as the possible adverse effects on human or animal health (neurobiological, developmental, reproductive, and immunological effects; and immunotoxicity, genotoxicity and carcinogenicity).¹⁰⁴³ However, the Panel found that the European Communities failed to evaluate specifically the third requirement, that is, the possibility that the identified adverse effects "came into being, originated, or resulted"¹⁰⁴⁴ from the presence of residues of oestradiol-17 β in meat or meat products as a result of the administration of that hormone to cattle for growth-promoting purposes. The Panel gave the following reasons for its decision.

507. First, the Panel rejected the European Communities' argument that the definition of "risk assessment" in Article 5 and Annex A of the *SPS Agreement* also included a "risk management" component, in which the WTO Member concerned "weigh[ed] policy alternatives in the light of the results of the risk assessment and, if required, select[ed] and implement[ed] appropriate control options, including regulatory measures."¹⁰⁴⁵ The Panel took note of the Appellate Body's finding that a risk assessment can take into account "matters not susceptible of quantitative analysis by the empirical or experimental laboratory methods commonly associated with the physical sciences".¹⁰⁴⁶ After discussing the Appellate Body's decision in *EC – Hormones*, the Panel reasoned that there is no textual basis in the *SPS Agreement* to support the inclusion of a "risk management" component in the definition of risk assessment.¹⁰⁴⁷

508. Secondly, the Panel "asked the experts whether the [SCVPH] Opinions identified the potential for adverse effects on human health, including the carcinogenic or genotoxic potential, of the residues of oestradiol-17 β 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."¹⁰⁴⁸ The Panel observed, in this regard, that four of the experts concurred that the scientific evidence adduced in

¹⁰⁴³Panel Report, *US – Continued Suspension*, para. 7.508; Panel Report, *Canada – Continued Suspension*, para. 7.480.

¹⁰⁴⁴Panel Report, *US – Continued Suspension*, para. 7.513; Panel Report, *Canada – Continued Suspension*, para. 7.485.

¹⁰⁴⁵Panel Report, *US – Continued Suspension*, para. 7.517; Panel Report, *Canada – Continued Suspension*, para. 7.489. (footnote omitted)

¹⁰⁴⁶Panel Report, *US – Continued Suspension*, para. 7.520; Panel Report, *Canada – Continued Suspension*, para. 7.492 (referring to Appellate Body Report, *EC – Hormones*, para. 187).

¹⁰⁴⁷Panel Report, *US – Continued Suspension*, paras. 7.519 and 7.520; Panel Report, *Canada – Continued Suspension*, paras. 7.491 and 7.492 (referring to Appellate Body Report, *EC – Hormones*, paras. 181 and 187).

¹⁰⁴⁸Panel Report, *US – Continued Suspension*, para. 7.521; Panel Report, *Canada – Continued Suspension*, para. 7.493 (referring to replies to Questions posed by the Panel to the scientific experts, Panel Reports, Annex D, para. 180).

relation to the possibility that carcinogenic or genotoxic effects would result from consumption of meat treated with oestradiol-17 β was either missing or insufficient.¹⁰⁴⁹ To the extent that the European Communities argued 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.¹⁰⁵⁰ The Panel then itself "looked at the Opinions and found statements that indicate that specific studies on the potential for the adverse health effects identified by the European Communities to arise from consumption of meat and meat products from cattle treated with oestradiol-17 β for growth promotion purposes were not conducted."¹⁰⁵¹

509. The Panel concluded:

All of the statements of the experts, and indeed statements from the Opinions, indicate that the European Communities 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 β as a 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 β as a result of the cattle being treated with the hormone for growth promotion purposes.¹⁰⁵²

¹⁰⁴⁹Panel Report, *US – Continued Suspension*, paras. 7.522-7.525; Panel Report, *Canada – Continued Suspension*, paras. 7.494-7.497 (referring to replies of Drs. Boobis, Guttenplan, Boisseau, and Cogliano to Questions posed by the Panel to the scientific experts, Panel Reports, Annex D, paras. 144, 145, 132, and 180, respectively).

¹⁰⁵⁰Panel Report, *US – Continued Suspension*, para. 7.529; Panel Report, *Canada – Continued Suspension*, para. 7.501 (referring to replies to Question 56 posed by the Panel to the scientific experts, Panel Reports, Annex D, paras. 422-431).

¹⁰⁵¹Panel Report, *US – Continued Suspension*, para. 7.531; Panel Report, *Canada – Continued Suspension*, para. 7.503. The Panel noted that the 1999 Opinion looked at three main areas of potential adverse effects: developmental effects on different stages of life; the relationship between oestrogens and cancer; and the effect of sex hormones on the immune system. (Panel Report, *US – Continued Suspension*, para. 7.532; Panel Report, *Canada – Continued Suspension*, para. 7.504)

¹⁰⁵²Panel Report, *US – Continued Suspension*, para. 7.537; Panel Report, *Canada – Continued Suspension*, para. 7.509.

510. Despite its finding, the Panel proceeded to examine the fourth element of the test that it had set out to determine whether the SCVPH met the definition of "risk assessment", that is, whether the conclusions of the SCVPH Opinions were sufficiently supported by the scientific evidence evaluated. On the basis of the opinions of the experts consulted and its own review of the SCVPH Opinions, the Panel found that the scientific evidence referred to in the SCVPH Opinions did not support the conclusion that the genotoxicity of oestradiol-17 β has been demonstrated and that residues of oestradiol-17 β in meat and meat products lead to increased risk of cancer or adverse immunological and developmental effects.¹⁰⁵³

511. Accordingly, the Panel concluded that the "[SCVPH] Opinions do not constitute a risk assessment because the Opinions do not satisfy the definition of a risk assessment contained in Annex A(4) second sentence and because the scientific evidence referred to in the Opinions does not support the conclusions therein".¹⁰⁵⁴ As a consequence of this finding, the Panel also found that the permanent ban on meat and meat products treated with oestradiol-17 β for growth-promoting purposes is not a measure "based on" a risk assessment within the meaning of Article 5.1 of the *SPS Agreement*.¹⁰⁵⁵ Therefore, the Panel concluded that "the [European Communities'] implementing measure on oestradiol-17 β is not compatible with Article 5.1 of the *SPS Agreement*."¹⁰⁵⁶

D. *Claims and Arguments on Appeal*

512. The European Communities challenges on appeal several aspects of the Panel's assessment of Directive 2003/74/EC under Article 5.1 of the *SPS Agreement*. First, the European Communities argues that the Panel erred in its interpretation of Article 5.1, as informed by Article 5.2, of the *SPS Agreement*, by excluding from the scope of its analysis arguments and evidence concerning the abusive use and difficulties of control in the administration of hormones to cattle for growth promotion.¹⁰⁵⁷ Secondly, the European Communities submits that the Panel erred in finding that the European Communities failed to evaluate specifically the risks arising from residues of oestradiol-17 β in bovine meat treated with this hormone for growth-promoting purposes.¹⁰⁵⁸ Thirdly, the European Communities alleges that the Panel erred in interpreting the definition of a risk assessment in

¹⁰⁵³Panel Report, *US – Continued Suspension*, para. 7.572; Panel Report, *Canada – Continued Suspension*, para. 7.540.

¹⁰⁵⁴Panel Report, *US – Continued Suspension*, para. 7.578; Panel Report, *Canada – Continued Suspension*, para. 7.548.

¹⁰⁵⁵*Ibid.*

¹⁰⁵⁶Panel Report, *US – Continued Suspension*, para. 7.579; Panel Report, *Canada – Continued Suspension*, para. 7.549.

¹⁰⁵⁷European Communities' appellant's submission, paras. 331 and 332.

¹⁰⁵⁸*Ibid.*, para. 343.

paragraph 4 of Annex A of the *SPS Agreement* as requiring the quantification of the risks arising from the consumption of residues of oestradiol-17 β in bovine meat.¹⁰⁵⁹

513. The European Communities also argues that the Panel erroneously allocated the burden of proof under Article 5.1 of the *SPS Agreement*, when it "shift[ed] the burden of proof to the European Communities without first examining, provision by provision under the *SPS Agreement* as required by the Appellate Body, whether the arguments of the United States and Canada had sufficient merits to shift the burden of proof back to the European Communities."¹⁰⁶⁰

514. Finally, the European Communities charges the Panel with failing to conduct an objective assessment of the facts of the case, as required by Article 11 of the DSU, in reaching its finding under Article 5.1 of the *SPS Agreement*. According to the European Communities, the Panel applied an improper standard of review to the evidence before it, by seeking to determine "the correct scientific conclusions"¹⁰⁶¹ as to the risks arising from the hormones at issue, even though Members are entitled to rely on divergent opinions coming from qualified and respected sources. Instead, the appropriate standard of review required the Panel to determine whether there was any "reasonable scientific basis"¹⁰⁶² for the European Communities' measure, while respecting the "important and autonomous" right of Members to set their level of SPS protection.¹⁰⁶³ The European Communities submits that a panel should not substitute its scientific judgement for that of the Member taking the measure and should recognize the significance of "genuine and legitimate scientific controversy".¹⁰⁶⁴ The European Communities challenges the Panel's examination of three distinct aspects of the European Communities' risk assessment of oestradiol-17 β : (i) the risks arising from exposure to hormones from multiple endogenous and exogenous sources¹⁰⁶⁵; (ii) actual or potential genotoxicity of oestradiol-17 β ¹⁰⁶⁶; and (iii) specificity or direct causality in the demonstration of risks arising from the consumption of bovine meat containing residues of oestradiol-17 β as a result of cattle being treated with this substance for growth promotion.¹⁰⁶⁷

515. The United States considers that the Panel did not err in finding that the European Communities' permanent ban on oestradiol-17 β was not based on a risk assessment within the meaning of Article 5.1 of the *SPS Agreement*. According to the United States, the Panel did not

¹⁰⁵⁹European Communities' appellant's submission, para. 355.

¹⁰⁶⁰*Ibid.*, para. 294.

¹⁰⁶¹*Ibid.*, para. 240.

¹⁰⁶²*Ibid.*, para. 243.

¹⁰⁶³*Ibid.*, para. 222 (quoting Appellate Body Report, *EC – Hormones*, para. 172). (emphasis omitted)

¹⁰⁶⁴*Ibid.*, para. 248.

¹⁰⁶⁵*Ibid.*, para. 249.

¹⁰⁶⁶*Ibid.*, paras. 250-258.

¹⁰⁶⁷*Ibid.*, paras. 259-270.

misinterpret Article 5.1 by excluding from its analysis evidence regarding misuse or abuse in the administration of oestradiol-17 β . Rather, the Panel "fully appreciated"¹⁰⁶⁸ the significance of the European Communities' assertion that misuse or abuse in the administration of oestradiol-17 β could add to the particular risk identified, but correctly held that those risks would only be relevant had the European Communities succeeded in demonstrating that a specific risk arose from residues of oestradiol-17 β in meat. With respect to the European Communities' allegation that the Panel erred in finding that it had failed to evaluate specifically the particular risks at issue, the United States maintains that the Panel's specificity requirement is based on a "careful tracing"¹⁰⁶⁹ of the Appellate Body's jurisprudence on Article 5.1, and that the evidentiary record before the Panel supported its conclusion that the European Communities "identified only 'general risks' and failed to address the specific risk required by the *SPS Agreement*."¹⁰⁷⁰ The United States argues that "one expert's statement, divorced from the rest of the evidentiary record"¹⁰⁷¹ is not sufficient to demonstrate that the European Communities evaluated the specific risk at issue. The United States also dismisses the European Communities' allegation that the Panel required the quantification of risks, because the Panel did not preclude a qualitative demonstration of risks. The Panel's reference to the potential occurrence of adverse effects focused instead on "whether the [European Communities'] purported risk assessment appeared to be 'sufficiently specific to the case at hand.'"¹⁰⁷²

516. Furthermore, the United States maintains that the Panel did not err in its allocation of the burden of proof under Article 5.1. The Panel was correct in allocating the initial burden of proving consistency with Article 5.1 to the European Communities, because its claim under Article 22.8 of the DSU was premised on an allegation of consistency of Directive 2003/74/EC. Having found that the European Communities had met this burden, the Panel shifted the burden of proof to the United States, and correctly found that the United States had rebutted the European Communities' allegation of consistency "by submitting positive evidence that demonstrated a breach of the *SPS Agreement* by the [European Communities]."¹⁰⁷³ As a result, the burden of proof "shifted back and forth between the parties"¹⁰⁷⁴ and the Panel rightly "followed the practice of other panels to weigh all the evidence before it."¹⁰⁷⁵

517. Finally, the United States rejects the European Communities' contention that the Panel failed to conduct an objective assessment of the matter in its appreciation of the evidence. The United

¹⁰⁶⁸United States' appellee's submission, para. 54.

¹⁰⁶⁹*Ibid.*, para. 57.

¹⁰⁷⁰*Ibid.*, para. 61.

¹⁰⁷¹*Ibid.*, para. 60.

¹⁰⁷²*Ibid.*, para. 64 (quoting Appellate Body Report, *EC – Hormones*, para. 200).

¹⁰⁷³*Ibid.*, para. 93.

¹⁰⁷⁴*Ibid.*, para. 94.

¹⁰⁷⁵*Ibid.* (quoting Panel Report, *US – Continued Suspension*, para. 7.386).

States submits that the more deferential "reasonableness" standard articulated by the European Communities for disputes under Article 5.1 has been rejected by the Appellate Body in *EC – Hormones* because it finds no support in the text of the *SPS Agreement* and "conflates the concept of 'standard of review' and the application of law to facts."¹⁰⁷⁶ Under the "objective assessment of the facts" standard that applies to disputes under the *SPS Agreement*, panels retain a margin of discretion as the triers of facts, and may properly "determine that certain elements of evidence should be accorded more weight than other elements."¹⁰⁷⁷ For the United States, the Panel's exercise of judgement in evaluating the evidence was "part and parcel"¹⁰⁷⁸ of its duty to make an objective assessment of the facts. Therefore, the Panel's findings in relation to the risks arising from exposure to hormone residues from multiple sources, the actual or potential genotoxicity of oestradiol-17 β , the specificity of the risk assessment, and the relevance of misuse and abuse in a risk assessment, were all within the bounds of the Panel's discretion as the trier of facts.

518. Canada submits that the Panel did not err in its interpretation of Article 5.1, as informed by Article 5.2, of the *SPS Agreement*. Canada argues that the Panel did not ignore evidence related to misuse and abuse in the administration of hormones in its analysis, but rather correctly considered that such evidence was not "material"¹⁰⁷⁹ to its analysis, having found earlier that the European Communities had failed to demonstrate specifically the possibility of adverse effects arising from the consumption of bovine meat containing residues of oestradiol-17 β . Canada additionally asserts that the Panel correctly held that the European Communities' risk assessment was not sufficiently specific to the particular risks at issue. The European Communities' assertion that the genotoxicity of oestradiol-17 β did not make it possible to perform a quantitative risk assessment is unsubstantiated by the evidence, because "the fact that a hormone may be an *in vitro* genotoxin does not mean that it is an *in vivo* genotoxin."¹⁰⁸⁰ Canada considers that the Panel had a "solid basis" for finding that the risk assessment was not sufficiently specific to the risk, because the scientific experts assisting the Panel "indicat[ed] very clearly that the [European Communities] did not have scientific evidence to support the assertion of the specific risk."¹⁰⁸¹ Canada also rejects the European Communities' allegation that the Panel erred in requiring a quantitative analysis of risk. According to Canada, the evidence upon which the European Communities' risk assessment relies does not contain either a qualitative or a quantitative analysis of risk, because the European Communities has offered no evidence demonstrating the genotoxicity of oestradiol-17 β *in vivo*.

¹⁰⁷⁶United States' appellee's submission, para. 39.

¹⁰⁷⁷*Ibid.*, para. 42 (quoting Appellate Body Report, *Japan – Apples*, para. 221).

¹⁰⁷⁸*Ibid.*, para. 47.

¹⁰⁷⁹Canada's appellee's submission, para. 88.

¹⁰⁸⁰*Ibid.*, para. 95.

¹⁰⁸¹*Ibid.*, para. 99.

519. Canada contends, moreover, that the Panel did not fail to conduct an objective assessment of the matter in reaching its finding under Article 5.1 of the *SPS Agreement*. As the trier of facts, the Panel retained the discretion "to give greater weight to advice of certain experts over that of others" and was not required to "treat all advice received from the experts on an equal footing."¹⁰⁸² Canada submits that the European Communities has failed to demonstrate that the Panel exceeded the bounds of its discretion in its analysis of the evidence on multiple exposure, genotoxicity, and specificity or direct causality.

520. Australia agrees with the European Communities' argument that the Panel erred in the standard of review that it applied in its assessment under Article 5.1 of the *SPS Agreement*. Australia submits that the standard of review applicable under Article 5.1 required the Panel to accord "considerable deference (but not total deference)"¹⁰⁸³ to a Member's risk assessment, and therefore the Panel should have focused on "whether the European Communities' risk assessment represented an objective and credible view"¹⁰⁸⁴ from a qualified and respected source.

521. New Zealand disagrees with the European Communities' claims that the Panel erred in its assessment of Directive 2003/74/EC under Article 5.1 of the *SPS Agreement*. In New Zealand's view, the Panel's conclusion that the permanent ban on oestradiol-17 β provided in Directive 2003/74/EC was not based on a risk assessment under Article 5.1 was supported by an exhaustive review of all the scientific evidence, drawing upon the expertise and knowledge of a group of eminent scientific and technical experts.¹⁰⁸⁵

E. *The Panel's Assessment of Directive 2003/74/EC under Article 5.1 of the SPS Agreement*

1. General Disciplines Applicable to the Adoption of an SPS Measure

522. The *SPS Agreement* recognizes the right of WTO Members to take measures necessary to protect human, animal or plant life or health. The right to take a protective measure must be exercised consistently with a series of obligations that are set forth in that Agreement, and that seek to ensure that such measures are properly justified.¹⁰⁸⁶

¹⁰⁸²Canada's appellee's submission, para. 73.

¹⁰⁸³Australia's third participant's submission, para. 36.

¹⁰⁸⁴*Ibid.*, para. 42.

¹⁰⁸⁵New Zealand's third participant's submission, para. 3.47.

¹⁰⁸⁶See the first Recital of the Preamble of the *SPS Agreement*. Article 2.3 of the *SPS Agreement* also provides that "Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members" and that SPS measures "shall not be applied in a manner which would constitute a disguised restriction on international trade."

523. There are several concepts that are defined in the *SPS Agreement* and that describe aspects of a WTO Member's decision-making process when taking an SPS measure. The "appropriate level of protection" is defined in paragraph 5 of Annex A to the *SPS Agreement* as "[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." It is the "prerogative"¹⁰⁸⁷ of a WTO Member to determine the level of protection that it deems appropriate.¹⁰⁸⁸ The SPS measure is the "instrument" chosen by the WTO Member to implement its sanitary or phytosanitary objective.¹⁰⁸⁹ Based on the wording of Article 5.6 of the *SPS Agreement*, the Appellate Body has explained that the "determination of the level of protection is an element in the decision-making process which logically precedes and is separate from the establishment or maintenance of the SPS measure".¹⁰⁹⁰ In other words, the appropriate level of protection determines the SPS measure to be introduced or maintained, rather than the appropriate level of protection being determined by the SPS measure.¹⁰⁹¹ The Appellate Body has also found that "the *SPS Agreement* contains an implicit obligation to determine the appropriate level of protection."¹⁰⁹² Although it need not be determined in quantitative terms, the level of protection cannot be determined "with such vagueness or equivocation that the application of the relevant provisions of the *SPS Agreement* ... becomes impossible".¹⁰⁹³

524. Another important aspect of the decision-making process is the "risk assessment". Pursuant to Article 5.1 of the *SPS Agreement*, an SPS measure must be "based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health". Under Article 5.7 of the *SPS Agreement*, WTO Members are also allowed to take an SPS measure, on a provisional basis, where certain conditions are fulfilled, including where the relevant scientific evidence is insufficient to perform a risk assessment. We examine Article 5.7 in more detail in section VII.

¹⁰⁸⁷ Appellate Body Report, *Australia – Salmon*, para. 199. (emphasis omitted)

¹⁰⁸⁸ Although it is for a WTO Member to choose its level of protection, the *SPS Agreement* provides for disciplines that a Member must respect when it has done so. Pursuant to Article 5.5, a WTO Member "shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade." Article 5.6 states that Members "shall ensure that [SPS] measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility". In addition, Article 5.4 provides that "Members should, when determining the appropriate level of sanitary or phytosanitary protection, take into account the objective of minimizing negative trade effects."

¹⁰⁸⁹ Appellate Body Report, *Australia – Salmon*, para. 200. (emphasis omitted)

¹⁰⁹⁰ *Ibid.*, para. 203. (emphasis omitted)

¹⁰⁹¹ *Ibid.*, para. 206.

¹⁰⁹² *Ibid.*

¹⁰⁹³ *Ibid.*, para. 203.

525. A "risk assessment" is defined in paragraph 4 of Annex A to the *SPS Agreement* as:

The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.

526. Article 5.1 is a "specific application of the basic obligations contained in Article 2.2 of the *SPS Agreement*."¹⁰⁹⁴ Article 2.2 focuses on the need for an SPS measure to be based on scientific principles and sufficient scientific evidence. It provides:

Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5.

The Appellate Body has observed that "Articles 2.2 and 5.1 should constantly be read together" because "Article 2.2 informs Articles 5.1: the elements that define the basic obligation set out in Article 2.2 impart meaning to Article 5.1."¹⁰⁹⁵

527. A list of factors that must be taken into account in a risk assessment is provided in Article 5.2. The list begins with "available scientific evidence" and also includes: "relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment." In *EC – Hormones*, the panel described a "risk assessment" as a "scientific process aimed at establishing the scientific basis" for the SPS measure.¹⁰⁹⁶ The Appellate Body understood the panel to refer to "a process characterized by systematic, disciplined and objective enquiry and analysis, that is, a mode of studying and sorting out facts and opinions".¹⁰⁹⁷ Science therefore plays a central role in a risk assessment. However, the Appellate Body has cautioned against taking too narrow an approach to a risk assessment:

It is essential to bear in mind that the risk that is to be evaluated in a risk assessment under Article 5.1 is not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist, in other words, the

¹⁰⁹⁴ Appellate Body Report, *EC – Hormones*, para. 180.

¹⁰⁹⁵ *Ibid.*

¹⁰⁹⁶ *Ibid.*, para. 187 (quoting Panel Report, *EC – Hormones (US)*, para. 8.107; and Panel Report, *EC – Hormones (Canada)*, para. 8.110).

¹⁰⁹⁷ *Ibid.*, para. 187.

actual potential for adverse effects on human health in the real world where people live and work and die.¹⁰⁹⁸

528. As we noted earlier, Article 5.1 requires that SPS measures be "based on" a risk assessment. This does not mean that the SPS measures have to "conform to" the risk assessment. Instead, "the results of the risk assessment must sufficiently warrant—that is to say, reasonably support—the SPS measure at stake".¹⁰⁹⁹ Put differently, there must be a "rational relationship" between the SPS measure and the risk assessment.¹¹⁰⁰

529. Moreover, the risk assessment need not "come to a monolithic conclusion that coincides with the scientific conclusion or view implicit in the SPS measure", nor does the risk assessment have to "embody only the view of a majority of the relevant scientific community."¹¹⁰¹ While recognizing that, in most cases, WTO Members "tend to base their legislative and administrative measures on 'mainstream' scientific opinion", the Appellate Body has observed that, "[i]n other cases, equally responsible and representative governments may act in good faith on the basis of what, at a given time, may be a divergent opinion coming from qualified and respected sources."¹¹⁰² The Appellate Body added that an approach based on a divergent opinion from a qualified and respected source, "does not necessarily signal the absence of a reasonable relationship between the SPS measure and the risk assessment, especially where the risk involved is life-threatening in character and is perceived to constitute a clear and imminent threat to public health and safety."¹¹⁰³

530. An SPS measure need not be based on a risk assessment performed by the WTO Member taking the measure. It can be based on a risk assessment performed by a relevant international organization or by another WTO Member.¹¹⁰⁴ The risk assessment can be quantitative or qualitative in nature.¹¹⁰⁵ Nevertheless, the Appellate Body has noted that "theoretical uncertainty"¹¹⁰⁶ is not the kind of risk to be assessed under Article 5.1; instead, the risk to be assessed must be an "ascertainable" risk.¹¹⁰⁷ In addition, the risk assessment must have the requisite degree of specificity. The assessment must be "sufficiently specific"¹¹⁰⁸ in terms of the harm concerned and the precise agent that may possibly cause the harm.¹¹⁰⁹

¹⁰⁹⁸ Appellate Body Report, *EC – Hormones*, para. 187.

¹⁰⁹⁹ *Ibid.*, para. 193.

¹¹⁰⁰ *Ibid.*

¹¹⁰¹ *Ibid.*, para. 194.

¹¹⁰² *Ibid.*

¹¹⁰³ *Ibid.*

¹¹⁰⁴ *Ibid.*, para. 190.

¹¹⁰⁵ *Ibid.*, para. 186.

¹¹⁰⁶ *Ibid.*

¹¹⁰⁷ *Ibid.*

¹¹⁰⁸ *Ibid.*, para. 200.

¹¹⁰⁹ Appellate Body Report, *Japan – Apples*, para. 202.

531. Whilst WTO Members have the right to take SPS measures, they are not required to do so. The risk assessment may conclude that there is no ascertainable risk, in which case no SPS measure can be taken. Alternatively, a WTO Member may conclude that an SPS measure is not necessary in the light of the risks determined in the risk assessment and the acceptable level of protection determined by that WTO Member.

532. International standards are given a prominent role under the *SPS Agreement*, particularly in furthering the objective of promoting the harmonization of sanitary and phytosanitary standards between WTO Members.¹¹¹⁰ This is to be achieved by encouraging WTO Members to base their SPS measures on international standards, guidelines or recommendations, where they exist.¹¹¹¹ There is a rebuttable presumption that SPS measures that conform to international standards, guidelines or recommendations are "necessary to protect human, animal or plant life or health, and ... [are] consistent with the relevant provisions of this Agreement and of GATT 1994".¹¹¹² While use of international standards is encouraged, the *SPS Agreement* recognizes the right of WTO Members to introduce or maintain an SPS measure which results in a higher level of protection than would be achieved by measures based on such international standards. Where a Member exercises its right to adopt an SPS measure that results in a higher level of protection, that right is qualified in that the SPS measure must comply with the other requirements of the *SPS Agreement*¹¹¹³, including the requirement to perform a risk assessment.¹¹¹⁴ However, the Appellate Body has found that the adoption of an SPS measure that does not conform to an international standard and results in a higher level of protection does not give rise to a more exacting burden of proof under the *SPS Agreement*:

The presumption of consistency with relevant provisions of the *SPS Agreement* that arises under Article 3.2 in respect of measures that conform to international standards may well be an *incentive* for Members so to conform their SPS measures with such standards. It is clear, however, that a decision of a Member not to conform a particular measure with an international standard does not authorize imposition of a special or generalized burden of proof upon that Member, which may, more often than not, amount to a *penalty*.¹¹¹⁵
(original emphasis)

533. At the oral hearing, we explored the relationship between the appropriate level of protection and the risk assessment. The European Communities considers that the appropriate level of protection can clearly be taken into account in a risk assessment and may, in some cases, be reflected in the

¹¹¹⁰See Article 3 and Recital 6 of the Preamble of the *SPS Agreement*.

¹¹¹¹Article 3.1 of the *SPS Agreement*.

¹¹¹²Article 3.2 of the *SPS Agreement*.

¹¹¹³Article 3.3 of the *SPS Agreement*.

¹¹¹⁴Appellate Body Report, *EC – Hormones*, paras. 176 and 177.

¹¹¹⁵*Ibid.*, para. 102.

mandate and parameters given to the risk assessors. The United States and Canada recognize that the acceptable level of risk may sometimes play a role, albeit a limited one, in respect of the risk assessment. The United States and Canada, however, caution about the need to maintain the objectivity of the risk assessment process and reject the notion that subjective policy choices have a role to play in a risk assessment. In their view, these policy choices may be taken into account by a WTO Member in determining its appropriate level of risk and in selecting the SPS measure, but should not be part of the risk assessment process, which must remain an objective and scientific evaluation.

534. The risk assessment cannot be entirely isolated from the appropriate level of protection. There may be circumstances in which the appropriate level of protection chosen by a Member affects the scope or method of the risk assessment. This may be the case where a WTO Member decides not to adopt an SPS measure based on an international standard because it seeks to achieve a higher level of protection. In such a situation, the fact that the WTO Member has chosen to set a higher level of protection may require it to perform certain research as part of its risk assessment that is different from the parameters considered and the research carried out in the risk assessment underlying the international standard. However, the chosen level of protection must not affect the rigour or objective nature of the risk assessment, which must remain, in its essence, a process in which possible adverse effects are evaluated using scientific methods.¹¹¹⁶ Likewise, whatever the level of protection a Member chooses does not pre-determine the results of the risk assessment. Otherwise, the purpose of performing the risk assessment would be defeated.¹¹¹⁷

535. We understand that Codex draws a distinction between "risk assessment" and "risk management".¹¹¹⁸ It defines "risk management" as "the process, *distinct from risk assessment*, of weighing policy alternatives ... considering risk assessment and other factors relevant for the health

¹¹¹⁶We recall, however, that the scientific process must not be understood narrowly as being confined to matters that are "susceptible of quantitative analysis by the empirical or experimental laboratory methods commonly associated with the physical sciences." Instead, the risk to be evaluated also includes the "risk in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die". (Appellate Body Report, *EC – Hormones*, para. 187)

¹¹¹⁷This is consistent with the Appellate Body's views about the relationship between the risk assessment and the SPS measure:

We understand this phrase to imply that a risk assessment should not be limited to an examination of the measure already in place or favoured by the importing Member. In other words, the evaluation contemplated in paragraph 4 of Annex A to the *SPS Agreement* should not be distorted by preconceived views on the nature and the content of the measure to be taken; nor should it develop into an exercise tailored to and carried out for the purpose of justifying decisions *ex post facto*.

(Appellate Body Report, *Japan – Apples*, para. 208)

¹¹¹⁸Codex Alimentarius Commission, Procedural Manual, 15th edition, p. 44. See also Panel Report, *US – Continued Suspension*, para. 7.515; and Panel Report, *Canada – Continued Suspension*, para. 7.487.

protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options."¹¹¹⁹ In *EC – Hormones*, the Appellate Body noted that the *SPS Agreement* does not refer to the concept of "risk management" and it rejected the panel's restrictive interpretation of a "risk assessment" based on that distinction.¹¹²⁰ The Appellate Body has not provided a clear demarcation of the factors that may be considered in a "risk assessment" under the *SPS Agreement*, but it has held that the list of factors provided in Article 5.2 is not a closed list and, in particular, that abuse or misuse and difficulties of control in the administration of hormones may be considered in the context of a risk assessment.¹¹²¹

536. Before we proceed to examine the European Communities' claims, we briefly summarize some of the relevant facts of this case. We note that Codex has adopted an international standard for oestradiol-17 β , based on evaluations carried out by JECFA.¹¹²² The European Communities asserts that it has determined a higher level of protection than that which would be achieved under Codex's standard. According to the European Communities, its level of protection is "no (avoidable) risk, that is a level of protection that does not allow any unnecessary addition from exposure to genotoxic chemical substances that are intended to be added deliberately to food."¹¹²³ The European Communities also notes that it has performed a risk assessment for meat from cattle treated with oestradiol-17 β for growth-promotion purposes. This risk assessment consists of the 1999, 2000, and 2002 Opinions, as supported by 17 studies conducted between 1998 and 2001. The European Communities further explains that its SPS measure—that is, the import and marketing ban applied pursuant to Directive 2003/74/EC—was taken in the light of the higher level of protection that it determined for itself and is properly based on its risk assessment.¹¹²⁴

2. The Panel's Interpretation and Application of Articles 5.1 and 5.2 of the *SPS Agreement*

537. We examine, first, the European Communities' claim that the Panel erred by adopting "an extremely narrow and consequently erroneous interpretation of Article 5.1 and failed to take into account that risk assessment and risk management partly overlap in the *SPS Agreement*".¹¹²⁵ The European Communities argues that the Panel's restrictive interpretation of risk assessment led it to

¹¹¹⁹Codex Alimentarius Commission, Procedural Manual, 15th edition, p. 45. (emphasis added)

¹¹²⁰Appellate Body Report, *EC – Hormones*, para. 181.

¹¹²¹*Ibid.*, paras. 187 and 206.

¹¹²²See *supra*, footnote 933.

¹¹²³Panel Report, *US – Continued Suspension*, para. 7.607; Panel Report, *Canada – Continued Suspension*, para. 7.585 (referring to replies of the European Communities to questions posed by the Panel after the second substantive meeting, Panel Reports, Annex C-1, para. 69). See also 1999 Opinion, section I.2.

¹¹²⁴Panel Report, *US – Continued Suspension*, para. 7.390; Panel Report, *Canada – Continued Suspension*, para. 7.387.

¹¹²⁵European Communities' appellant's submission, para. 308.

wrongfully exclude from the scope of its analysis under Article 5.1 evidence concerning misuse or abuse and difficulties of control in the administration of hormones to cattle for growth promotion.

538. We begin by reviewing the Panel's understanding of the Appellate Body's interpretation of Article 5.1 in *EC – Hormones* and particularly its discussion of the relevance of risk management factors for the purposes of a risk assessment within the meaning of Annex A and Article 5.1 of the *SPS Agreement*. The Panel in this case interpreted the Appellate Body's ruling in *EC – Hormones* as follows:

Although the Appellate Body disapproved of the original panel's distinction between "risk assessment" and "risk management" because it had no textual basis in the Agreement, this Panel can find no statement by the Appellate Body confirming that what the European Communities describes as risk management is included within the definition of a risk assessment as set forth in Annex A(4) of the *SPS Agreement*. In fact, the Appellate Body stressed that Article 5 and Annex A speak of *risk assessment* only and that the term *risk management* is not to be found either in Article 5 or in any other provision of the *SPS Agreement*.

The Panel agrees with the Appellate Body that its role as a treaty interpreter is to "read and interpret the words actually used by the agreement under examination, and not words which the interpreter may feel should have been used." The Panel takes note of the Appellate Body's finding that a risk assessment can take into account "matters not susceptible of quantitative analysis by the empirical or experimental laboratory methods commonly associated with the physical sciences." However, the Panel finds that neither that finding nor the text of the Agreement includes within the definition of a risk assessment the concepts put forward by the European Communities as "risk management."¹¹²⁶ (footnote omitted)

539. Therefore, the Panel stated that it would ask questions of the experts relating to whether the SCVPH Opinions identified the potential for adverse effects on human health of residues of oestradiol-17 β in the meat of cattle treated with this hormone when applied in accordance with good veterinary practice.¹¹²⁷

¹¹²⁶Panel Report, *US – Continued Suspension*, paras. 7.519 and 7.520; Panel Report, *Canada – Continued Suspension*, paras. 7.491 and 7.492.

¹¹²⁷Panel Report, *US – Continued Suspension*, para. 7.521; Panel Report, *Canada – Continued Suspension*, para. 7.493.

540. At the interim review stage, the European Communities asserted that the Panel "misinterpret[ed]" what the Appellate Body had said in *EC – Hormones*.¹¹²⁸ In response, the Panel explained:

The Appellate Body disapproved of the panel's use in the original *EC – Hormones* dispute of the distinction between "risk assessment" and "risk management" because it had no textual basis. However, this did not mean that the Appellate Body endorsed an interpretation of Article 5.1 or Annex A(4) of the *SPS Agreement* that included a risk management stage. In fact, it emphatically stated that the term "risk management" is not to be found in Article 5 or any other provision of the *SPS Agreement*. The Panel, therefore, finds no basis for the European Communities' assertion that the Appellate Body "confirmed that a risk assessment within the meaning of Article 5.1 includes a risk management stage which is the responsibility of the regulator to carry out and not of the scientific bodies."¹¹²⁹ (footnote omitted)

541. We find it difficult to reconcile the Panel's understanding of *EC – Hormones* with what the Appellate Body held in that Report. As we noted above, in that case, the Appellate Body rejected the rigid distinction drawn by the panel between "risk assessment" and "risk management", explaining:

We must stress, in this connection, that Article 5 and Annex A of the *SPS Agreement* speak of "risk assessment" only and that the term "risk management" is not to be found either in Article 5 or in any other provision of the *SPS Agreement*. Thus, the Panel's distinction,

¹¹²⁸Panel Report, *US – Continued Suspension*, para. 6.97; Panel Report, *Canada – Continued Suspension*, para. 6.89.

¹¹²⁹Panel Report, *US – Continued Suspension*, para. 6.99; Panel Report, *Canada – Continued Suspension*, para. 6.91. The Panel added:

Nowhere in the texts of Article 5.1 and Annex A(4) does the Panel find support for the European Communities' contention that a risk assessment within the meaning of the *SPS Agreement* includes "weighing policy alternatives in light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures." What the European Communities seems to be describing is how a government chooses an appropriate SPS measure based on a risk assessment. The Panel does not find that this is contemplated by the texts of Article 5.1 and Annex A(4) of the *SPS Agreement*.

(Panel Report, *US – Continued Suspension*, para. 6.102; Panel Report, *Canada – Continued Suspension*, para. 6.94. (footnote omitted)) Similarly, the Panel did not address evidence on misuse or abuse in the administration of the hormones in its analysis under Article 5.7 of the *SPS Agreement*. The Panel reasoned that:

... Article 5.7 is applicable when relevant scientific evidence is not sufficient to undertake a risk assessment in conformity with Article 5.1. Whether instances of misuse or abuse in the administration of hormones exist or not is not as such a scientific issue likely to make a risk assessment within the meaning of Article 5.1 and Annex A(4) of the *SPS Agreement* impossible.

(Panel Report, *US – Continued Suspension*, para. 7.603; Panel Report, *Canada – Continued Suspension*, para. 7.578)

which it apparently employs to achieve or support what appears to be a restrictive notion of risk assessment, has no textual basis.¹¹³⁰

Subsequently in the same Report, the Appellate Body reiterated its view that "the concept of 'risk management' is not mentioned in any provision of the *SPS Agreement* and, as such, cannot be used to sustain a more *restrictive* interpretation of 'risk assessment' than is justified by the actual terms of Article 5.2, Article 8 and Annex C of the *SPS Agreement*".¹¹³¹

542. Therefore, in our view, the Panel's interpretation of "risk assessment" resulted in the same "restrictive notion of risk assessment"¹¹³² that the Appellate Body found to be erroneous in *EC – Hormones*. The Panel sought in this case to rewrite the Appellate Body Report in *EC – Hormones* and to re-establish the rigid distinction between "risk assessment" and "risk management" that the Appellate Body had rejected in that case.

543. We set out above our understanding of the Appellate Body's finding in *EC – Hormones* in so far as the distinction between "risk assessment" and "risk management" is concerned. We now turn to the European Communities' argument that the distinction that the Panel drew between "risk assessment" and "risk management" resulted in the exclusion of certain factors from the Panel's analysis under Article 5.1 of the *SPS Agreement*. In particular, the European Communities asserts that the Panel improperly excluded the evidence concerning misuse or abuse and difficulties of control in the administration of hormones to cattle for growth promotion.¹¹³³

544. The relevance of the risks relating to abuse or misuse in the administration of hormones was also addressed in *EC – Hormones*. In that case, the Appellate Body noted that "[s]ome of the kinds of factors listed in Article 5.2 such as 'relevant processes and production methods' and 'relevant inspection, sampling and testing methods' are not necessarily or wholly susceptible of investigation according to laboratory methods of, for example, biochemistry or pharmacology" and that "there is nothing to indicate that the listing of factors that may be taken into account in a risk assessment of Article 5.2 was intended to be a closed list."¹¹³⁴ It then specifically examined whether risks relating to

¹¹³⁰ Appellate Body Report, *EC – Hormones*, para. 181.

¹¹³¹ *Ibid.*, para. 206. (emphasis added) The Appellate Body considered that the language in Article 5.2 ("relevant processes and production methods; relevant inspection, sampling and testing methods"), Article 8, and Annex C ("control, inspection and approval procedures") "is amply sufficient to authorize the taking into account of risks arising from failure to comply with the requirements of good veterinary practice in the administration of hormones for growth promotion purposes, as well as risks arising from difficulties of control, inspection and enforcement of the requirements of good veterinary practice." (*Ibid.*, para. 205)

¹¹³² *Ibid.*, para. 181.

¹¹³³ European Communities' appellant's submission, para. 325. At the oral hearing, the European Communities confirmed that its appeal focuses on misuse and abuse in the administration of hormones only, and that it is not claiming that the Panel erroneously excluded other factors on the basis of its general distinction between "risk assessment" and "risk management".

¹¹³⁴ Appellate Body Report, *EC – Hormones*, para. 187.

misuse or abuse in the administration of the hormones could be considered as part of the "risk assessment":

Where the condition of observance of good veterinary practice (which is much the same condition attached to the standards, guidelines and recommendations of Codex with respect to the use of the five hormones for growth promotion) is *not* followed, the logical inference is that the use of such hormones for growth promotion purposes may or may not be "safe". 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. Clearly, the necessity or propriety of examination and evaluation of such risks would have to be addressed on a case-by-case basis. What, in our view, is a fundamental legal error is to exclude, on an *a priori* basis, any such risks from the scope of application of Articles 5.1 and 5.2. We disagree with the Panel's suggestion that exclusion of risks resulting from the combination of potential abuse and difficulties of control is justified by distinguishing between "risk assessment" and "risk management". As earlier noted, the concept of "risk management" is not mentioned in any provision of the *SPS Agreement* and, as such, cannot be used to sustain a more restrictive interpretation of "risk assessment" than is justified by the actual terms of Article 5.2, Article 8 and Annex C of the *SPS Agreement*.¹¹³⁵ (original emphasis; footnote omitted)

545. Thus, the risks arising from the abuse or misuse in the administration of hormones can properly be considered as part of a risk assessment. Where a WTO Member has taken such risks into account, they must be considered by a panel reviewing that Member's risk assessment. Any suggestion that such risks cannot form part of a risk assessment would constitute legal error.

546. At the interim review stage, the Panel dismissed the relevance of the evidence concerning misuse or abuse in the administration of hormones under Article 5.1 for the following reasons¹¹³⁶:

¹¹³⁵Appellate Body Report, *EC – Hormones*, para. 206.

¹¹³⁶At the interim review stage, the European Communities criticized the Panel for referring to misuse or abuse only in the analysis of whether the European Communities had taken account of the factors listed under Article 5.2, which the Panel examined at the request of the United States. The European Communities asserted "that the Panel's discussion of the potential misuse and abuse in the administration of hormones is in the wrong place, to the extent that this is an aspect of risk assessment, in the sense of Article 5.1 to 5.3 of the *SPS Agreement*, that is applicable across all identified potential risks and for all six hormones." (Panel Report, *US – Continued Suspension*, para. 6.164; Panel Report, *Canada – Continued Suspension*, para. 6.154)

The Panel agrees with the European Communities that the question of misuse and abuse in the administration of hormones may apply to all six hormones at issue and is an element that can be taken into account in risk assessment, as set forth in Article 5.2 of the *SPS Agreement* and confirmed by the Appellate Body in *EC – Hormones*. However, the Panel did not deem it necessary to address this question in the section regarding the conformity with Article 5.1 of the definitive ban on oestradiol-17 β , to the extent that the question whether misuse or abuse exists in the administration of hormones did not have an impact on the issues addressed by the Panel under Article 5.1. 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. As stated by the 1999 Opinion, it is an aspect of exposure assessment. In this case, the Panel found that the European Communities had not evaluated specifically the possibility that the adverse effect[s] that it had identified in its risk assessment come into being, originate, or result from the consumption of meat or meat products which contain veterinary residues of oestradiol-17 β as a result of the cattle being treated with this hormone for growth promotion purposes. Therefore, whether the concentrations of hormone residues in meat and meat products could be higher as a result of misuse or abuse did not have to be addressed. The Panel does not deem it necessary to move this section to another part of its findings.¹¹³⁷ (footnote omitted)

547. The United States and Canada consider that this statement indicates that the Panel did address the European Communities' arguments relating to misuse or abuse.¹¹³⁸ We note that in this statement, the Panel acknowledges that those risks are "an element that can be taken into account in risk assessment, as set forth in Article 5.2 of the *SPS Agreement* and confirmed by the Appellate Body in *EC – Hormones*." Although the Panel does not seem to reject *a priori* the relevance of the potential risks of misuse or abuse, it then states that it was not necessary to address this question in its analysis, to the extent that it did not have an impact on the issues addressed by the Panel under Article 5.1. However, some of the scientific experts consulted by the Panel indicated that risks arising from residues of oestradiol-17 β in bovine meat are likely to increase where good veterinary practices in the administration of this hormone are not followed. Indeed, these experts agreed that their conclusions in relation to the risks posed by oestradiol-17 β were predicated on good veterinary practices being followed. Accordingly, the abuse or misuse in the administration of oestradiol-17 β has a bearing on the particular risks being assessed by the European Communities. The Panel's conclusion was thus premature because the Panel could not have decided whether the European Communities failed to evaluate specifically the possible adverse effects of residues of oestradiol-17 β in meat before

¹¹³⁷Panel Report, *US – Continued Suspension*, para. 6.164; Panel Report, *Canada – Continued Suspension*, para. 6.154.

¹¹³⁸United States' appellee's submission, para. 54; and Canada's response to questioning at the oral hearing.

considering the evidence on abuse or misuse. The Panel's summary dismissal of the relevance of the evidence on misuse or abuse at the interim review stage gives the appearance of being an *ex post* rationalization of an earlier decision to exclude such risks from consideration.

548. The risks of abuse or misuse of the hormones at issue were examined by the European Communities as part of its risk assessment. The 1999 Opinion examines the risks arising from misplaced implants and the consumption of meat from implantation sites, off-label use of the hormones (such as in animals for which the implant or feed pre-mix is not approved), possible uses of non-authorized pharmaceutical formulations, and secondary risks for residues of other drugs.¹¹³⁹ The 1999 Opinion concludes:

it has to be noted that misplaced implants and black market drugs comprise the risk that extremely high levels of residues of hormones remain in edible tissues of animals. In addition, it has to be noted that the contemporaneous use of growth promoting hormones and veterinary therapeutics drugs increases the prevalence of undesirable r[e]sidues in edible tissues of bovines.¹¹⁴⁰

549. The 2002 Opinion also addresses the risks of abuse or misuse.¹¹⁴¹ It refers to a study that simulated the disregard of good veterinary practices and to two studies relating to MGA. The 2002 Opinion concludes:

... these experiments clearly identify a risk for excessive exposure of consumers to residues from misplaced or off-label used implants and incorrect dose regimes. In these cases, levels of oestradiol and its metabolites in muscle, fat, liver and kidney from hormone treated cattle may be 2-fold up to several hundred folds higher as compared to untreated meat. The level of increase depends on the treatment regime and the actual hormone levels in the implants used.¹¹⁴²

550. In its consultations with the scientific experts, the Panel explored the relevance of the failure to observe good veterinary practices. The Panel asked the experts whether identification of oestradiol-17 β as a human carcinogen indicates that there are potential adverse effects on human health when it is consumed in meat from cattle treated with hormones for growth-promotion purposes.

¹¹³⁹1999 Opinion, pp. 30-32.

¹¹⁴⁰*Ibid.*, p. 32.

¹¹⁴¹2002 Opinion, pp. 11 and 12. The 2002 Opinion also concludes that "[MGA] applied in concentrations exceeding the licensed doses by a factor of 3 would result in a violation of the tolerance levels as proposed by US-FDA." (2002 Opinion, p. 11) Similarly, the 2002 Opinion found that "[m]odel calculations indicated that, depending on the actual implanted total dose, processing of such injection sites can contaminate tons of (minced) meat or meat products with hormone concentrations violating the ADI/MRL levels as proposed by JECFA and other regulatory bodies." (*Ibid.*, p. 11)

¹¹⁴²*Ibid.*, pp. 11 and 12.

The experts were also asked whether their answer would depend on whether good veterinary practices are followed.¹¹⁴³ Dr. Guttenplan responded:

If potential is taken to mean possible, then an adverse effect cannot be ruled out, but it is unlikely if good veterinary practices are followed. If good veterinary practices are not followed, the potential for adverse effects may be significant.¹¹⁴⁴

In response to another question on the subject posed by the Panel, Dr. De Brabander recognized that "[i]mproper administration of implants or misplaced implants create potential hazards to human health".¹¹⁴⁵

551. The European Communities also submitted to the Panel the final reports of two missions carried out in the United States and Canada to evaluate their control procedures.¹¹⁴⁶ The Panel asked the scientific experts whether this evidence "call[ed] into question the potential applicability of Codex standards with regard to imports of meat from cattle treated with hormones from the United States and Canada."¹¹⁴⁷ Dr. De Brabander agreed that this evidence was relevant:

The material put forth by the European Communities regarding misuse or abuse of the hormones at issue in the United States and Canada calls indeed into question the potential applicability of Codex standards with regard to imports of meat from cattle treated with hormones from the United States and Canada.¹¹⁴⁸

¹¹⁴³Panel Reports, Annex D, p. D-26, Question 15.

¹¹⁴⁴*Ibid.*, para. 155. Dr. Cogliano disagreed. In his view, the "answer does not depend on whether good veterinary practices are followed. It depends on the presence of the hormone in the meat that people consume". (*Ibid.*, para. 154)

¹¹⁴⁵*Ibid.*, para. 393. Dr. Boobis also recognized the potential hazards arising from abuse or misuse, although his response was qualified:

In my view, the potential hazards from the use of large quantities of the six hormones in dispute are those dependent on their endocrine activity, including cancer in hormonally responsive tissues. However, I should stress that this is their potential hazard. The potential risk, i.e. the probability that effects would occur, would depend on a number of factors. These include the magnitude of the exposure, the duration of the exposure and the life stage of the exposed individual. From the range of exposures likely from anticipated misuse or abuse the risks are likely to be very low (see Question 62).

(*Ibid.*, para. 392)

¹¹⁴⁶See Final Report of a mission carried out in the United States from 19-30 June 2000 in order to review the systems in place for approval, control and supervision of cold stores and the certification of fresh meat and meat products, DG(Sanco)/1176/2000-MR Final, and Final Report of a mission carried out in Canada from 19-29 September 2000 in order to evaluate the control of residues in live animals and animal products, DG(Sanco)/1188/2000-MR final (Exhibits EC-67 and EC-68 submitted by the European Communities to the Panel).

¹¹⁴⁷Panel Reports, Annex D, p. D-83, Question 51.

¹¹⁴⁸*Ibid.*, para. 403.

552. As noted earlier, the relevance of abuse or misuse in the administration of the hormones at issue was recognized by the Appellate Body in *EC – Hormones*. The Appellate Body observed that, "[w]here the condition of observance of good veterinary practice (which is much the same condition attached to the standards, guidelines and recommendations of Codex with respect to the use of the five hormones for growth promotion) is *not* followed, the logical inference is that the use of such hormones for growth promotion purposes may or may not be 'safe'."¹¹⁴⁹

553. The Panel does not address the evidence on misuse or abuse referred to in the 1999 and 2002 Opinions in its analysis under Article 5.1 of the *SPS Agreement*. Neither does the Panel discuss the testimony of the scientific experts that recognized the relevance of this evidence and the potential adverse effects of the misuse or abuse in the administration of the hormones. The Panel summarily dismissed the relevance of the evidence on misuse or abuse stating that it relates to exposure assessment and adding that it is not necessary to address it given the finding that the European Communities had not evaluated *specifically* the possibility that the adverse effects arise from the consumption of meat from cattle treated with oestradiol-17 β for growth-promotion purposes. We recognize that the 1999 Opinion examines the risks of misuse or abuse under the heading "Exposure considerations upon misuse".¹¹⁵⁰ After discussing the evidence on misuse and abuse, the 2002 Opinion states that "these data have to be considered in any quantitative exposure assessment exercise."¹¹⁵¹ This, however, cannot justify the Panel's failure to address the evidence on misuse or abuse. The European Communities made it clear that the risks of abuse or misuse were a relevant consideration in its risk assessment. This is confirmed in the 1999 and 2002 Opinions. At least two of the scientific experts consulted by the Panel recognized that the misuse or abuse in the administration of the hormones could give rise to adverse effects. The Panel had a duty to engage with this evidence and with the discussion of this evidence in the SCVPH Opinions. By summarily dismissing the evidence on the misuse or abuse in the administration of the hormones and the consequent conclusions in the SCVPH Opinions in the manner that it did, the Panel incorrectly applied Article 5.1 and the definition of "risk assessment" in Annex A of the *SPS Agreement*, as interpreted by the Appellate Body.

554. The United States and Canada submit that there are no economic incentives to fail to observe good veterinary practices by, for example, giving higher doses of hormones to the cattle.¹¹⁵² This is something the Panel could have examined, but it did not. Therefore, it cannot justify the Panel's inadequate treatment of the issue.

¹¹⁴⁹ Appellate Body Report, *EC – Hormones*, para. 206. (original emphasis; footnote omitted)

¹¹⁵⁰ 1999 Opinion, p. 30.

¹¹⁵¹ 2002 Opinion, p. 12.

¹¹⁵² Canada's appellee's submission, para. 87; and United States' responses to questioning at the oral hearing.

555. Accordingly, we find that the Panel erred in its interpretation and application of Article 5.1 of the *SPS Agreement* in relation to risks of misuse and abuse in the administration of hormones to cattle for growth-promoting purposes.

3. The Panel's Specificity Requirement

556. The European Communities claims that the Panel erred in finding that the European Communities had acted inconsistently with Article 5.1 of the *SPS Agreement* by failing to evaluate specifically the risks arising from residues of oestradiol-17 β in meat from cattle treated with this hormone for growth promotion. The European Communities argues that "[a]t no stage did the Panel[] correctly identify what the Appellate Body found to be wanting in the risk assessments carried out for the purposes of Directive 96/22/EC in the original hormones dispute."¹¹⁵³

557. Relying on the Appellate Body's findings in *EC – Hormones*, the Panel observed that "a risk assessment in this instance required not a general evaluation of the carcinogenic potential of entire categories of hormones, but rather should include an examination of residues of those hormones found in meat derived from cattle to which the hormones had been administered for growth promotion purposes."¹¹⁵⁴ The Panel also noted the Appellate Body's finding in *Japan – Apples* that "a risk assessment should refer in general to the harm concerned as well as to the precise agent that may possibly cause the harm"¹¹⁵⁵, and its explanation that "an evaluation of risk must connect the possibility of adverse effects with an antecedent or cause."¹¹⁵⁶ The Panel concluded:

[T]he European Communities was required to evaluate the possibility that the identified adverse effect came into being, originated, or resulted from the presence of residues of oestradiol-17 β in meat or meat products as a result of the cattle being treated with the hormone for growth promoting purposes.¹¹⁵⁷

558. The European Communities alleges that the Panel improperly required demonstration of *actual* effects while the Appellate Body had required mere demonstration of the *possibility of adverse effects*.¹¹⁵⁸ The European Communities' allegation is unfounded. In the statement quoted above, the Panel focused on the *possibility* that the adverse effects could arise from the consumption of meat

¹¹⁵³European Communities' appellant's submission, para. 341.

¹¹⁵⁴Panel Report, *US – Continued Suspension*, para. 7.511; Panel Report, *Canada – Continued Suspension*, para. 7.483 (referring to Appellate Body Report, *EC – Hormones*, para. 200).

¹¹⁵⁵Panel Report, *US – Continued Suspension*, para. 7.512; Panel Report, *Canada – Continued Suspension*, para. 7.484 (referring to Appellate Body Report, *Japan – Apples*, para. 202). (emphasis omitted)

¹¹⁵⁶*Ibid.* (quoting Appellate Body Report, *Japan – Apples*, footnote 372 to para. 202).

¹¹⁵⁷Panel Report, *US – Continued Suspension*, para. 7.513; Panel Report, *Canada – Continued Suspension*, para. 7.485.

¹¹⁵⁸European Communities' appellant's submission, para. 261.

from cattle treated with oestradiol-17 β . The test articulated by the Panel is compatible with the definition of the term "risk assessment" in paragraph 4 of Annex A of the *SPS Agreement* and with the interpretation developed by the Appellate Body in *EC – Hormones*. In that dispute, the European Communities presented a number of scientific studies and opinions of individual scientists indicating that the hormones at issue in that case had "carcinogenic potential".¹¹⁵⁹ Yet, the Appellate Body found that those studies fell short of the requirements of paragraph 4 of Annex A of the *SPS Agreement*, because:

The 1987 IARC Monographs and the articles and opinions of individual scientists submitted by the European Communities constitute general studies which do indeed show the existence of a general risk of cancer; but they do not focus on and do not address the particular kind of risk here at stake—the carcinogenic or genotoxic potential of the residues of those hormones found in meat derived from cattle to which the hormones had been administered for growth promotion purposes—as is required by paragraph 4 of Annex A of the *SPS Agreement*. Those general studies, are in other words, relevant but do not appear to be sufficiently specific to the case at hand.¹¹⁶⁰

559. The definition of a risk assessment in paragraph 4 of Annex A, as interpreted by the Appellate Body, required the European Communities to conduct a risk assessment that addresses the specific risk at issue. The particular risk being evaluated by the European Communities in this case was the potential for neurobiological, developmental, reproductive, and immunological effects, as well as immunotoxic, genotoxic and carcinogenic effects¹¹⁶¹ from the residues of oestradiol-17 β found in meat derived from cattle to which this hormone was administered for growth-promoting purposes. Although the European Communities is correct in arguing that it was not required to demonstrate that these adverse health effects would actually arise, it was nevertheless required to demonstrate that these adverse effects could arise from the presence of residues of oestradiol-17 β in meat from treated cattle. In our view, this is what the Panel required when it examined whether the European Communities had "evaluate[d] the possibility that the identified adverse effect ... resulted from the presence of residues of oestradiol-17 β in meat or meat products as a result of the cattle being treated with the hormone for growth promoting purposes."¹¹⁶²

¹¹⁵⁹Appellate Body Report, *EC – Hormones*, para. 199.

¹¹⁶⁰*Ibid.*, para. 200.

¹¹⁶¹Panel Report, *US – Continued Suspension*, para. 7.508; *Canada – Continued Suspension*, para. 7.480 (referring to 1999 Opinion, p. 72).

¹¹⁶²Panel Report, *US – Continued Suspension*, para. 7.513; *Canada – Continued Suspension*, para. 7.485.

560. The European Communities also argues that the Panel erred by requiring a demonstration of "direct causality", which the European Communities posits constitutes "a very narrow reading" by the Panel of the definition of risk assessment in paragraph 4 of Annex A.¹¹⁶³

561. The Appellate Body explained in *Japan – Apples* that:

Indeed, we are of the view that, as a general matter, "risk" cannot usually be understood only in terms of the disease or adverse effects that may result. Rather, an evaluation of risk must connect the possibility of adverse effects with an antecedent or cause. For example, the abstract reference to the "risk of cancer" has no significance, in and of itself, under the *SPS Agreement*; but when one refers to the "risk of cancer from smoking cigarettes", the particular risk is given content.¹¹⁶⁴

562. The particular risk being assessed by the European Communities is the possibility of adverse health effects from the consumption of residues of oestradiol-17 β in meat treated with this hormone for growth promotion. In *EC – Hormones*, the Appellate Body required evaluation of "the carcinogenic or genotoxic potential of the residues of [the] hormones"¹¹⁶⁵ at issue found in meat from treated cattle. In this case, the European Communities had to evaluate whether a causal connection exists between the consumption of meat from cattle treated with oestradiol-17 β and the possibility of adverse health effects. This does not mean that the European Communities was required to establish a direct causal relationship between the possibility of adverse health effects and the residues of oestradiol-17 β in bovine meat. In order to meet the requirements of Article 5.1 and Annex A of the *SPS Agreement*, it was sufficient for the European Communities to demonstrate that the additional human exposure to residues of oestradiol-17 β in meat from treated cattle is one of the factors contributing to the possible adverse health effects. The European Communities was not required to isolate the contribution made by residues of oestradiol-17 β in meat from cattle treated with the hormone for growth promotion from the contributions made by other sources.¹¹⁶⁶ Where multiple factors may contribute to a particular risk, a risk assessor is not required to differentiate the individual contribution made by each factor. Article 5.1 requires that SPS measures be based on a risk assessment "as appropriate to the circumstances", which suggests that the scientific inquiry involved in a risk assessment must take due account of particular methodological difficulties posed by the nature and characteristics of the particular substance and risk being evaluated. However, that does not

¹¹⁶³European Communities' appellant's submission, para. 260.

¹¹⁶⁴Appellate Body Report, *Japan – Apples*, footnote 372 to para. 202.

¹¹⁶⁵Appellate Body Report, *EC – Hormones*, para. 200.

¹¹⁶⁶In this respect, we recall that in *EC – Hormones*, the Appellate Body considered that "there is a fundamental distinction between added hormones (natural or synthetic) and naturally-occurring hormones in meat and other foods." (*Ibid.*, para. 221) It also noted that regulatory action in respect of the latter would "entail[] such a comprehensive and massive governmental intervention in nature and in the ordinary lives of people" as to reduce the comparison between these types of hormones "to an absurdity". (*Ibid.*)

excuse the risk assessor from evaluating whether there is a connection between the particular substance being evaluated and the possibility that adverse health effects may arise.

563. Finally, we are not persuaded by the European Communities suggestion that the Panel required testing in humans in order to specifically evaluate the risks associated with the consumption of meat from cattle treated with oestradiol-17 β .¹¹⁶⁷ We do not see this as a necessary implication of the Panel's analysis. There is no indication in the Panel Report to suggest that the evaluation could not proceed on the basis of experimentation in laboratory animals and extrapolating the results to humans, or by other means. Certainly, where a substance may be potentially toxic, requiring a WTO Member to evaluate specifically the risks through actual human consumption of the substance would be unethical and would not be "appropriate to the circumstances" within the meaning of Article 5.1.

564. For these reasons, we find that the Panel did not err in requiring a specific evaluation of the risks arising from the presence of residues of oestradiol-17 β in meat or meat products from cattle treated with the hormone for growth-promoting purposes.¹¹⁶⁸

565. The European Communities makes two additional arguments relating to the specificity requirement. First, the European Communities asserts that the Panel's analysis and the legal test it used "are simply a cover for allowing the Panel[] to decide *what the correct science in [its] view is*, not on assessing whether the scientific evidence evaluated in the Opinions of the SCVPH *focussed on and addressed* 'the particular kind of risk here at stake—carcinogenic or genotoxic potential of the residues of those hormones found in meat derived from cattle to which [17 β -oestradiol] had been administered for growth promotion purposes', as identified by the Appellate Body in the original case."¹¹⁶⁹ Second, the European Communities argues that, because the SCVPH Opinions demonstrated that oestradiol-17 β is a "complete carcinogen by exerting tumour initiating and promoting effects", "it has to be concluded that no quantitative estimate of risk related to residues in meat could be presented".¹¹⁷⁰ According to the European Communities, "[t]his conclusion alone demonstrates that the Opinions focussed on and addressed very specifically the particular kind of risk here at stake—carcinogenic and genotoxic potential of the residues of those hormones found in meat derived from cattle to which [17 β -oestradiol] had been administered for growth promotion purposes as identified by the Appellate Body."¹¹⁷¹ In our view, both of these arguments relate to the standard of

¹¹⁶⁷European Communities' appellant's submission, para. 263.

¹¹⁶⁸Panel Report, *US – Continued Suspension*, para. 7.513; Panel Report, *Canada – Continued Suspension*, para. 7.485.

¹¹⁶⁹European Communities' appellant's submission, para. 341. (original emphasis).

¹¹⁷⁰*Ibid.*, para. 337.

¹¹⁷¹*Ibid.* (original emphasis and footnote omitted)

review applied by the Panel and to the Panel's evaluation of the evidence before it. We address this aspect of the European Communities' appeal in section VI.D.6.

4. Quantification of Risk

566. Next, we turn to the European Communities' claim that the Panel erred in requiring the quantification of the risks arising from the consumption of meat containing residues of oestradiol-17 β . The European Communities asserts that, by referring to "potential occurrence"¹¹⁷² of adverse effects when asking questions to the experts, the Panel incorrectly "imposed a quantitative method of risk assessment on the European Communities borrowed from Codex Alimentarius and JECFA."¹¹⁷³

567. In *EC – Hormones*, the Appellate Body held that:

What needs to be pointed out at this stage is that the Panel's use of "probability" as an alternative term for "potential" creates a significant concern. The ordinary meaning of "potential" relates to "possibility" and is different from the ordinary meaning of "probability". "Probability" implies a higher degree or a threshold of potentiality or possibility. It thus appears that here the Panel introduces a quantitative dimension to the notion of risk.¹¹⁷⁴
(footnote omitted)

568. The Appellate Body further stated that:

It is not clear in what sense the Panel uses the term "scientifically identified risk." The Panel also frequently uses the term "identifiable risk", and does not define this term either. The Panel might arguably have used the terms "scientifically identified risk" and "identifiable risk" simply to refer to an ascertainable risk: if a risk is not ascertainable, how does a Member ever know or demonstrate that it exists? In one part of its Reports, the Panel opposes a requirement of an "identifiable risk" to the uncertainty that theoretically always remains since science can *never* provide *absolute* certainty that a given substance will not *ever* have adverse health effects. We agree with the Panel that this theoretical uncertainty is not the kind of risk which, under Article 5.1, is to be assessed. In another part of its Reports, however, the Panel appeared to be using the term "scientifically identified risk" to prescribe implicitly that a certain *magnitude* or threshold level of risk be demonstrated in a risk assessment if an SPS measure based thereon is to be regarded as consistent with Article 5.1. To the extent that the Panel purported to require a risk assessment to establish a minimum magnitude of risk, we must note that imposition of such a quantitative requirement finds

¹¹⁷²European Communities' appellant's submission, para. 346.

¹¹⁷³*Ibid.*, para. 308.

¹¹⁷⁴Appellate Body Report, *EC – Hormones*, para. 184.

no basis in the *SPS Agreement*.¹¹⁷⁵ (original emphasis; footnotes omitted;)

569. Although the definition of a risk assessment does not require WTO Members to establish a minimum magnitude of risk, it is nevertheless difficult to understand the concept of risk as being devoid of any indication of potentiality. A risk assessment is intended to identify adverse effects and evaluate the possibility that such adverse effects might arise. This distinguishes an ascertainable risk from theoretical uncertainty. However, the assessment of risk need not be expressed in numerical terms or as a minimum quantification of the level of risk. We are also mindful that the risk assessment at issue in this case concerns the *potential* for adverse effects under the second sentence of paragraph 4 of Annex A and not an evaluation of likelihood under the first sentence of paragraph 4.¹¹⁷⁶

570. The European Communities' challenge in this case is directed at the following question that the Panel posed to the scientific experts:

The Panel specifically asked the experts whether the [European Communities] Opinions identified the potential for adverse effects on human health, including the carcinogenic or genotoxic potential, of the residues of oestradiol-17 β 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.¹¹⁷⁷

571. The European Communities does not consider this formulation to be "problematic" as such. The European Communities argues, however, that if this formulation is understood as requiring a Member to specify in quantitative terms "to what extent [it] evaluated *the potential occurrence* of these adverse effects"¹¹⁷⁸, it would lead to an error in law. The European Communities submits that this is precisely how the Panel addressed the issue and how it invited the experts to analyse the SCVPH Opinions.¹¹⁷⁹

¹¹⁷⁵Appellate Body Report, *EC – Hormones*, para. 186. Similarly, in *Australia – Salmon*, the Appellate Body referred to the first sentence of the definition of a "risk assessment" in paragraph 4 of Annex A of the *SPS Agreement*, and noted that the *SPS Agreement* "does not require that the evaluation of the likelihood needs to be done quantitatively. The likelihood may be expressed either quantitatively or qualitatively." (Appellate Body Report, *Australia – Salmon*, para. 124)

¹¹⁷⁶The Appellate Body found in *EC – Hormones* that the term "potential" in the second sentence of paragraph 4 of Annex A refers to the "possibility" of occurrence of adverse effects, which implies a lower degree of potentiality than "probability". (Appellate Body Report, *EC – Hormones*, para. 184).

¹¹⁷⁷Panel Report, *US – Continued Suspension*, para. 7.521; Panel Report, *Canada – Continued Suspension*, para. 7.493.

¹¹⁷⁸European Communities' appellant's submission, para. 344 (quoting Panel Report, *US – Continued Suspension*, para. 7.521; and Panel Report, *Canada – Continued Suspension*, para. 7.493) (original emphasis)

¹¹⁷⁹*Ibid.*, para. 344. (footnote omitted)

572. As the European Communities acknowledges, "a quantitative dimension may not be immediately evident from the ordinary meaning of the words 'potential occurrence'."¹¹⁸⁰ The terms "potential occurrence of adverse effects" can be understood as referring to the possibility that the adverse effects might occur, without necessarily requiring that this be expressed in numerical terms. This would be consistent with the definition of "risk assessment" in paragraph 4 of Annex A of the *SPS Agreement*, as interpreted by the Appellate Body. Moreover, it would be consistent with the Appellate Body's view that "theoretical uncertainty"¹¹⁸¹ is not the kind of risk to be assessed under Article 5.1, but rather the risk to be assessed must be an "ascertainable" risk.¹¹⁸² In this sense, we agree with Canada that "to examine the 'potential' for adverse effects is to ask whether those adverse effects could ever occur".¹¹⁸³

573. Other statements by the Panel confirm that it did not require that the possibility of the risks arising be expressed in numerical terms. For example, the Panel took note of the Appellate Body's finding that a risk assessment can take into account "matters not susceptible of quantitative analysis by the empirical or experimental laboratory methods commonly associated with the physical sciences."¹¹⁸⁴ The Panel also stated that "it must determine whether the European Communities evaluated the *possibility* that the identified adverse effects came into being, originated, or resulted from the presence of residues of oestradiol-17 β in meat or meat products as a result of the cattle being treated with the hormone for growth promotion purposes."¹¹⁸⁵

574. The European Communities additionally draws attention to the Panel's use of the term "magnitude" in the following statement:

Indeed, whether a Member considers that its population should be exposed or not to a particular risk, or at what level, is not relevant to determining whether a risk exists and what its magnitude is. *A fortiori*, it should have no effect on whether there is sufficient evidence of the existence and magnitude of this risk.

A risk-averse Member may be inclined to take a protective position when considering the measure to be adopted. However, the determination of whether scientific evidence is sufficient to assess

¹¹⁸⁰European Communities' appellant's submission, para. 346.

¹¹⁸¹Appellate Body Report, *EC – Hormones*, para. 186.

¹¹⁸²In *Japan – Apples*, the Appellate Body cautioned, however, that "scientific prudence" should "not be 'completely assimilated'" to such theoretical uncertainty. (Appellate Body Report, *Japan – Apples*, para. 241)

¹¹⁸³Canada's appellee's submission, para. 107. (original underlining)

¹¹⁸⁴Panel Report, *US – Continued Suspension*, para. 7.520; Panel Report, *Canada – Continued Suspension*, para. 7.492 (quoting Appellate Body Report, *EC – Hormones*, para. 187).

¹¹⁸⁵Panel Report *US – Continued Suspension*, para. 7.520; Panel Report, *Canada – Continued Suspension*, para. 7.492. (emphasis added)

the existence and *magnitude* of a risk must be disconnected from the intended level of protection.¹¹⁸⁶ (emphasis added)

We note that these statements were made by the Panel in its discussion of the consistency of the European Communities' provisional ban in respect of the other five hormones and, therefore, was not made in the context of the Panel's examination of the European Communities' import ban on meat from cattle treated with oestradiol-17 β . However, we recall that a "risk assessment" involves an indication of potentiality, even though this need not be expressed in numerical terms or as a minimum quantification of the level of risk. In this sense, the Panel's reference to "magnitude" is in our view not sufficient to establish that the Panel incorrectly interpreted Article 5.1 and paragraph 4 of Annex A as requiring a quantitative risk assessment.

575. For these reasons, we consider that the Panel's reference to "potential occurrence" of adverse health effects could be read consistently with the definition of a risk assessment in paragraph 4 of Annex A of the *SPS Agreement*, as interpreted by the Appellate Body. Accordingly, we dismiss the European Communities' claim that the Panel incorrectly interpreted Article 5.1 and paragraph 4 of Annex A of the *SPS Agreement* as requiring quantification of risk.

5. Burden of Proof

576. We now examine the European Communities' claim that the Panel erred by incorrectly allocating the burden of proof. The European Communities argues that the fact that it is the complaining party in this case "does not change the basic standard on the burden of proof under the *SPS Agreement*."¹¹⁸⁷ According to the European Communities, the Panel "erred in law in shifting the burden of proof to the European Communities without first examining, provision by provision under the *SPS Agreement* as required by Appellate Body, whether the arguments of the United States and Canada had sufficient merits to shift the burden of proof back to the European Communities".¹¹⁸⁸

577. The United States argues that the Panel was correct in initially allocating to the European Communities the burden of proving its claim that the United States acted inconsistently with Article 22.8 of the DSU. The United States considers that the Panel properly found that the European Communities' claim was premised on an assertion by the European Communities that it had brought itself into conformity with the *SPS Agreement* through Directive 2003/74/EC. For this reason, the Panel was justified in allocating to the European Communities the burden of establishing a *prima facie* case of conformity with the *SPS Agreement*, including Article 5.1. The United States accepts

¹¹⁸⁶Panel Report, *US – Continued Suspension*, paras. 7.611 and 7.612; Panel Report, *Canada – Continued Suspension*, paras. 7.589 and 7.590.

¹¹⁸⁷European Communities' appellant's submission, para. 286.

¹¹⁸⁸*Ibid.*, para. 294.

that, once the Panel found that the European Communities had established such *prima facie* case, the burden of proof shifted to the United States. However, the Panel then rightly found that the United States had rebutted the European Communities' *prima facie* case of consistency through positive evidence of breach of the *SPS Agreement*. On this basis, the United States suggests 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."¹¹⁸⁹

578. Canada agrees with the United States that the European Communities has the burden of proving that it has removed the inconsistent measure within the meaning of Article 22.8 of the DSU.¹¹⁹⁰ Canada asserts that, in order to demonstrate that the suspension of concessions is no longer justified, the European Communities must establish that it has brought its measure into compliance with Article 5.1 of the *SPS Agreement*.

579. The Panel explained how it would allocate the burden of proof as follows:

With respect to the violation of Article 22.8 as such, the Panel considered that it had, in principle, no reason to address [the] burden of proof any differently than any other panel established under Article 6 of the DSU. Indeed, as stated by the Complainant itself, this case is about a measure taken by [the United States and Canada]. The fact that this dispute takes place in the context of the [European Communities'] alleged compliance with the recommendations and rulings of the DSB in the *EC – Hormones* dispute should have no impact on the question of the burden of proof regarding the actual *claim* before us. This means that the principles identified by the Appellate Body above apply, and that the European Communities must prove its claim that [the United States and Canada] breach[] Article 22.8 of the DSU.

Yet, one of the particularities of this case is that the [European Communities'] claim of violation of Article 22.8 of the DSU by [the United States and Canada] is premised on the removal of the European Communities' measure found to be inconsistent with the *SPS Agreement*. In other words, in order to demonstrate that [the United States and Canada have] breached Article 22.8, the European Communities also alleges that its implementing measure is itself in conformity with the *SPS Agreement*.

In theory, this should not raise any difficulty in terms of burden of proof since it is well established that each party has to prove its own allegations. We agree, however, with the European Communities that in a case like this one, this could generate for the complainant at the beginning of the proceedings a situation equivalent to having to "prove a negative", since the spectrum of provisions against which

¹¹⁸⁹United States' appellee's submission, para. 94 (referring to Panel Report, *US – Continued Suspension*, para. 7.386).

¹¹⁹⁰Canada's responses to questioning at the oral hearing.

the legality of the [European Communities'] measure may have to be reviewed remains very broad as long as the respondent has not made its own allegations of inconsistency of the implementing measure. However, we recall that we found above that the European Communities enjoyed a presumption of good faith compliance, even though that presumption was rebuttable before this Panel. As soon as the European Communities established a prima facie case thanks to the presumption of good faith compliance, the burden shifted on the [the United States and Canada] to rebut that presumption. We recall that "... a prima facie case is one which, in the absence of effective refutation by the defending party, requires a panel, as a matter of law, to rule in favour of the complaining party presenting the prima facie case." We believe that the [United States and Canada] sufficiently refuted the [European Communities'] allegation of compliance in [their] first written submission through positive evidence of breach of the *SPS Agreement* by the European Communities. In its subsequent submissions before the Panel, the European Communities responded to the allegations of violation made by [the United States and Canada]. Thus, the European Communities never actually had to "prove a negative" in this case.

While the presumptions based on good faith enjoyed by each party may have played a role in the burden of proof in the early stage of the Panel proceedings, it is the opinion of the Panel that they eventually "neutralized" each other since each party also submitted evidence in support of its allegations. Ultimately, each party had to prove its specific allegations in response to the evidence submitted by the other party. Thereafter, 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.¹¹⁹¹ (original emphasis: footnotes omitted)

580. In section IV, we explained that this case involves a disagreement as to the consistency of a measure taken to comply and, therefore, should have properly been brought under Article 21.5 of the DSU. We also explained how the burden of proof should have been allocated had the dispute been brought under Article 21.5. Although these proceedings were not brought under Article 21.5, the Panel said that it "perform[ed] functions similar to those of an Article 21.5 panel".¹¹⁹² The European Communities had to provide a clear description of its implementing measure, and an adequate explanation regarding how this measure rectifies the inconsistencies found in the original proceedings, so as to have placed the Panel in a position to make an objective assessment of the matter and, in the absence of rebuttal, to rule in favour of the original respondent. Therefore, to the extent the Panel did not allocate the burden of proof in its analysis of whether Directive 2003/74/EC met the requirements

¹¹⁹¹Panel Report, *US – Continued Suspension*, paras. 7.383-7.386; Panel Report, *Canada – Continued Suspension*, paras. 7.380-7.383.

¹¹⁹²Panel Report, *US – Continued Suspension*, para. 7.376; Panel Report, *Canada – Continued Suspension*, para. 7.373.

of Article 5.1 of the *SPS Agreement* according to the principles outlined above, we find that the Panel has erred.

581. We have, moreover, several additional concerns with the Panel's analysis. First, as we indicated in section IV, we do not believe that it was sufficient for the European Communities to have based its case under Article 22.8 on a presumption of good faith. The European Communities may be presumed to have acted in good faith in adopting Directive 2003/74/EC, but this does not respond to the question as to whether Directive 2003/74/EC achieved substantive compliance. Thus, it was incorrect for the Panel to have relied on a presumption of good faith compliance for purposes of determining the allocation of the burden of proof and finding that the European Communities established a *prima facie* case.

582. Secondly, we have difficulty following the reasoning behind the Panel's conclusion that the presumptions of good faith enjoyed by each party "eventually 'neutralized' each other" and that "[u]ltimately, each party had to prove its specific allegations in response to the evidence submitted by the other party."¹¹⁹³ The statement is ambiguous about which party made which allegation and how the burden of proof was allocated. In the section in which the Panel describes the scope of its review and circumscribes its terms of reference, the Panel states that, in submissions subsequent to the first written submission, "the European Communities has argued the compatibility of its implementing measure with the provisions referred to in the quotation above (i.e. Article[s] 5.1 and 5.7 of the *SPS Agreement*)".¹¹⁹⁴ However, a few paragraphs later, the Panel refers to the allegation of incompatibility with Article 5.1 of the *SPS Agreement* as an allegation made by the United States and Canada.¹¹⁹⁵ Thus, it is difficult to understand which party had the burden of proving which allegation.

583. Thirdly, we note the Panel's statement that the United States and Canada "sufficiently refuted the [European Communities'] allegation of compliance in [their] first written submission through positive evidence of breach of the *SPS Agreement* by the European Communities".¹¹⁹⁶ This statement is made before the Panel has undertaken any analysis of the conformity of Directive 2003/74/EC with Article 5.1 of the *SPS Agreement*. In its appellant's submission, the European Communities takes issue with this statement and argues that the Panel should have first examined "provision by provision ... whether the arguments of the United States and Canada had

¹¹⁹³Panel Report, *US – Continued Suspension*, para. 7.386; Panel Report, *Canada – Continued Suspension*, para. 7.383.

¹¹⁹⁴Panel Report, *US – Continued Suspension*, para. 7.400; Panel Report, *Canada – Continued Suspension*, para. 7.397.

¹¹⁹⁵Panel Report, *US – Continued Suspension*, para. 7.405; Panel Report, *Canada – Continued Suspension*, para. 7.398.

¹¹⁹⁶Panel Report, *US – Continued Suspension*, para. 7.385; Panel Report, *Canada – Continued Suspension*, para. 7.382.

sufficient merits to shift the burden of proof back to the European Communities".¹¹⁹⁷ We agree that it was premature for the Panel to have stated that the United States and Canada had succeeded in refuting the European Communities' allegation of compliance before the Panel had addressed the consistency of Directive 2003/74/EC with the *SPS Agreement*.

584. Accordingly, we find that the Panel erred in the allocation of the burden of proof in its assessment of the consistency of Directive 2003/74/EC with Article 5.1 of the *SPS Agreement*. We discuss the consequences of this error in section E below.

6. The Panel's Articulation and Application of the Standard of Review under Article 5.1 of the *SPS Agreement*

585. We turn next to the European Communities' claim that the Panel erred in the standard that it applied to review whether Directive 2003/74/EC was based on a risk assessment within the meaning of Article 5.1 of the *SPS Agreement*. The European Communities argues that the Panel sought to determine "what the correct scientific conclusions are"¹¹⁹⁸ in relation to the hormones at issue. The European Communities adds that, instead of determining whether "there was any reputable support within the relevant scientific community for the determination made by the European Communities in the light of its chosen level of protection"¹¹⁹⁹, the Panel decided "to become the jury on the correct science ... by picking and choosing between conflicting and contradictory opinions of the experts in an arbitrary manner."¹²⁰⁰ As a result, the Panel impermissibly engaged in a *de novo* review of the European Communities' risk assessment, and failed to take into account diverging views among the experts reflecting a "genuine and legitimate scientific controversy"¹²⁰¹ concerning three particular issues: exposure of humans to hormones from multiple endogenous and exogenous sources; genotoxicity of oestradiol-17 β ; and specificity or direct causality.¹²⁰²

586. The United States and Canada consider that the Panel identified and applied the correct standard of review to the facts before it, and maintain that the Panel did not exceed the bounds of its discretion as the trier of facts when assessing the weight and determining the credibility to be attributed to the opinions of the scientific experts.

587. We discuss our views on the applicable standard of review before turning to our examination of the Panel's assessment of Directive 2003/74/EC. The European Communities claims that the

¹¹⁹⁷European Communities' appellant's submission, para. 294.

¹¹⁹⁸*Ibid.*, para. 240.

¹¹⁹⁹*Ibid.*

¹²⁰⁰*Ibid.*, para. 239. (emphasis added)

¹²⁰¹*Ibid.*, para. 248.

¹²⁰²*Ibid.*

appropriate standard of review is one which limits a panel's mandate to determining whether there is any "reasonable scientific basis" for the SPS measure.¹²⁰³ The United States and Canada object to such a standard. We recall that in *EC – Hormones*, the Appellate Body rejected the European Communities' argument that a "deferential 'reasonableness' standard" is applicable under the *SPS Agreement* to "all highly complex factual situations, including the assessment of the risks to human health arising from toxins and contaminants".¹²⁰⁴ The Appellate Body cautioned that the applicable standard of review "must reflect the balance established in [the *SPS Agreement*] between the jurisdictional competences conceded by the Members to the WTO and the jurisdictional competences retained by the Members for themselves" and concluded that Article 11 of the DSU "articulates with great succinctness but with sufficient clarity the appropriate standard of review for panels"¹²⁰⁵ reviewing the assessment of facts under the *SPS Agreement*.

588. Article 11 of the DSU states, in relevant part:

[A] panel should make an objective assessment of the matter before it, including an objective assessment of the facts of the case and the applicability of and conformity with the relevant covered agreements.

589. The Appellate Body has observed that, so far as fact-finding by panels is concerned, the applicable standard is "neither *de novo* review as such, nor 'total deference', but rather the 'objective assessment of facts'".¹²⁰⁶ It further explained that, while panels are "poorly suited to engage in [a *de novo*] review", "'total deference to the findings of the national authorities' ... 'could not ensure an 'objective assessment' as foreseen by Article 11 of the DSU'".¹²⁰⁷

590. A panel reviewing the consistency of an SPS measure with Article 5.1 must determine whether that SPS measure is "based on" a risk assessment. It is the WTO Member's task to perform the risk assessment. The panel's task is to review that risk assessment. Where a panel goes beyond this limited mandate and acts as a risk assessor, it would be substituting its own scientific judgement for that of the risk assessor and making a *de novo* review and, consequently, would exceed its functions under Article 11 of the DSU. Therefore, the review power of a panel is not to determine whether the risk assessment undertaken by a WTO Member is correct, but rather to determine whether that risk assessment is supported by coherent reasoning and respectable scientific evidence and is, in this sense, objectively justifiable.

¹²⁰³European Communities' appellant's submission, para. 243.

¹²⁰⁴Appellate Body Report, *EC – Hormones*, paras. 113 and 114.

¹²⁰⁵*Ibid.*, paras. 115 and 116.

¹²⁰⁶*Ibid.*, para. 117.

¹²⁰⁷*Ibid.* (quoting Panel Report, *US – Underwear*, para. 7.10).

591. The Appellate Body has observed that a WTO Member may properly base an SPS measure on divergent or minority views, as long as these views are from qualified and respected sources.¹²⁰⁸ This must be taken into account in defining a panel's standard of review. Accordingly, a panel reviewing the consistency of an SPS measure with Article 5.1 of the *SPS Agreement* must, first, identify the scientific basis upon which the SPS measure was adopted. This scientific basis need not reflect the majority view within the scientific community but may reflect divergent or minority views. Having identified the scientific basis underlying the SPS measure, the panel must then verify that the scientific basis comes from a respected and qualified source. Although the scientific basis need not represent the majority view within the scientific community, it must nevertheless have the necessary scientific and methodological rigour to be considered reputable science. In other words, while the correctness of the views need not have been accepted by the broader scientific community, the views must be considered to be legitimate science according to the standards of the relevant scientific community. A panel should also assess whether the reasoning articulated on the basis of the scientific evidence is objective and coherent. In other words, a panel should review whether the particular conclusions drawn by the Member assessing the risk find sufficient support in the scientific evidence relied upon. Finally, the panel must determine whether the results of the risk assessment "sufficiently warrant" the SPS measure at issue.¹²⁰⁹ Here, again, the scientific basis cited as warranting the SPS measure need not reflect the majority view of the scientific community provided that it comes from a qualified and respected source.

592. A panel may and should rely on the advice of experts in reviewing a WTO Member's SPS measure, in accordance with Article 11.2 of the *SPS Agreement* and Article 13.1 of the DSU. In doing so, however, a panel must respect the due process rights of the parties.¹²¹⁰ Moreover, a panel may not rely on the experts to go beyond its limited mandate of review. The purpose of a panel consulting with experts is not to perform its own risk assessment. The role of the experts must reflect the limited task of a panel. The panel may seek the experts' assistance in order to identify the scientific basis of the SPS measure and to verify that this scientific basis comes from a qualified and respected source, irrespective of whether it represents minority or majority scientific views. It may also rely on the experts to review whether the reasoning articulated on the basis of the scientific evidence is objective and coherent, and whether the particular conclusions drawn by the Member assessing the risk find sufficient support in the evidence. The experts may also be consulted on the relationship between the risk assessment and the SPS measure in order to assist the panel in determining whether the risk assessment "sufficiently warrants" the SPS measure. The consultations

¹²⁰⁸ Appellate Body Report, *EC – Hormones*, para. 194.

¹²⁰⁹ *Ibid.*, para. 193.

¹²¹⁰ See *supra*, section V.

with the experts, however, should not seek to test whether the experts would have done a risk assessment in the same way and would have reached the same conclusions as the risk assessor. In other words, the assistance of the experts is constrained by the kind of review that the panel is required to undertake.

593. In this case, the Panel correctly identified Article 11 of the DSU as setting out the standard of review applicable to its examination of the consistency of the European Communities' risk assessment with Article 5.1 of the *SPS Agreement*.¹²¹¹ The Panel also referred to the guidance provided by the Appellate Body in *EC – Hormones* concerning the standard of review.¹²¹² Moreover, the Panel made reference to the interpretation of Article 5.1 of the *SPS Agreement* developed by the Appellate Body in *EC – Hormones* and acknowledged that a risk assessment may be based on divergent or minority views.¹²¹³

594. Next, the Panel referred to its consultations with scientific experts, noting that it had consulted six scientific experts individually, and not as an expert review group. The Panel stated that:

Although 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.¹²¹⁴

595. The analogy that the Panel draws between its situation and that of a risk assessor is unfortunate, but is not in itself a sufficient indication that the Panel incorrectly understood the applicable standard of review. We do not think that the Panel meant to suggest that it saw its task under Article 5.1 as requiring it to perform a risk assessment. At the beginning of the statement, the Panel expressly recognizes that it "is not carrying out its own risk assessment".

596. The Panel then elaborated on the approach it would take in respect of the testimony of the experts:

We note that, 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

¹²¹¹Panel Report, *US – Continued Suspension*, para. 7.413; Panel Report, *Canada – Continued Suspension*, para. 7.404.

¹²¹²Panel Report, *US – Continued Suspension*, paras. 7.414-7.416; Panel Report, *Canada – Continued Suspension*, paras. 7.405-7.407.

¹²¹³Panel Report, *US – Continued Suspension*, para. 7.417; Panel Report, *Canada – Continued Suspension*, para. 7.408 (quoting Appellate Body Report, *EC – Hormones*, para. 194).

¹²¹⁴Panel Report, *US – Continued Suspension*, para. 7.418; Panel Report, *Canada – Continued Suspension*, para. 7.409.

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.¹²¹⁵ (footnotes omitted)

597. The European Communities submits that "the majority view is not probative simply because it represents the majority".¹²¹⁶ We agree that automatically giving more weight to the testimony of the majority of experts would be too rigid an approach. The fact that a majority in the spectrum of the scientific experts consulted by the Panel had a particular view is not a proper basis for determining whether a WTO Member's risk assessment complies with the requirements of Article 5.1 and Annex A of the *SPS Agreement*.

598. Looking at the Panel's analysis of whether the European Communities specifically assessed the risks arising from the consumption of meat from cattle treated with oestradiol-17 β , we note that a significant portion of the Panel's reasoning consists of summaries of the responses of the experts. It is only after summarizing the experts' responses that the Panel describes some of the issues discussed in the 1999 Opinion. Given the applicable standard of review and the role of the Panel that is determined by it, the Panel's analysis should have proceeded differently. The Panel should have first looked at the European Communities' risk assessment. It should then have determined whether the scientific basis relied upon in that risk assessment came from a respected and qualified source. The Panel should have sought assistance from the scientific experts in confirming that it had properly identified the scientific basis underlying the European Communities' risk assessment or to determine whether that scientific basis originated in a respected and qualified source. The Panel should also have sought the experts' assistance in determining whether the reasoning articulated by the European Communities on the basis of the scientific evidence is objective and coherent, so that the conclusions reached in the risk assessment sufficiently warrant the SPS measure. Instead, the Panel seems to have conducted a survey of the advice presented by the scientific experts and based its decisions on whether the majority of the experts, or the opinion that was most thoroughly reasoned or specific to the question at issue, agreed with the conclusion drawn in the European Communities' risk assessment. This approach is not consistent with the applicable standard of review under the *SPS Agreement*.

¹²¹⁵Panel Report, *US – Continued Suspension*, para. 7.420; Panel Report, *Canada – Continued Suspension*, para. 7.411. At the interim stage, the Panel further explained that "in case of divergence of opinions between the experts, and having due regard to the comments of the parties and the clarifications provided by the experts at the meeting with the Panel, it was a sound approach to take into account, in forming its own opinion, the opinions that were the most precise and elaborate." (Panel Report, *US – Continued Suspension*, para. 6.72; Panel Report, *Canada – Continued Suspension*, para. 6.67).

¹²¹⁶European Communities' appellant's submission, para. 240.

599. The Panel's flawed approach is evident in its analysis of the genotoxicity of oestradiol-17 β , one of the central issues in the European Communities' risk assessment.¹²¹⁷ The 1999 Opinion refers to several studies that investigated the genotoxicity of oestradiol.¹²¹⁸ It also states that certain metabolites of oestradiol-17 β "have been found to be directly or indirectly genotoxic" and that "[t]his implies that 17- β oestradiol may act as tumor initiator as well as tumor promoter".¹²¹⁹ The 1999 Opinion goes on to state that "[t]his implies that any excess exposure towards 17- β oestradiol and its metabolites resulting from the consumption of meat and meat products presents a potential risk to public health in particular to those groups of the population which have been identified as particularly sensitive such as prepubertal children".¹²²⁰ Finally, the 1999 Opinion explains that a threshold cannot be established for these genotoxic metabolites.¹²²¹ The European Communities explained that a "threshold" is the "level below which intakes from residue should be considered to be safe."¹²²²

600. The genotoxicity of oestradiol-17 β is also examined in the 2002 Opinion, which concludes:

Convincing data have been published confirming the mutagenic and genotoxic potential of 17 β -oestradiol as a consequence of metabolic activation to reactive quinines. *In vitro* experiments indicated that oestrogenic compounds *might* alter the expression of an array of genes.¹²²³ (original emphasis)

601. Following the approach that we outlined earlier regarding the applicable standard of review, the first step in the Panel's analysis should have been to identify what in the European Communities' risk assessment was the scientific basis for the conclusions on the genotoxicity of oestradiol-17 β ; verify whether this scientific basis came from a respected and qualified source; and determine whether the reasoning articulated on the basis of that scientific evidence is objective and coherent. As a second step, the Panel should have pursued a similar inquiry concerning the conclusion that the genotoxicity of oestradiol-17 β did not permit the establishment of a threshold, as the European Communities submits. In that context, the Panel would have sought the experts' view as to whether the conclusions reached by the European Communities can find support in the scientific evidence relied upon by the European Communities (even if the expert in question was of a different scientific view).

¹²¹⁷The United States characterizes the issue of genotoxicity as a "central underpinning" of the European Communities' risk assessment relating to oestradiol-17 β . (Panel Report, *US – Continued Suspension*, para. 7.543)

¹²¹⁸1999 Opinion, pp. 39-41.

¹²¹⁹*Ibid.*, p. 75.

¹²²⁰*Ibid.*

¹²²¹*Ibid.*

¹²²²Panel Report, *US – Continued Suspension*, para. 4.238. See also Panel Report, *Canada – Continued Suspension*, footnote 259 to para. 6.88.

¹²²³2002 Opinion, p. 21.

602. Rather than turning first to the European Communities' risk assessment in order to identify the scientific basis for the conclusions on the genotoxicity of oestradiol-17 β , the Panel begins with a survey of the views of the scientific experts on this issue in general. The Panel tries to justify its approach on its inability to evaluate the evidence itself:

The Panel is not in a position to evaluate the scientific data the SCVPH reviewed in drawing its conclusions. For this reason, the Panel consulted a group of scientific experts and asked them to evaluate the [European Communities'] Opinions as well as the underlying science.¹²²⁴

However, under the applicable standard of review, neither the Panel nor the experts it consulted were called upon to evaluate the correctness of the European Communities' risk assessment. The Panel's role was more limited and consisted, as we explained earlier, of identifying the scientific basis and evidence relied upon in the risk assessment; verifying that the scientific evidence comes from respected and qualified sources; and determining whether the reasoning articulated by the European Communities on the basis of the scientific evidence is objective and coherent.

603. The summary of the experts' opinions, which constitutes the lengthiest portion of the Panel's reasoning, often appears to be a general discussion as to whether the genotoxicity of oestradiol-17 β is widely accepted by the broader scientific community, rather than a discussion of the evidence relied upon in the European Communities' risk assessment. The Panel concludes that the "scientific evidence referred to in the Opinions does not support the European Communities' conclusion that for oestradiol-17 β genotoxicity had already been demonstrated explicitly."¹²²⁵ The Panel's conclusion appropriately focuses on the scientific evidence in the SCVPH Opinions. Yet, the Panel's reasoning reveals several flaws. First, some of the experts seemed to accept the European Communities' position on the genotoxicity of oestradiol-17 β . For example, the Panel quotes the following opinion of Dr. Cogliano in its reasoning:

Dr. Cogliano explained that "the [European Communities'] statement that a threshold cannot be identified reflects their view of genotoxic mechanisms, just as the contrary statement that there is a threshold and that this threshold is above the levels found in meat residues reflects how Canada and the [United States] view genotoxic mechanisms. Neither statement has been demonstrated by the

¹²²⁴Panel Report, *US – Continued Suspension*, para. 7.553; Panel Report, *Canada – Continued Suspension*, para. 7.521.

¹²²⁵Panel Report, *US – Continued Suspension*, para. 7.572; Panel Report, *Canada – Continued Suspension*, para. 7.540 (referring to 1999 Opinion, p. 75).

scientific evidence, rather, they are different assumptions that each party uses in their interpretation of the available evidence."¹²²⁶

604. The Panel also refers to the following testimony of Dr. Cogliano:

Dr. Cogliano stated in his written responses that the identification of oestradiol-17 β as a human carcinogen indicates that there are potential adverse effects on human health when oestradiol-17 β is consumed in meat from cattle treated with hormones for growth promotion purposes. At the meeting with the Panel, Dr. Cogliano clarified that the IARC has classified oestradiol-17 β as possibly carcinogenic based on sufficient evidence in experimental animals. The agents that are known to be carcinogenic in humans are the steroidal oestrogens, non-steroidal oestrogens, and various oestrogen-progestin combinations as used either as birth-control pills or menopausal therapy.¹²²⁷

605. The Panel should have addressed whether Dr. Cogliano's statements provided evidence that the European Communities' position on the genotoxicity of oestradiol-17 β had some acceptance in the scientific community, even if it did not constitute the majority view. At the interim review, the Panel rejected the relevance of Dr. Cogliano's statement, explaining that "the *SPS Agreement* requires an analysis that goes beyond the identification of a potential adverse effect".¹²²⁸ According to the Panel, "[t]he analysis must include an examination of the potential for that adverse affect to come into being, originate, or result from the presence of the specific substance under review in food, beverages, or feedstuffs, in this case oestradiol-17 β in meat and meat products derived from cattle treated with the hormone for growth promotion purposes."

606. There is no indication in the Panel's reasoning about how to reconcile Dr. Cogliano's statements with the Panel's conclusion that the scientific evidence in the SCVPH Opinions do not support the European Communities' conclusions that "for oestradiol-17 β genotoxicity had already been demonstrated explicitly" or that the "presence of residues of oestradiol-17 β in meat and meat products as a result of the cattle being treated with the hormone for growth promotion purposes leads to increased cancer risk."¹²²⁹

¹²²⁶Panel Report, *US – Continued Suspension*, para. 7.559; Panel Report, *Canada – Continued Suspension*, para. 7.527 (referring to replies of the scientific experts to questions posed by the Panel, Panel Reports, Annex D, para. 186).

¹²²⁷Panel Report, *US – Continued Suspension*, para. 7.561; Panel Report, *Canada – Continued Suspension*, para. 7.529 (referring to replies of the scientific experts to questions posed by the Panel, Panel Reports, Annex D, para. 154, and transcript of the Panel meeting with the scientific experts, Panel Reports, Annex G, para. 327).

¹²²⁸Panel Report, *US – Continued Suspension*, para. 6.118; Panel Report, *Canada – Continued Suspension*, para. 6.110.

¹²²⁹Panel Report, *US – Continued Suspension*, para. 7.572; Panel Report, *Canada – Continued Suspension*, para. 7.540. (footnote omitted)

607. The genotoxicity of oestradiol-17 β also comes up in connection with the European Communities' conclusion that a threshold could not be established for oestradiol-17 β . As with genotoxicity, the risk assessment would need to provide a scientific basis for the conclusion that a threshold could not be established for oestradiol-17 β . The Panel does not identify what was the scientific basis for this conclusion, as it should have done. Rather, the Panel's reasoning reproduces the views of the experts on the issue of genotoxicity, with some of them mentioning the distinction between *in vivo* and *in vitro* genotoxicity. The discussion seeks to establish whether the genotoxicity *in vivo* of oestradiol-17 β had been accepted by the general scientific community, rather than whether the European Communities' risk assessment provided scientific evidence of the genotoxicity *in vivo* of oestradiol-17 β and whether this evidence came from a respected and qualified source. For example, the Panel relies on the following opinion provided by Dr. Boobis:

Dr. Boobis concluded that there is no good evidence that oestradiol is genotoxic *in vivo* or that it causes cancer by a genotoxic mechanism. Indeed the evidence is against this. Hence, the scientific evidence does not support the European Communities' position that the levels of the hormones in meat from treated cattle are not of relevance.¹²³⁰

608. Dr. Boisseau's response also goes beyond a verification of whether the European Communities' evidence on genotoxicity came from a respected and qualified source, into an examination of the general acceptance of the scientific basis of the European Communities' risk assessment:

In a review of the scientific literature and the 1999 report of the Committee for Veterinary Medicinal Products of the European Medicine Agency, Dr. Boisseau concluded that the demonstration remains to be made that the observed indicator effects are representative of mutagenesis at the gene or chromosome level and also occur in somatic cells *in vivo*. This is not likely in the view of the following: earlier studies had mostly indicated that hormones do not induce micronuclei or other chromosomes aberration types *in vivo*. With the exception of the study reported by Dhillon and Dhillon, the recent data confirm the earlier findings and clearly indicate that hormones and/or their synthetic analogues are not associated with genotoxicity properties in the bone marrow micronucleus assay *in vivo*.¹²³¹

609. At the same time, the Panel fails to explain how it reconciled its conclusion with the testimony of other experts that appear to acknowledge that the European Communities' risk

¹²³⁰Panel Report, *US – Continued Suspension*, para. 7.562; Panel Report, *Canada – Continued Suspension*, para. 7.530 (referring to replies of the scientific experts to questions posed by the Panel, Panel Reports, Annex D, para. 184).

¹²³¹Panel Report, *US – Continued Suspension*, para. 7.563; Panel Report, *Canada – Continued Suspension*, para. 7.531 (referring to replies of the scientific experts to questions posed by the Panel, Panel Reports, Annex D, para. 136).

assessment was based on evidence of genotoxicity *in vivo* of oestradiol-17 β . In his written responses to questions by the Panel, Dr. Guttenplan referred to a study, cited by the European Communities, allegedly indicating that the reactive metabolite oestradiol-3, 4-quinone induces mutations in mice skin *in vivo*.¹²³² Dr. Guttenplan testified that "[t]he catechol oestrogen-quinone form DNA adducts in cultured cells and in mouse skin", and concluded that "[t]his evidence was stronger compared to previous reports", adding that "the evidence now is much stronger."¹²³³ The Panel further explained, in the interim review, that it did "not read this statement as implying that the residues of oestradiol-17 β in meat from treated cattle are definitely genotoxic".¹²³⁴ The Panel added that, "even if this were the case, the issue of genotoxicity is only relevant to the issue of whether a threshold could be determined for this substance."¹²³⁵

610. We reiterate that the Panel was not called upon to determine whether there is general acceptance that oestradiol-17 β is genotoxic *in vivo* or that it causes cancer by a genotoxic mechanism. Instead, the focus should have been on the evidence relied upon by the European Communities in its risk assessment. As we noted earlier, the 1999 Opinion refers to several studies on the genotoxicity of oestradiol-17 β .¹²³⁶ Additional studies are discussed in the 2002 Opinion.¹²³⁷ These studies should have been the focus of the Panel's analysis, yet they are not mentioned in the Panel's analysis. The Panel does not give any reasons why it did not consider them relevant.

611. The European Communities' risk assessment also focused on the endogenous levels of hormones in pre-pubertal children and observed that these levels were lower than previously thought.¹²³⁸ Dr. Guttenplan seemed to accept the European Communities' position on this issue:

Dr. Guttenplan found that the levels in meat could result in bioavailable oestrogen exceeding the daily production rate of oestradiol in pre-pubertal children. "For pre-pubertal children, even with the low bioavailability of estrogen ... and its low levels in meats, it appears possible that intake levels would be within an order of magnitude of those of the daily production rate. This is greater than FDA's [(Food and Drug Administration of the United States)] ADI and suggests some risk to this population. If there [are] genotoxic effects of estradiol in children, they may be reflected over a lifetime, as mutations arising from DNA damage are permanent. It seems the more accurate methods of analysis could now be used to measure the effect of eating hormone-treated beef on blood levels of estrogen in

¹²³²Replies of the scientific experts to questions posed by the Panel, Panel Reports, Annex D, para. 181.

¹²³³*Ibid.*

¹²³⁴Panel Report, *US – Continued Suspension*, para. 6.113; Panel Report, *Canada – Continued Suspension*, para. 6.105.

¹²³⁵*Ibid.*

¹²³⁶1999 Opinion, pp. 39-41.

¹²³⁷2002 Opinion, pp. 13 and 14.

¹²³⁸1999 Opinion, p. 38.

children and post-menopausal women. If practical, this experiment would be important in establishing or refuting the arguments of the [European Communities]."¹²³⁹

The Panel does not address this statement further nor does the Panel explain how Dr. Guttenplan's conclusion should be reconciled with the Panel's conclusion that the European Communities' risk assessment did not examine the specific risks arising from the consumption of meat from cattle treated with oestradiol-17 β .

612. We have identified above how the Panel approached its task without proper regard to the standard of review and the limitations this places upon the appraisal of expert testimony. Ultimately, the Panel reviewed the scientific experts' opinions and somewhat peremptorily decided what it considered to be the best science, rather than following the more limited exercise that its mandate required. In addition, the European Communities has drawn our attention to the following response provided by Dr. Guttenplan to the Panel's question on the specificity of the European Communities' risk analysis:

I believe the [European Communities] has done a thorough job in identifying the potential for adverse effects on human health of oestradiol-17 β found in meat derived from cattle to which this hormone had been administered. They have identified a number of potential adverse effects of oestradiol-17 β in humans. They have established metabolic pathways relevant to these effects, and have examined mechanisms of these effects. In addition they have performed thorough studies of residue levels in cattle, and the environment. The evidence evaluating the occurrence of adverse effects is weak. Animal models are very limited and the target organs do not coincide well with the target organs in humans. There are basically no epidemiological studies comparing matched populations consuming meat from untreated and hormone-treated cattle. Thus, little can be inferred about the potential occurrence of the adverse effects, the potential for adverse effects seems reasonable.¹²⁴⁰

613. In his response, Dr. Guttenplan seems to recognize that the European Communities' risk assessment did specifically examine the potential for adverse effects from the consumption of meat from cattle treated with oestradiol-17 β . Dr. Guttenplan's response is summarized in the Panel's reasoning.¹²⁴¹ Yet, the Panel does not address that response any further. Given that the European

¹²³⁹Panel Report, *US – Continued Suspension*, para. 7.528; Panel Report, *Canada – Continued Suspension*, para. 7.500 (quoting replies of the scientific experts to Question 52 posed by the Panel, Panel Reports, Annex D, para. 413).

¹²⁴⁰Replies of the scientific experts to questions posed by the Panel, Panel Reports, Annex D, para. 145).

¹²⁴¹Panel Report, *US – Continued Suspension*, para. 7.523; Panel Report, *Canada – Continued Suspension*, para. 7.495.

Communities was entitled to rely on minority views, the Panel was required to explain why it did not consider that Dr. Guttenplan's testimony supported the European Communities' position.

614. An additional flaw in the Panel's reasoning relates to the following remark at the end of Panel's summary of the experts' responses:

Additionally, in response to direct questioning during the Panel meeting with the experts, Drs. Boobis, Boisseau, and Guttenplan all agreed that there is no appreciable risk of cancer from residues of oestradiol-17 β in meat and meat products from cattle treated with the hormone for growth promotion purposes. While all the experts who responded to the question agreed that a zero risk could not be guaranteed, the actual level of risk was in their view so small as to not be calculable.¹²⁴²

It was not the Panel's task, much less that of the experts that the Panel consulted, to determine whether there is an appreciable risk of cancer arising from the consumption of meat from cattle treated with oestradiol-17 β . Instead, the Panel was called upon to review the European Communities' risk assessment.

615. The United States and Canada argue that the Panel properly exercised its discretion as the trier of facts.¹²⁴³ We have found that the Panel did not apply the proper standard of review. This is a legal error and does not fall within the authority of the Panel as the trier of facts. Moreover, we have found instances in which the Panel exceeded its authority in the assessment of the testimony of the scientific experts. By merely reproducing testimony of some experts that would appear to be favourable to the European Communities' position, without addressing its significance, the Panel effectively disregarded evidence that was potentially relevant for the European Communities' case. This cannot be reconciled with the Panel's duty to make an "objective assessment of the facts of the case" pursuant to Article 11 of the DSU.

616. For these reasons, we find that the Panel failed to conduct an objective assessment of the facts of the case, as required by Article 11 of the DSU, in determining whether the European Communities' risk assessment satisfied the requirements of Article 5.1 and Annex A of the *SPS Agreement*.

F. *Conclusion*

617. We recall that we have found above that the Panel erred in its interpretation and application of Article 5.1 in relation to risks of misuse and abuse in the administration of hormones to cattle for

¹²⁴²Panel Report, *US – Continued Suspension*, para. 7.569; Panel Report, *Canada – Continued Suspension*, para. 7.537 (referring to the transcript of the Panel meeting with the scientific experts, Panel Reports, Annex G, paras. 707-742).

¹²⁴³United States' appellee's submission, para. 47; Canada's appellee's submission, para. 73.

growth-promoting purposes. We have also found that the Panel misallocated the burden of proof, and failed to conduct an objective assessment of the facts, in its analysis of whether the European Communities' risk assessment met the requirements of Article 5.1 of the *SPS Agreement*.

618. In addition, we found earlier that the Panel has infringed the European Communities' due process rights by inappropriately relying on the testimony of Drs. Boisseau and Boobis in its evaluation of the consistency with Article 5.1 of the *SPS Agreement* of the European Communities' risk assessment relating to oestradiol-17 β . Thus, the Panel's conclusions rest, to a large extent, on an improper evidentiary basis.

619. Accordingly, we reverse the Panel's finding that the European Communities has not satisfied the requirements of Article 5.1 and Annex A, paragraph 4, of the *SPS Agreement*. As a consequence, we also reverse the Panel's findings that Directive 2003/74/EC was not based on a risk assessment within the meaning of Article 5.1 of the *SPS Agreement* and that the European Communities' "implementing measure on oestradiol-17 β is not compatible with Article 5.1 of the *SPS Agreement*."¹²⁴⁴

620. Having reversed the Panel, we must now determine whether we can complete the analysis by reviewing ourselves the consistency of the European Communities' risk assessment relating to oestradiol-17 β with Article 5.1 of the *SPS Agreement*. In the past, the Appellate Body has completed the analysis when there were sufficient factual findings by the panel or undisputed facts on the Panel record to enable it to do so.¹²⁴⁵ In light of the numerous flaws we have found in the Panel's analysis, and the highly contested nature of the facts, we do not consider it possible to complete the analysis in this case. Thus, we make no findings on the consistency or inconsistency of the European Communities' import ban relating to oestradiol-17 β .

VII. The Consistency with Article 5.7 of the *SPS Agreement* of the European Communities' Provisional Import Ban on Meat from Cattle Treated with Testosterone, Progesterone, Trenbolone Acetate, Zeranol, and MGA for Growth-Promotion Purposes

A. Introduction

621. We turn finally to the European Communities' appeal of the Panel's finding that the European Communities' provisional ban on meat from cattle treated with testosterone, progesterone, trenbolone acetate, zeranol, and MGA failed to meet the requirements of Article 5.7 of the *SPS Agreement* because the relevant scientific evidence was not "insufficient" within the meaning of that provision.

¹²⁴⁴Panel Report, *US – Continued Suspension*, para. 7.579; Panel Report, *Canada – Continued Suspension*, para. 7.549.

¹²⁴⁵Appellate Body Report, *US – Section 211 Appropriations Act*, para. 343.

Section B describes the conclusions of the European Communities' evaluation of the potential adverse health effects of the five hormones, and section C summarizes the Panel's findings under Article 5.7 of the *SPS Agreement*. Section D provides an overview of the claims and arguments raised on appeal. In section E, we review the Panel's findings that the relevant scientific evidence in relation to the five hormones was not "insufficient" within the meaning of Article 5.7. Our conclusions are set out in section F.

B. *The European Communities' Evaluation of the Five Hormones Subject to the Provisional Ban*

622. As we noted above¹²⁴⁶, following the adoption of the DSB's recommendations and rulings in *EC – Hormones*, the European Communities initiated 17 scientific studies aimed at evaluating, *inter alia*, the potential for adverse effects to human health from residues in bovine meat and meat products resulting from the use of oestradiol-17 β , testosterone, progesterone, zeranol, trenbolone acetate, and MGA. The results of these studies, as well as other publicly available information, were reviewed by the SCVPH. On 30 April 1999, the SCVPH issued the "1999 Opinion, in which it concluded that "in view of the intrinsic properties of hormones and epidemiological findings, a risk to the consumer has been identified with different levels of conclusive evidence for the six hormones in question."¹²⁴⁷ As regards the five hormones, the 1999 Opinion further provided that "in spite of the individual toxicological and epidemiological data described in the report, the current state of knowledge did not allow a quantitative estimate of the risk."¹²⁴⁸ The European Communities concluded that "the currently available information for testosterone, progesterone and the synthetic hormones zeranol, trenbolone and particularly MGA has been considered inadequate to complete [a risk] assessment."¹²⁴⁹ The 1999 Opinion also states that "no final conclusions can be drawn with respect to the safety" of the five hormones.¹²⁵⁰

623. The SCVPH subsequently reviewed the 1999 Opinion in 2000 and 2002, in the light of additional scientific information it received, but did not find it necessary to amend the conclusions originally reached in the 1999 Opinion. The 2000 Opinion emphasized "the obvious gaps in the present knowledge on target animal metabolism and residue disposition of the hormones under

¹²⁴⁶See *supra*, sections I and IV.B.

¹²⁴⁷1999 Opinion, p. 73.

¹²⁴⁸Panel Report, *US – Continued Suspension*, para. 7.391 (quoting 1999 Opinion (Exhibit US-4 submitted by the United States to the Panel), p. 73); Panel Report, *Canada – Continued Suspension*, para. 7.388 (quoting 1999 Opinion (Exhibit CDA-2 submitted by Canada to the Panel), p. 73). The 1999 Opinion also concludes that "endocrine, developmental, immunological, neurobiological, immunotoxic, genotoxic and carcinogenic effects could be envisaged" for the five hormones, but "[i]n view of the intrinsic properties of the hormones and in consideration of epidemiological findings, no threshold levels could be defined". (See *ibid.*)

¹²⁴⁹1999 Opinion, p. 75.

¹²⁵⁰*Ibid.*

consideration, including the synthetic hormones", and stated that it expected "that the on-going [European Communities'] research programs will provide additional data on both topics".¹²⁵¹ The 2002 Opinion arrived at the following specific conclusions in relation to potential risks arising from residues of the five hormones in bovine meat:

(e) No new data regarding testosterone and progesterone relevant to bovine meat or meat products were available. However, it was emphasized that these natural hormones were used only in combination with oestradiol-17 β or other oestrogenic compounds in commercial preparations.

(f) Experiments with zeranol and trenbolone acetate suggested a more complex oxidative metabolism than previously assumed. These data needed further clarification as they might influence a risk assessment related to tissue residues of these compounds.

(g) Zeranol and trenbolone acetate had been tested for their mutagenic and genotoxic potential in various systems with different endpoints. Both compounds exhibited only very weak effects.

(h) Data on the genotoxicity of [MGA] indicated only weak effects. However, pro-apoptotic effects were noted in some cell-based assays, which were attributed to the impurities in commercial formulation. Further experiments should clarify the toxicological significance of these impurities.

(i) Model experiments with rabbits treated with zeranol, trenbolone acetate or [MGA], mirroring their use in bovines, were designed to study the consequences of pre- and perinatal exposure to exogenous hormones. All compounds crossed the placental barrier easily and influenced to varying degrees the development of the fetus, at the doses used in the experiments.

...

(k) Several studies were devoted to the potential impact of the extensive use of hormones on the environment. Convincing data were presented indicating the high stability of trenbolone acetate and [MGA] in the environment, whereas preliminary data were provided on the potential detrimental effects of hormonal compounds in surface water.¹²⁵²

624. The European Communities enacted Directive 2003/74/EC, which provides for a *provisional* ban on meat and meat products from cattle treated with progesterone, testosterone, zeranol, trenbolone

¹²⁵¹Panel Report, *US – Continued Suspension*, para. 7.392 (quoting 2000 Opinion (Exhibit US-17 submitted by the United States to the Panel), p. 4); Panel Report, *Canada – Continued Suspension*, para. 7.389 (quoting 2000 Opinion (Exhibit CDA-4 submitted by Canada to the Panel), p. 4).

¹²⁵²Panel Report, *US – Continued Suspension*, para. 7.393 (quoting 2002 Opinion (Exhibit US-1 submitted by the United States to the Panel), pp. 21 and 22); Panel Report, *Canada – Continued Suspension*, para. 7.390 (quoting 2002 Opinion (Exhibit CDA-7 submitted by Canada to the Panel), pp. 21 and 22).

acetate and MGA for growth-promotion purposes. Before the Panel, the European Communities argued that the SCVPH Opinions and supporting studies provided the "available pertinent information" within the meaning of Article 5.7 on the basis of which the provisional ban on the five hormones had been enacted.¹²⁵³

C. *The Panel's Findings*

625. At the outset of its analysis, the Panel recalled its earlier conclusion that the measure at issue, to the extent that it provisionally bans the importation of meat from cattle treated with the hormones progesterone, testosterone, zeranol, trenbolone acetate, and MGA, is an SPS measure within the meaning of Article 1 and paragraph 1 of Annex A to the *SPS Agreement*.¹²⁵⁴ The Panel, furthermore, observed that the "parties address the issue of the compatibility of the provisional ban on the above-mentioned five hormones with the provisions of Article 5.7 of the *SPS Agreement*" and that "[n]one ... discussed the compatibility of the ban imposed with respect to these five hormones with Article 5.1".¹²⁵⁵ Therefore, the Panel stated that it would "limit its review to the conformity of the [European Communities'] ban on the five hormones with the requirements of Article 5.7".¹²⁵⁶

626. Having identified Article 5.7 as the relevant provision, the Panel referred to the Appellate Body's interpretation of this provision as setting out the following four cumulative requirements that must be satisfied in order to adopt and maintain a provisional measure under the *SPS Agreement*:

- (a) the measure is imposed in respect to a situation where "relevant scientific evidence is insufficient";
- (b) the measure is adopted "on the basis of available pertinent information";
- (c) the WTO Member which adopted the measure must "seek to obtain the additional information necessary for a more objective assessment of risk"; and

¹²⁵³Panel Report, *US – Continued Suspension*, para. 7.581; Panel Report, *Canada – Continued Suspension*, para. 7.551.

¹²⁵⁴Panel Report, *US – Continued Suspension*, para. 7.590; Panel Report, *Canada – Continued Suspension*, para. 7.565. (footnote omitted)

¹²⁵⁵Panel Report, *US – Continued Suspension*, para. 7.591; Panel Report, *Canada – Continued Suspension*, para. 7.566. (footnote omitted)

¹²⁵⁶*Ibid.*

- (d) the Member which adopted the measure must "review the ... measure accordingly within a reasonable period of time".¹²⁵⁷

627. Turning to the first requirement, the Panel referred to the Appellate Body's statement in *Japan – Apples* that scientific evidence will be insufficient for purposes of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate risk assessment.¹²⁵⁸ Recalling the approach it had adopted under Articles 5.1 and 5.2, the Panel dismissed the relevance of instances of misuse or abuse and difficulties of control in the administration of the five hormones for the purposes of its determination of whether the relevant scientific evidence on the five hormones was insufficient under Article 5.7. The Panel reasoned that instances of misuse and abuse are not, as such, a scientific issue likely to make a risk assessment impossible, and concluded that:

In our opinion, the scientific issue is related to the effect of the ingestion of high doses of hormones residues, not to potential or actual misuse or abuse in the administration of hormones. Therefore, we will not address the issue of non compliance with good veterinary practices in our analysis under Article 5.7 of the *SPS Agreement*.¹²⁵⁹

628. The Panel then addressed the European Communities' argument that the appropriate level of protection is relevant for the purposes of determining whether the scientific evidence is insufficient.¹²⁶⁰ The Panel rejected the European Communities' argument on the basis of the following reasoning:

We note that sufficient scientific evidence is what is needed to make a risk assessment. The assessment whether there is sufficient scientific evidence or not to perform a risk assessment should be an objective process. The level of protection defined by each Member may be relevant to determine the measure to be selected to address the assessed risk, but it should not influence the performance of the risk assessment as such.

¹²⁵⁷Panel Report, *US – Continued Suspension*, para. 7.593; Panel Report, *Canada – Continued Suspension*, para. 7.568 (quoting Appellate Body Report, *Japan – Agricultural Products II*, para. 89).

¹²⁵⁸Panel Report, *US – Continued Suspension*, para. 7.608; Panel Report, *Canada – Continued Suspension*, para. 7.586.

¹²⁵⁹Panel Report, *US – Continued Suspension*, para. 7.603; Panel Report, *Canada – Continued Suspension*, para. 7.578.

¹²⁶⁰The Panel described the European Communities' level of protection as:
no (avoidable) risk, that is a level of protection that does not allow any unnecessary addition from exposure to genotoxic chemical substances that are intended to be added deliberately to food.
(Panel Report, *US – Continued Suspension*, para. 7.607; Panel Report, *Canada – Continued Suspension*, para. 7.585 (quoting replies of the European Communities to questions posed by the Panel after the second Panel meeting, Panel Reports, Annex C-1, para. 69))

Indeed, whether a Member considers that its population should be exposed or not to a particular risk, or at what level, is not relevant to determining whether a risk exists and what its magnitude is. *A fortiori*, it should have no effect on whether there is sufficient evidence of the existence and magnitude of this risk.

A risk-averse Member may be inclined to take a protective position when considering the measure to be adopted. However, the determination of whether scientific evidence is sufficient to assess the existence and magnitude of a risk must be disconnected from the intended level of protection.¹²⁶¹

629. The Panel next observed that the United States and Canada argued that JECFA and several national regulatory bodies have determined that the scientific evidence regarding these hormones is adequate or sufficient to conduct a risk assessment. The Panel, however, agreed with the parties that scientific evidence which was previously deemed to be sufficient could subsequently become insufficient.¹²⁶² On this basis, the Panel sought to determine under what circumstances could relevant, previously sufficient, scientific evidence become insufficient within the meaning of Article 5.7.

630. Recalling the Appellate Body's decision in *Japan – Apples*, the Panel reasoned that "Article 5.7 will apply in situations where, in substance, the relevant scientific evidence does not allow the completion of an objective evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages, or feedstuffs."¹²⁶³ Also referring to the Appellate Body's decision in *Japan – Apples*, the Panel stated that "the existence of scientific uncertainty does not automatically amount to a situation of insufficiency of relevant scientific evidence".¹²⁶⁴ The Panel added that, although it agreed that "under certain circumstances what was previously sufficient evidence could become insufficient", it did 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*".¹²⁶⁵

631. The Panel then turned to examine the relationship between insufficiency of the evidence and

¹²⁶¹Panel Report, *US – Continued Suspension*, paras. 7.610-7.612; Panel Report, *Canada – Continued Suspension*, paras. 7.588-7.590.

¹²⁶²Panel Report, *US – Continued Suspension*, para. 7.620; Panel Report, *Canada – Continued Suspension*, para. 7.598.

¹²⁶³Panel Report, *US – Continued Suspension*, para. 7.628; Panel Report, *Canada – Continued Suspension*, para. 7.606 (referring to Appellate Body Report, *Japan – Apples*, para. 179).

¹²⁶⁴Panel Report, *US – Continued Suspension*, para. 7.631; Panel Report, *Canada – Continued Suspension*, para. 7.609 (referring to Appellate Body Report, *Japan – Apples*, para. 184).

¹²⁶⁵Panel Report, *US – Continued Suspension*, para. 7.637; Panel Report, *Canada – Continued Suspension*, para. 7.615. In this respect, the Panel referred to the comments of Drs. Boisseau and Boobis on how scientific uncertainty is addressed in risk assessment. (Panel Report, *US – Continued Suspension*, para. 7.635; Panel Report, *Canada – Continued Suspension*, para. 7.613)

the existence of an international standard. According to the Panel, "[t]he presumption of consistency of measures conforming to international standards, guidelines and recommendations with the relevant provisions of the *SPS Agreement* implies that these standards, guidelines or recommendations, particularly those referred to in this case, are based on risk assessments that meet the requirements of the *SPS Agreement*."¹²⁶⁶ The Panel recognized that "science continuously evolves", and that it "cannot be excluded that new scientific evidence or information calls into question existing evidence" or that "different risk assessments reach different interpretations of the same scientific evidence".¹²⁶⁷ For the Panel, the existence of international standards meant "that there was sufficient evidence for JECFA to undertake the appropriate risk assessments".¹²⁶⁸ The Panel added:

As a result, we consider that, in order to properly take into account the existence of international standards, guidelines and recommendations in this case, our approach should be to assess whether scientific evidence has become insufficient by determining whether the European Communities has produced any evidence of some sufficient change in the scientific knowledge so that what was once sufficient to perform an adequate risk assessment has now become insufficient (i.e., "deficient in force, quality or amount"). In this respect, suggesting hypothetical correlations or merely arguing that there could be more evidence on one concern or another should not be deemed sufficient to successfully claim that relevant scientific evidence has become *insufficient*.¹²⁶⁹ (original emphasis; footnote omitted)

632. The Panel concluded:

... if relevant evidence already exists, not any degree of insufficiency will satisfy the criterion under Article 5.7 that "relevant scientific evidence is insufficient". Having regard to our reasoning above, particularly with respect to scientific uncertainty and the existence of international standards, we consider that, depending on the existing relevant evidence, there must be a *critical mass* of new evidence and/or information that calls into question the fundamental precepts of previous knowledge and evidence so as to make relevant, previously sufficient, evidence now insufficient. In the present case where risk assessments have been performed and a large body of quality evidence has been accumulated, this would be possible only if it put into question existing relevant evidence *to the point that* this evidence is no longer sufficient to support the conclusions of existing

¹²⁶⁶Panel Report, *US – Continued Suspension*, para. 7.644; Panel Report, *Canada – Continued Suspension*, para. 7.622.

¹²⁶⁷Panel Report, *US – Continued Suspension*, para. 7.645; Panel Report, *Canada – Continued Suspension*, para. 7.623.

¹²⁶⁸Panel Report, *US – Continued Suspension*, para. 7.644; Panel Report, *Canada – Continued Suspension*, para. 7.622.

¹²⁶⁹Panel Report, *US – Continued Suspension*, para. 7.647; Panel Report, *Canada – Continued Suspension*, para. 7.625.

risks assessments. We therefore need to determine whether this is the case here.¹²⁷⁰ (original emphasis; footnote omitted)

633. Next, the Panel sought to identify the alleged insufficiencies in the scientific evidence that it would have to address. The Panel observed that, "[w]hereas, in 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."¹²⁷¹ The Panel further noted 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*."¹²⁷² The Panel also recalled "the consequence of the presumption of consistency with the *SPS Agreement* and the GATT 1994 of measures which conform to international standards, guidelines and recommendations on the risk assessments on which such measures are based."¹²⁷³ From this, the Panel reasoned that, "[s]ince, in that context, the European Communities argues that the relevant scientific evidence is insufficient, we consider that it is for the European Communities to identify the issues for which such evidence is insufficient."¹²⁷⁴ Thus, the Panel did "not consider that, as Panel, we have any obligation to go beyond the insufficiencies identified by the European Communities."¹²⁷⁵

634. Before turning to the alleged insufficiencies of the scientific evidence, however, the Panel noted that arguments and information presented to it were sometimes general and did not permit the Panel to address each insufficiency on a hormone-specific basis. For this reason, the Panel decided to address separately, on the basis of the insufficiencies discussed and identified by the European Communities: (i) the insufficiencies commonly identified for all of the five hormones at issue, "to the extent that information was not submitted on a hormone-specific basis, or to the extent an issue was

¹²⁷⁰Panel Report, *US – Continued Suspension*, para. 7.648; Panel Report, *Canada – Continued Suspension*, para. 7.626.

¹²⁷¹Panel Report, *US – Continued Suspension*, para. 7.652; Panel Report, *Canada – Continued Suspension*, para. 7.629. (footnote omitted)

¹²⁷²*Ibid.*

¹²⁷³*Ibid.*

¹²⁷⁴*Ibid.*

¹²⁷⁵Panel Report, *US – Continued Suspension*, para. 7.653; Panel Report, *Canada – Continued Suspension*, para. 7.630. The Panel also stated its view "that it is incumbent upon a party making a particular allegation to identify in its submissions the *relevance* of the evidence on which it relies to support its arguments". (Panel Report, *US – Continued Suspension*, para. 7.658; Panel Report, *Canada – Continued Suspension*, para. 7.635) (original emphasis) The Panel observed that, "in light of its functions under the DSU, it should limit its review of alleged insufficiencies in the relevant scientific evidence to those specifically discussed by the European Communities in its submissions", and would "only address the issues identified in the Opinions to the extent they are sufficiently related to an issue *discussed* by the European Communities." (Panel Report, *US – Continued Suspension*, para. 7.659; Panel Report, *Canada – Continued Suspension*, para. 7.636) (original emphasis)

raised with respect to all hormones, but evidence submitted only for one or two of them"¹²⁷⁶; and (ii) the insufficiencies alleged for each hormone on the basis of the information that was specific for that hormone.

635. The Panel stated that the following insufficiencies in the relevant scientific evidence were identified and discussed by the European Communities in relation to all the five hormones at issue: (a) effects of hormones on certain categories of the population, such as pre-pubertal children; (b) dose response; (c) bioavailability; (d) long latency period for cancer; (e) the impact of the five hormones on the immune system; and (f) the impact of the five hormones at issue on development and reproduction.¹²⁷⁷

636. With regard to the effects of the hormones on certain categories of the population, the Panel referred to the conclusions in the European Communities' risk assessment that individuals that have the lowest endogenous levels of sex hormones, particularly prepubescent children and post-menopausal women, might be at an increased risk of adverse health effects associated with exposure to exogenous sources of both oestrogens and testosterone.¹²⁷⁸ The Panel noted that the European Communities' risk assessment made reference to the development of new detection methods that had identified considerably lower levels of oestradiol endogenously produced by pre-pubertal children than the levels previously identified using traditional detection methods. The Panel also observed the European Communities' statement in the 1999 Opinion that "this is a critical area requiring additional study".¹²⁷⁹

637. The Panel recalled the "critical mass" standard that it had developed to assess the insufficiency of the relevant scientific evidence under Article 5.7, and concluded that its task was to examine "whether the more sensitive detection methods which identified lower hormonal levels in prepubertal children than thought until now are such as to call into question the range of physiological levels of the sex hormones in humans currently believed to exist".¹²⁸⁰

¹²⁷⁶Panel Report, *US – Continued Suspension*, para. 7.661; Panel Report, *Canada – Continued Suspension*, para. 7.638.

¹²⁷⁷Panel Report, *US – Continued Suspension*, para. 7.663; Panel Report, *Canada – Continued Suspension*, para. 7.640. The European Communities also referred to "misuse and abuse (unspecified implants, off-label use, black market drugs, etc.)" in its first submission to the Panel. The Panel believed that this issue was not relevant to the insufficiency of the relevant scientific evidence under Article 5.7. (Panel Report, *US – Continued Suspension*, footnote 787 to para. 7.654, and para. 7.483; Panel Report, *Canada – Continued Suspension*, footnote 734 to para. 7.631)

¹²⁷⁸See Panel Report, *US – Continued Suspension*, para. 7.664; and Panel Report, *Canada – Continued Suspension*, para. 7.641.

¹²⁷⁹Panel Report, *US – Continued Suspension*, para. 7.665; Panel Report, *Canada – Continued Suspension*, para. 7.642. (footnote omitted)

¹²⁸⁰Panel Report, *US – Continued Suspension*, para. 7.666; Panel Report, *Canada – Continued Suspension*, para. 7.643.

638. The Panel concluded that:

We note that the evidence presented relates only to oestradiol, but that the claim we are examining with regard to the insufficiencies of the evidence are with respect to the five other hormones at issue, not oestradiol. We note furthermore that the 2002 Opinion concludes that these more sensitive detection methods have not yet been validated.

... we are not convinced that the studies discussed by the experts call into question the fundamental precepts of previous knowledge and evidence so as to make relevant, previously sufficient evidence now insufficient in relation to the effect of the five hormones on pre-pubertal children. Particularly, it has not been established that the data regarding the effects of hormones on which the JECFA assessments are based are insufficient in light of new evidence relating to the other five hormones at issue.¹²⁸¹

639. Regarding dose response, the Panel noted that the European Communities questioned JECFA's findings on dose response, in the light of new detection methods that called into question previous knowledge about the endogenous production levels of hormones in pre-pubertal children. The Panel then observed that JECFA could identify a dose response for the five hormones at issue. It also noted that the European Communities' argument was premised on the notion that endogenous production of natural hormones was lower than previously thought, and recalled its previous conclusion that scientific studies in support of this notion were not yet validated and applied exclusively to oestradiol. The Panel found that "it has not been established that new evidence was such as to put into question existing data on dose response and prevent the performance of a risk assessment."¹²⁸²

640. With respect to bioavailability, the Panel observed that the new studies performed by the European Communities related exclusively to the bioavailability of oestradiol-17 β , and that it was unclear whether their findings would be relevant to hormones other than oestrogens.¹²⁸³ The Panel then stated that "bioavailability would be an issue if the new evidence suggested that bioavailability in the case of ingestion of meat treated for growth promotion purposes is higher than previously

¹²⁸¹Panel Report, *US – Continued Suspension*, paras. 7.670 and 7.671; Panel Report, *Canada – Continued Suspension*, paras. 7.647 and 7.648.

¹²⁸²Panel Report, *US – Continued Suspension*, para. 7.675; Panel Report, *Canada – Continued Suspension*, para. 7.652.

¹²⁸³Panel Report, *US – Continued Suspension*, para. 7.677; Panel Report, *Canada – Continued Suspension*, para. 7.654 (referring to European Communities' second written submission to the Panel, paras. 123 and 124). These paragraphs describe excerpts contained in the 1999 and 2002 Opinions, which call into question NOEL (no-observed effect level) studies conducted by JECFA. (See 1999 Opinion, pp. 36 and 37, and 2002 Opinion, p. 12)

thought."¹²⁸⁴ However, the Panel noted that, in the absence of data, JECFA appears to have assumed 100 per cent bioavailability. The Panel referred to the testimony of Drs. Boisseau and Boobis, which confirmed that the bioavailability of the synthetic hormones in humans has not been determined, and for this reason JECFA assumed 100 per cent bioavailability.¹²⁸⁵ For these reasons, the Panel concluded that it was not established that "any new evidence on bioavailability has been developed regarding specifically the five hormones at issue, which would affect the current knowledge on the subject."¹²⁸⁶

641. Regarding the long latency period¹²⁸⁷ of cancer and confounding factors¹²⁸⁸, the Panel noted the European Communities' allegation that "it may not be in a position to demonstrate the existence of a clear harm in case of cancer because of the long latency period and the numerous confounding factors that play a role in the development of cancer."¹²⁸⁹ The Panel then observed that Drs. Boobis, Cogliano, and Guttenplan agreed that it was important to take account of the long latency period of cancer in conducting a risk assessment.¹²⁹⁰ The Panel noted further Drs. Boisseau's and Boobis' opinions that epidemiological studies, even if taking into account long latency periods for cancer, might not be able to identify the specific agent that has caused the disease, by virtue of the many confounding factors.¹²⁹¹ In this respect, the Panel referred to Dr. Cogliano's statement that "it was generally possible to identify confounding factors in epidemiological studies" but it was often difficult to "determine whether the observed tumours can be attributed to the agent under study or to a confounding factor".¹²⁹² The Panel observed that Drs. Cogliano, Guttenplan, and Boobis expressed the view that the epidemiological studies submitted by the European Communities did not establish a

¹²⁸⁴Panel Report, *US – Continued Suspension*, para. 7.679; Panel Report, *Canada – Continued Suspension*, para. 7.656.

¹²⁸⁵Panel Report, *US – Continued Suspension*, paras. 7.680 and 7.682; Panel Report, *Canada – Continued Suspension*, para. 7.657 and 7.659 (quoting replies of the scientific experts to Question 43 posed by the Panel, Panel Reports, Annex D, paras. 347 and 351).

¹²⁸⁶Panel Report, *US – Continued Suspension*, para. 7.684; Panel Report, *Canada – Continued Suspension*, para. 7.661.

¹²⁸⁷A "latency period" is the period between exposure to an agent or process and the appearance of symptoms. (*Merriam-Webster Medical Dictionary* available at: <www.merriam-webster.com>)

¹²⁸⁸Confounding factors are factors other than the one investigated which may also correlate with the disease endpoint. (Replies of the scientific experts to Question 24 posed by the Panel, Panel Reports, Annex D, para. 221)

¹²⁸⁹Panel Report, *US – Continued Suspension*, para. 7.685; Panel Report, *Canada – Continued Suspension*, para. 7.662.

¹²⁹⁰Panel Report, *US – Continued Suspension*, paras. 7.687-7.690; Panel Report, *Canada – Continued Suspension*, paras. 7.664-7.667 (quoting replies of the scientific experts to Question 23 posed by the Panel, Panel Reports, Annex D, paras. 210, 213, and 214).

¹²⁹¹Panel Report, *US – Continued Suspension*, paras. 7.691 and 7.692; Panel Report, *Canada – Continued Suspension*, paras. 7.668 and 7.669 (quoting replies of the scientific experts to Question 23 posed by the Panel, Panel Reports, Annex D, paras. 209 and 211).

¹²⁹²Panel Report, *US – Continued Suspension*, para. 7.693; Panel Report, *Canada – Continued Suspension*, para. 7.670 (quoting replies of the scientific experts to Question 24 posed by the Panel, Panel Reports, Annex D, para. 220).

link or correlation between higher incidence of cancer and the consumption of residues of hormones in treated meat¹²⁹³, and found that:

On the one hand, the comments of the experts suggest that epidemiological studies have not been able to single out residues of hormones in meat treated for growth promotion purposes as a cause of cancer, and that this would be difficult. On the other hand, the Panel notes that it is possible to assess long term effects through long term studies of experimental animals, even if they involve much higher doses than would be encountered in consumption of meat from animals treated with growth promoting hormones. It has also been possible to take into account the risk attached to latency through the setting of ADI. The European Communities has not identified any evidence quantitatively and qualitatively sufficient to call into question the fundamental precepts of existing knowledge and evidence and the approach followed so far in order to integrate the long latency period of cancer in risk assessment.¹²⁹⁴

642. Turning to the effects of the hormones on the immune system, the Panel noted the conclusion contained in the 1999 Opinion that there is insufficient evidence as to the effects of the hormones on the immune system. The Panel rejected the European Communities' contention that it was for the responding parties to present evidence that adverse immune effects could not occur from residues of hormone-treated meat, because all the responding parties had to prove was their assertion that the relevant scientific evidence on these particular risks was sufficient to perform an adequate risk assessment.¹²⁹⁵ Next, the Panel observed that the experts identified potential adverse effects on the immune system arising exclusively from oestrogens¹²⁹⁶, and that there was no evidence to suggest that those risks could not be addressed through a dose-response approach.¹²⁹⁷ The Panel also concluded that the 1999 Opinion itself does not provide evidence of impact of any of the five hormones on the immune system.¹²⁹⁸ For these reasons, the Panel found that "it is not established that there exists a critical mass of new evidence and/or information that calls into question the fundamental precepts of

¹²⁹³Panel Report, *US – Continued Suspension*, paras. 7.695-7.697; Panel Report, *Canada – Continued Suspension*, paras. 7.672-7.674 (quoting replies of the scientific experts to Question 26 posed by the Panel, Panel Reports, Annex D, paras. 241, 242, and 239).

¹²⁹⁴Panel Report, *US – Continued Suspension*, para. 7.699; Panel Report, *Canada – Continued Suspension*, para. 7.676.

¹²⁹⁵Panel Report, *US – Continued Suspension*, para. 7.705; Panel Report, *Canada – Continued Suspension*, para. 7.682.

¹²⁹⁶Panel Report, *US – Continued Suspension*, para. 7.706; Panel Report, *Canada – Continued Suspension*, para. 7.683.

¹²⁹⁷Panel Report, *US – Continued Suspension*, para. 7.707; Panel Report, *Canada – Continued Suspension*, para. 7.684.

¹²⁹⁸Panel Report, *US – Continued Suspension*, para. 7.706; Panel Report, *Canada – Continued Suspension*, para. 7.683 (referring to 1999 Opinion, pp. 51, 55, 60, and 66).

previous knowledge and evidence so as to make relevant, previously sufficient, evidence on hormone effects on the immune system now insufficient."¹²⁹⁹

643. Finally, as regards the effects on growth and reproduction, the Panel initially observed that the European Communities had advanced no specific argument in relation to the insufficiency of the evidence of adverse effects of the five hormones on growth and reproduction. Nevertheless, the Panel decided to address this issue in light of the European Communities' contention that the new data revealed "important gaps, insufficiencies and contradictions"¹³⁰⁰ in the relevant scientific evidence. The Panel observed that Dr. Guttenplan initially identified a number of gaps in the scientific evidence that could relate to growth and reproduction, but subsequently declared that it was possible to conduct a risk assessment of the five hormones.¹³⁰¹ Dr. Boobis, in turn, expressed the view that the scientific studies do not "support the contention that they have identified important new gaps, insufficiencies and contradictions in the scientific information" and that additional information obtained "was often not definitive, sometimes it was not relevant, in some instances it confirmed or expanded on previous knowledge".¹³⁰² Next, the Panel dismissed the opinions of Drs. Sippell and Guttenplan about potential developmental effects of hormones in children on the basis that these statements reflected "doubts" but did not constitute "evidence of risks".¹³⁰³ Finally, the Panel considered that the evidence referred to by the European Communities related only to oestradiol-17 β , and that the European Communities had not substantiated its assertion that the scientific evidence was insufficient to conduct a risk assessment with respect to the other five hormones. On this basis, the Panel concluded that "it has not been established that there is a critical mass of new evidence ... so as to make relevant, previously sufficient evidence now insufficient in relation to the growth and reproduction effects".¹³⁰⁴

644. Next, the Panel turned to the specific insufficiencies alleged in relation to each of the five hormones individually.

645. In relation to progesterone, the Panel focused on the European Communities' allegation that

¹²⁹⁹Panel Report, *US – Continued Suspension*, para. 7.708; Panel Report, *Canada – Continued Suspension*, para. 7.685.

¹³⁰⁰Panel Report, *US – Continued Suspension*, para. 7.709; Panel Report, *Canada – Continued Suspension*, para. 7.686.

¹³⁰¹Panel Report, *US – Continued Suspension*, para. 7.710; Panel Report, *Canada – Continued Suspension*, para. 7.687.

¹³⁰²Panel Report, *US – Continued Suspension*, para. 7.711; Panel Report, *Canada – Continued Suspension*, para. 7.688 (quoting replies of the scientific experts to Question 62 posed by the Panel, Panel Reports, Annex D, para. 495).

¹³⁰³Panel Report, *US – Continued Suspension*, para. 7.719; Panel Report, *Canada – Continued Suspension*, para. 7.696 (quoting transcript of the Panel's joint meeting with scientific experts on 27-28 September 2006, Panel Reports, Annex G, paras. 1061 and 1063).

¹³⁰⁴Panel Report, *US – Continued Suspension*, para. 7.721; Panel Report, *Canada – Continued Suspension*, para. 7.698.

the relevant scientific evidence on carcinogenic or genotoxic potential of this hormone was insufficient, because the other insufficiencies identified by the European Communities had already been addressed by the Panel in its analysis of the insufficiencies common to the five hormones.¹³⁰⁵ The Panel noted that the 2002 Opinion concluded that "[t]here is no evidence that progesterone or testosterone have genotoxic potential".¹³⁰⁶ The Panel observed that Drs. Boisseau, Boobis, and Guttenplan agreed that there was no evidence that progesterone was genotoxic. The Panel also referred to Dr. Boisseau's opinion that the scientific evidence submitted by the European Communities did not support the conclusion that carcinogenic effects of progesterone are related to a mechanism other than hormonal activity.¹³⁰⁷ The Panel noted further that IARC opinions had not evaluated the carcinogenicity of residues of progesterone in beef, and quoted the opinions of Drs. Boobis and Guttenplan that the relevant scientific evidence on progesterone was sufficient to conduct a risk assessment.¹³⁰⁸ The Panel concluded that it had not been established that the relevant scientific evidence with respect to progesterone was insufficient within the meaning of Article 5.7 of the *SPS Agreement*.

646. Turning to testosterone, the Panel noted that many of the insufficiencies in the relevant scientific evidence had been addressed in common with the other four hormones.¹³⁰⁹ The Panel's analysis therefore focused on the evidence of genotoxicity and carcinogenicity of testosterone. The Panel observed that the 1999 Opinion stated that no information was available on DNA damage induced by testosterone or its metabolites, and that "[w]hereas the evidence in favour of carcinogenicity was considered sufficient for testosterone in experimental animals, data in humans are limited".¹³¹⁰ According to the Panel, this statement had to be read in conjunction with the conclusion that "the evidence regarding the role of testosterone in prostate cancer is currently weak".¹³¹¹ In the Panel's view, this evidence did not meet the "critical mass" test that it articulated to assess insufficiency within the meaning of Article 5.7. The Panel noted, moreover, Dr. Boisseau's opinion that the scientific evidence submitted by the European Communities did not support the conclusion

¹³⁰⁵Panel Report, *US – Continued Suspension*, para. 7.729; Panel Report, *Canada – Continued Suspension*, para. 7.706.

¹³⁰⁶Panel Report, *US – Continued Suspension*, para. 7.731; Panel Report, *Canada – Continued Suspension*, para. 7.708 (quoting 2002 Opinion, section 4.3, p. 15).

¹³⁰⁷Panel Report, *US – Continued Suspension*, paras. 7.738; Panel Report, *Canada – Continued Suspension*, para. 7.715 (quoting replies of the scientific experts to Question 16 posed by the Panel, Panel Reports, Annex D, para. 158).

¹³⁰⁸Panel Report, *US – Continued Suspension*, paras. 7.740 and 7.741; Panel Report, *Canada – Continued Suspension*, paras. 7.717 and 7.718.

¹³⁰⁹Panel Report, *US – Continued Suspension*, para. 7.746; Panel Report, *Canada – Continued Suspension*, para. 7.726.

¹³¹⁰Panel Report, *US – Continued Suspension*, para. 7.749; Panel Report, *Canada – Continued Suspension*, para. 7.729 (quoting 1999 Opinion, p. 49).

¹³¹¹Panel Report, *US – Continued Suspension*, para. 7.749; Panel Report, *Canada – Continued Suspension*, para. 7.729.

that carcinogenic effects of testosterone are related to a mechanism other than hormonal activity.¹³¹² The Panel therefore found that it had not been established that the relevant scientific evidence with respect to testosterone was insufficient within the meaning of Article 5.7 of the *SPS Agreement*.

647. The Panel limited its analysis concerning trenbolone acetate to two distinct "insufficiencies" that were identified by the European Communities in the scientific evidence: (i) the metabolism of trenbolone acetate; and (ii) inadequate evidence of carcinogenicity in humans.¹³¹³ Regarding the metabolism of trenbolone, the Panel contrasted the statement in the 2002 Opinion that "experiments with ... trenbolone acetate suggested a more complex oxidative metabolism than previously assumed"¹³¹⁴ with Dr. Boobis' opinion that "these data do not affect the risk assessment of trenbolone acetate."¹³¹⁵ In relation to the evidence on carcinogenicity of trenbolone, the Panel referred to Dr. Boobis' opinion that "[t]hese data are insufficient ... to alter the conclusion that ... trenbolone acetate has genotoxic potential in vivo"¹³¹⁶; Dr. Guttenplan's view that "[t]renbolone is either negative or marginally active in *in vitro* genotoxic assays"¹³¹⁷; and Dr. Boisseau's statement that "the scientific evidence relied upon in the SCVPH Opinions does not support the conclusion that the carcinogenic effects of trenbolone are related to a mechanism other than hormonal activity."¹³¹⁸ The Panel also noted Dr. Boobis' opinion that the information available was sufficient for the European Communities to conduct a risk assessment in relation to the six hormones. In addition, the Panel observed that, although Dr. Guttenplan stated that no "accurate ADIs can be established [for trenbolone] at this point"¹³¹⁹, he later clarified that this "does not mean that you can't make a risk

¹³¹²Panel Report, *US – Continued Suspension*, paras. 7.752; Panel Report, *Canada – Continued Suspension*, para. 7.732 (quoting replies of the scientific experts to Question 16 posed by the Panel, Panel Reports, Annex D, para. 160).

¹³¹³Panel Report, *US – Continued Suspension*, para. 7.761; Panel Report, *Canada – Continued Suspension*, para. 7.743.

¹³¹⁴Panel Report, *US – Continued Suspension*, para. 7.762; Panel Report, *Canada – Continued Suspension*, para. 7.744 (quoting 2002 Opinion, section 7, p. 21).

¹³¹⁵Panel Report, *US – Continued Suspension*, para. 7.763; Panel Report, *Canada – Continued Suspension*, para. 7.745 (quoting replies of the scientific experts to Question 62 posed by the Panel, Panel Reports, Annex D, para. 480).

¹³¹⁶Panel Report, *US – Continued Suspension*, para. 7.770; Panel Report, *Canada – Continued Suspension*, para. 7.752 (quoting replies of the scientific experts to Question 62 posed by the Panel, Panel Reports, Annex D, para. 483).

¹³¹⁷Panel Report, *US – Continued Suspension*, para. 7.771; Panel Report, *Canada – Continued Suspension*, para. 7.753 (quoting replies of the scientific experts to Question 21 posed by the Panel, Panel Reports, Annex D, para. 200).

¹³¹⁸Panel Report, *US – Continued Suspension*, para. 7.775; Panel Report, *Canada – Continued Suspension*, para. 7.757 (quoting replies of the scientific experts to Question 16 posed by the Panel, Panel Reports, Annex D, para. 164).

¹³¹⁹Panel Report, *US – Continued Suspension*, para. 7.779; Panel Report, *Canada – Continued Suspension*, para. 7.761 (quoting replies of the scientific experts to Question 61 posed by the Panel, Panel Reports, Annex D, para. 457).

assessment, it just means that the accuracy of the risk assessment is different."¹³²⁰ Thus, the Panel concluded that the relevant scientific evidence on trenbolone was not insufficient within the meaning of Article 5.7.

648. As regards zeranol, the Panel began by recalling the 1999 Opinion's conclusion that the scientific evidence "gave equivocal results insufficient for an evaluation of the mutagenic/genotoxic properties of zeranol" and that, as far as carcinogenicity of zeranol was concerned, "there is clear evidence for the induction of liver adenomas and carcinomas in one animal species, but no assessment of the possible carcinogenicity of zeranol can be made."¹³²¹ The Panel then analyzed the views expressed by the experts on the scientific evidence relating to the mutagenic, genotoxic and carcinogenic properties of zeranol, in particular Dr. Boisseau's remark that JECFA "concluded that the 'tumorigenic effect of zeranol was associated with its oestrogenic properties'"¹³²² and the statement in the 2002 Opinion that an *in vitro* study of zeranol in which it "did not induce genotoxicity or mutagenicity."¹³²³ Dr. Sippell opined that zeranol and its metabolites "have been shown to be as potent as [oestradiol] ... in increasing the expression of estrogen-related genes in human breast cancer cells."¹³²⁴ However, referring to the same evidence, Dr. Boobis noted that *in vitro* studies have limited relevance "to the situation *in vivo*, where kinetic and metabolic factors will influence the magnitude of the response".¹³²⁵ Therefore, according to Dr. Boobis, "[t]hese data are insufficient to support the conclusion that these hormones have genotoxic potential *in vivo*."¹³²⁶ Dr. Guttenplan also noted that "[z]eranol can induce transformation of breast epithelial cells in culture with efficiency similar to that of oestradiol, but the mechanism is now known, and it is negative or marginally active in other assays."¹³²⁷ Dr. Boisseau opined that "the scientific evidence relied upon in the SCVPH

¹³²⁰Panel Report, *US – Continued Suspension*, para. 7.780; Panel Report, *Canada – Continued Suspension*, para. 7.762 (quoting transcript of the Panel's joint meeting with scientific experts on 27-28 September 2006, Panel Reports, Annex G, para. 983).

¹³²¹Panel Report, *US – Continued Suspension*, para. 7.788; Panel Report, *Canada – Continued Suspension*, para. 7.772 (referring to 1999 Opinion, sections 4.5.5 to 4.5.7, pp. 64 and 65).

¹³²²Panel Report, *US – Continued Suspension*, para. 7.790; Panel Report, *Canada – Continued Suspension*, para. 7.774 (quoting replies of the scientific experts to Question 16 posed by the Panel, Panel Reports, Annex D, para. 165).

¹³²³Panel Report, *US – Continued Suspension*, para. 7.791; Panel Report, *Canada – Continued Suspension*, para. 7.775 (quoting 2002 Opinion, section 4.4.3, p. 16).

¹³²⁴Panel Report, *US – Continued Suspension*, para. 7.792; Panel Report, *Canada – Continued Suspension*, para. 7.776 (quoting replies of the scientific experts to Question 41 posed by the Panel, Panel Reports, Annex D, para. 336).

¹³²⁵*Ibid.* (quoting replies of the scientific experts to Question 62 posed by the Panel, Panel Reports, Annex D, para. 475).

¹³²⁶Panel Report, *US – Continued Suspension*, para. 7.793; Panel Report, *Canada – Continued Suspension*, para. 7.777 (quoting replies of the scientific experts to Question 21 posed by the Panel, Panel Reports, Annex D, para. 198).

¹³²⁷Panel Report, *US – Continued Suspension*, para. 7.795; Panel Report, *Canada – Continued Suspension*, para. 7.779 (quoting replies of the scientific experts to Question 21 posed by the Panel, Panel Reports, Annex D, para. 200).

Opinions does not support the conclusion that the carcinogenic effects of zeranol are related to a mechanism other than hormonal activity."¹³²⁸ Finally, the Panel also referred to Dr. Guttenplan's opinion that a more recent study suggested a risk from zeranol, but "the results were obtained in cultured cells and the relevance to human exposure to hormone-treated [meat] cannot be extrapolated from this study because of a myriad of uncertainties in such extrapolation. The study does suggest that additional tests of zeranol should be carried out."¹³²⁹ On this basis, the Panel concluded that "it is not established that relevant scientific evidence is insufficient in relation to the carcinogenicity of zeranol, within the meaning of Article 5.7 of the *SPS Agreement*."¹³³⁰

649. Finally, in relation to MGA, the Panel focused on two distinct "insufficiencies" in the scientific evidence: (i) whether only limited data were available on residues of MGA in treated cattle; and (ii) whether the evidence for carcinogenicity of MGA in humans was inadequate.¹³³¹ As a preliminary remark, however, the Panel noted that no international standards for MGA existed, but "intensive work" had been performed on MGA at the international level, particularly two risk assessments by JECFA.¹³³² The Panel observed that MGA was on Codex's priority list for recalculation of Maximum Residue Levels ("MRLs"), and that the draft MRL for MGA was at Step 7 of the Codex elaboration procedure. The Panel stated that "the role of JECFA in the international risk assessment process is such that some degree of relevance should be given to that work"¹³³³, and, on this basis, concluded that the existence of assessments by JECFA "suggests that evidence has been at one point sufficient."¹³³⁴

650. As for the data on residues of MGA, which the European Communities suggested were outdated, the Panel noted that both Drs. Boisseau and De Brabander recognized that nearly all studies used by JECFA dated back to the 1960s and 1970s. Neither of them, however, stated that those studies were no longer valid. The Panel also recalled its earlier conclusion that the fact that a study is

¹³²⁸Panel Report, *US – Continued Suspension*, para. 7.796; Panel Report, *Canada – Continued Suspension*, para. 7.780 (quoting replies of the scientific experts to Question 16 posed by the Panel, Panel Reports, Annex D, para. 166).

¹³²⁹Panel Report, *US – Continued Suspension*, para. 7.797; Panel Report, *Canada – Continued Suspension*, para. 7.781 (quoting replies of the scientific experts to Question 25 posed by the Panel, Panel Reports, Annex D, para. 234).

¹³³⁰Panel Report, *US – Continued Suspension*, para. 7.800; Panel Report, *Canada – Continued Suspension*, para. 7.784.

¹³³¹Panel Report, *US – Continued Suspension*, para. 7.812; Panel Report, *Canada – Continued Suspension*, para. 7.798.

¹³³²Panel Report, *US – Continued Suspension*, para. 7.806; Panel Report, *Canada – Continued Suspension*, para. 7.799.

¹³³³Panel Report, *US – Continued Suspension*, para. 7.813; Panel Report, *Canada – Continued Suspension*, para. 7.799.

¹³³⁴Panel Report, *US – Continued Suspension*, para. 7.827; Panel Report, *Canada – Continued Suspension*, para. 7.813.

old does not *per se* put in doubt the validity of the study.¹³³⁵ The Panel, furthermore, quoted opinions by Drs. Boisseau and Boobis to the effect that new scientific studies did not undermine the MRLs for MGA calculated by JECFA, because the latter were based on very conservative assumptions.¹³³⁶

651. Turning to the evidence on the carcinogenicity in humans of MGA, the Panel noted that the statement in the 2002 Opinion that "[t]he results [for genotoxicity of MGA] were negative in several experiments"¹³³⁷ seemed to confirm JECFA's conclusions. The Panel also made reference to Dr. Boobis' opinion that "[MGA was] negative in a range of tests for genotoxicity"¹³³⁸, and Dr. Guttenplan's statement that "MGA is negative in genotoxic assays".¹³³⁹ On the potential carcinogenicity of MGA, the Panel stressed that IARC has not assessed the specific risks of cancer arising from the consumption of meat treated with MGA, and recalled Dr. Boisseau's view that "the scientific evidence relied upon in the SCVPH Opinions does not support the conclusion that the carcinogenic effects of [MGA] are related to a mechanism other than hormonal activity."¹³⁴⁰ The Panel also referred to Dr. Boobis' opinion that the evidence was sufficient to conduct a risk assessment in relation to all six hormones at issue, and Dr. Guttenplan's statements that "[JECFA's] assessment for [MGA] seems sound" and that "[t]horough metabolic and estrogenic studies have been carried out."¹³⁴¹ The Panel concluded that the relevant evidence for MGA was not insufficient within the meaning of Article 5.7.¹³⁴²

652. At the end of its analysis, the Panel said that it had asked the scientific experts whether the scientific evidence relied upon by the European Communities supported the European Communities' contention that the scientific studies initiated since 1997 had identified new important gaps, insufficiencies and contradictions in the scientific information and knowledge available on these

¹³³⁵Panel Report, *US – Continued Suspension*, para. 7.816 (referring to *ibid.*, para. 7.423 *et seq.*); Panel Report, *Canada – Continued Suspension*, para. 7.802 (referring to *ibid.*, paras. 7.414 *et seq.*).

¹³³⁶Panel Report, *US – Continued Suspension*, paras. 7.817 and 7.818; Panel Report, *Canada – Continued Suspension*, para. 7.803 and 7.804 (quoting replies of the scientific experts to Panel Questions 35 and 62, Panel Reports, Annex D, paras. 303 and 484).

¹³³⁷Panel Report, *US – Continued Suspension*, para. 7.820; Panel Report, *Canada – Continued Suspension*, para. 7.806 (quoting 2002 Opinion, section 4.5.3, p. 18).

¹³³⁸Panel Report, *US – Continued Suspension*, para. 7.822; Panel Report, *Canada – Continued Suspension*, para. 7.808 (quoting replies of the scientific experts to Question 21 posed by the Panel, Panel Reports, Annex D, para. 198).

¹³³⁹Panel Report, *US – Continued Suspension*, para. 7.823; Panel Report, *Canada – Continued Suspension*, para. 7.809 (quoting replies of the scientific experts to Question 21 posed by the Panel, Panel Reports, Annex D, para. 200).

¹³⁴⁰Panel Report, *US – Continued Suspension*, para. 7.826; Panel Report, *Canada – Continued Suspension*, para. 7.812 (quoting replies of the scientific experts to Question 16 posed by the Panel, Panel Reports, Annex D, para. 162).

¹³⁴¹Panel Report, *US – Continued Suspension*, para. 7.829; Panel Report, *Canada – Continued Suspension*, para. 7.815 (quoting replies of the scientific experts to Question 61 posed by the Panel, Panel Reports, Annex D, para. 458).

¹³⁴²Panel Report, *US – Continued Suspension*, para. 7.830; Panel Report, *Canada – Continued Suspension*, para. 7.816.

hormones such that more scientific studies are necessary before the risk to human health from the consumption of meat from cattle treated with these hormones for growth-promotion purposes can be assessed. The Panel recalled its test that there must be a critical mass of new evidence and/or information that calls into question the fundamental precepts of previous knowledge and evidence so as to make relevant, previously sufficient evidence now insufficient and noted that the experts who expressed themselves in detail on this matter confirmed, both in general and for each of the five hormones subject to a provisional ban, that such critical mass had not been reached.¹³⁴³

653. Thus, the Panel found:

For all these reasons, we conclude that it has not been demonstrated that relevant scientific evidence was insufficient, within the meaning of Article 5.7 of the *SPS Agreement*, in relation to any of the five hormones with respect to which the European Communities applies a provisional ban.¹³⁴⁴

654. Having made this finding, the Panel recalled that the four requirements outlined by the Appellate Body in *Japan – Agricultural Products II* applied cumulatively.¹³⁴⁵ The Panel added that, "[s]ince we found that the first requirement (the measure is imposed in respect to a situation where 'relevant scientific evidence is insufficient') has not been satisfied, we do not find it necessary to address any of the three other requirements."¹³⁴⁶ The Panel concluded:

We therefore conclude that the [European Communities'] compliance measure does not meet the requirements of Article 5.7 of the *SPS Agreement* as far as the provisional ban on progesterone, testosterone, zeranol, trenbolone acetate and melengestrol acetate is concerned.¹³⁴⁷

655. After setting out its conclusion, the Panel made the following clarification of its implications:

Having reached that conclusion, we want to make clear that we only determined that it had not been established that the existing relevant scientific evidence was insufficient. This does not mean that no measure can be imposed by the European Communities under the *SPS Agreement* in relation to the five hormones at issue. Indeed, our determinations are without prejudice to the legality of any [European Communities'] measure regarding these hormones, should the

¹³⁴³Panel Report, *US – Continued Suspension*, para. 7.834; Panel Report, *Canada – Continued Suspension*, para. 7.820.

¹³⁴⁴Panel Report, *US – Continued Suspension*, para. 7.835; Panel Report, *Canada – Continued Suspension*, para. 7.821.

¹³⁴⁵Panel Report, *US – Continued Suspension*, para. 7.836; Panel Report, *Canada – Continued Suspension*, para. 7.822.

¹³⁴⁶*Ibid.*

¹³⁴⁷*Ibid.*

European Communities decide to complete its risk assessments pursuant to Article 5.1 of the *SPS Agreement*.¹³⁴⁸

D. *Claims and Arguments on Appeal*

656. The European Communities claims that the Panel erred in finding that the relevant scientific evidence on the five hormones was not "insufficient" within the meaning of Article 5.7 of the *SPS Agreement* and that, consequently, the provisional ban on the importation and marketing of meat from cattle treated with the five hormones does not meet the requirements of that provision.

657. First, the European Communities argues that the Panel erred in finding that the European Communities' chosen level of protection was not relevant for the determination of whether the relevant scientific evidence on the five hormones was "insufficient" within the meaning of Article 5.7. The European Communities emphasizes that Article 3.3 of the *SPS Agreement* permits it to adopt SPS measures that result in a higher level of protection than the one "implied or encapsulated"¹³⁴⁹ in the relevant international standards, and for this reason its intended level of protection must be relevant for determining whether the scientific evidence is "insufficient" within the meaning of Article 5.7.

658. Secondly, the European Communities challenges the Panel's finding that the presumption of consistency that applies under Article 3.2 of the *SPS Agreement* to measures that conform to international standards "implies that these standards ... are based on risk assessments that meet the requirements of the *SPS Agreement*" and that therefore "there was sufficient evidence for JECFA to undertake the appropriate risk assessments."¹³⁵⁰ According to the European Communities, the presumption that applies to measures that conform to international standards does not necessarily mean that the international standards themselves are based on a risk assessment within the meaning of Article 5.1 because the international standard may not be based on a risk assessment, or it may be based on an assessment that takes into account different factors or outdated scientific opinions.

659. Thirdly, the European Communities argues that the Panel erred in allocating to the European Communities the burden of demonstrating that the provisional ban on meat and meat products treated with the five hormones met the requirements of Article 5.7 of the *SPS Agreement*. In doing so, the Panel erroneously interpreted Article 5.7 to be an exception to Article 5.1. The European Communities maintains that Article 5.7 confers on WTO Members a "qualified right"¹³⁵¹ to take

¹³⁴⁸Panel Report, *US – Continued Suspension*, para. 7.837; Panel Report, *Canada – Continued Suspension*, para. 7.823.

¹³⁴⁹European Communities' appellant's submission, para. 397.

¹³⁵⁰European Communities' appellant's submission, para. 387 (quoting Panel Report, *US – Continued Suspension*, para. 7.644; and Panel Report, *Canada – Continued Suspension*, para. 7.622).

¹³⁵¹European Communities' appellant's submission, para. 368.

provisional SPS measures in cases where they consider that the relevant scientific evidence is insufficient. Therefore, the United States and Canada bore the burden of demonstrating that this condition had not been fulfilled by the European Communities. The European Communities asserts that the Panel mistakenly shifted the burden of proof under Article 5.7 to the European Communities by limiting its review exclusively to the "insufficiencies" in the scientific evidence that were identified by the European Communities in its submissions.¹³⁵²

660. Fourthly, the European Communities argues that the Panel erred in finding that, where international standards for a substance exist, a "critical mass" of new scientific evidence that calls into question the fundamental precepts of previous knowledge is required to render the relevant scientific evidence "insufficient" within the meaning of Article 5.7.¹³⁵³ The European Communities suggests that, if a Member may legitimately follow a "respectable minority view" in its risk assessment, "it must be incorrect and entirely disproportionate to exclude *a priori* that a respectable minority could not make the available scientific evidence insufficient."¹³⁵⁴ Thus, the Panel's "critical mass" standard imposed an excessively "high quantitative and qualitative threshold"¹³⁵⁵ with respect to the new scientific evidence that is required to render the relevant scientific evidence insufficient. According to the European Communities, the quality of the scientific evidence is more important than the quantity, and even a single study made by qualified and respectable scientists could be *a priori* sufficient to conclude that the scientific relevant scientific evidence is insufficient, provided that its merits are particularly relevant for the circumstances of the risk assessment.¹³⁵⁶ The European Communities also submits that the Panel's "critical mass" standard effectively "preclude[d] [the] application"¹³⁵⁷ of the precautionary principle in the interpretation of Articles 5.1 and 5.7, because it implies that the relevant scientific evidence passes immediately from a state of insufficiency under Article 5.7 to a state of complete knowledge under Article 5.1; there will be no transitional period in which Article 5.7 could apply.¹³⁵⁸ Furthermore, the European Communities submits that the application of the "critical mass" standard led the Panel to "ignore highly relevant scientific evidence"¹³⁵⁹, which demonstrated that the relevant scientific evidence was insufficient to perform a risk assessment. According to the European Communities, the relevant scientific evidence was insufficient to perform a risk assessment in the areas of: (i) effects of hormones on certain population groups; (ii) dose

¹³⁵²European Communities' appellant's submission, para. 380 (referring to Panel Report, *US – Continued Suspension*, para. 7.653; and Panel Report, *Canada – Continued Suspension*, para. 7.630).

¹³⁵³*Ibid.*, para. 409 (quoting Panel Report, *US – Continued Suspension*, para. 7.648; and Panel Report, *Canada – Continued Suspension*, para. 7.626).

¹³⁵⁴*Ibid.*, para. 409.

¹³⁵⁵*Ibid.*, para. 412.

¹³⁵⁶*Ibid.*, para. 413.

¹³⁵⁷*Ibid.*, para. 427.

¹³⁵⁸European Communities' statement at the oral hearing.

¹³⁵⁹European Communities' appellant's submission, para. 447.

response; (iii) long latency periods for cancer and confounding factors; and (iv) adverse effects of the five hormones on growth and reproduction. The European Communities also asserts that the relevant scientific evidence was insufficient in relation to each of the five hormones assessed individually.

661. Finally, the European Communities asserts that the Panel failed to make an objective assessment of the facts, as required by Article 11 of the DSU, in reaching its findings under Article 5.7 of the *SPS Agreement*. The European Communities charges the Panel with ignoring Dr. Cogliano's statement that "the data are not sufficient" to conduct a "low-dose prediction of risk at levels you might find in hormone-treated meat."¹³⁶⁰ The European Communities adds that the Panel "arbitrarily chose between different scientific opinions" instead of determining whether the European Communities had "followed a scientifically plausible alternative"¹³⁶¹ when adopting Directive 2003/74/EC. Therefore, the Panel impermissibly engaged in a *de novo* review of the scientific evidence in relation to the five hormones, in violation of Article 11 of the DSU.

662. The United States responds that the Panel correctly found that the relevant scientific evidence on the five hormones subject to the provisional ban was not "insufficient" within the meaning of Article 5.7 of the *SPS Agreement*.

663. The United States submits that the Panel correctly interpreted Article 5.7, taking into account the context provided by Articles 3.2 and 3.3 of the *SPS Agreement*. This is because, in light of the presumption of consistency with the *SPS Agreement* that applies to measures which conform to international standards under Article 3.2, the Panel was justified in finding that the existence of such standards indicated that there had been sufficient scientific evidence to conduct a risk assessment within the meaning of Article 5.1 for the five hormones at issue.¹³⁶² The United States also argues that the Panel correctly concluded that the European Communities' desired level of protection was irrelevant for the determination of whether the relevant scientific evidence on the five hormones was "insufficient" within the meaning of Article 5.7. The United States suggests that the European Communities failed to demonstrate that its chosen level of protection is different from the level of protection that the Codex standards for the hormones at issue are designed to achieve.¹³⁶³ The United States adds that a risk assessment is a scientific process aimed at identifying whether a risk exists and,

¹³⁶⁰European Communities' appellant's submission, para. 279 (quoting transcript of the Panel's joint meeting with the scientific experts, Panel Reports, Annex G, para. 871).

¹³⁶¹*Ibid.*, para. 281.

¹³⁶²United States' appellee's submission, para. 70.

¹³⁶³*Ibid.*, para. 71.

for this reason, risk assessors "need not have any particular level of protection in mind in conducting the risk assessment."¹³⁶⁴

664. The United States also rejects the European Communities' assertion that the Panel misallocated the burden of proof in its analysis under Article 5.7. The United States argues that the Panel correctly noted that "one of the particularities of this case"¹³⁶⁵ was that the European Communities' claim that the United States breached Article 22.8 of the DSU was premised on an assertion that the European Communities had brought itself into conformity with the *SPS Agreement*. Taking into account the European Communities' concern that it should not be required to "prove a negative", all the Panel initially required was that the European Communities established a *prima facie* case of conformity with the *SPS Agreement*.¹³⁶⁶ According to the United States, the Panel only shifted the burden of proof to the United States once it had found that the European Communities had established such a *prima facie* case, and subsequently found that the United States had rebutted the European Communities' *prima facie* case of conformity with the *SPS Agreement* "by submitting positive evidence that demonstrated a breach of the *SPS Agreement*".¹³⁶⁷ The United States agrees with the Panel that "the burden [of proof] shifted back and forth between the parties and eventually 'neutralized' each other since each party also submitted evidence in support of its allegations".¹³⁶⁸ The United States further notes that "the Panel never described or treated Article 5.7 as an exception to Article 5.1"¹³⁶⁹, and for this reason the European Communities' allegation that the Panel interpreted Article 5.7 to be an exception to Article 5.1 is "speculation".¹³⁷⁰

665. The United States maintains that the Panel did not err in finding that "a critical mass of new evidence" is required to render previously sufficient scientific evidence "insufficient" within the meaning of Article 5.7. In the United States' view, the Panel's "critical mass" standard did not impose a minimum quantitative requirement, because it refers to situations where "evidence becomes so quantitatively and qualitatively sufficient to call into question the fundamental precepts of previous knowledge and evidence", such that new scientific information is "at the origin of a change in the understanding of a scientific issue."¹³⁷¹ The United States considers that it was "appropriate" for the Panel to focus on the question of "whether the relevant scientific evidence had *become* insufficient"¹³⁷², because the five hormones at issue had been studied intensively for decades,

¹³⁶⁴United States' appellee's submission, para. 72.

¹³⁶⁵*Ibid.*, para. 93 (quoting Panel Report, *US – Continued Suspension*, para. 7.384).

¹³⁶⁶*Ibid.*

¹³⁶⁷*Ibid.*, para. 93.

¹³⁶⁸*Ibid.*, para. 94 (referring to Panel Report, *US – Continued Suspension*, para. 7.386).

¹³⁶⁹*Ibid.*, para. 96.

¹³⁷⁰*Ibid.*

¹³⁷¹*Ibid.*, para. 78 (quoting Panel Report, *US – Continued Suspension*, para. 6.141). (emphasis omitted)

¹³⁷²*Ibid.*, para. 80. (original emphasis)

international standards for four of them had existed for over 20 years, and because the European Communities itself had argued in *EC – Hormones* that the relevant scientific evidence on the five hormones was sufficient for it to conduct a risk assessment. Thus, there was "plentiful" evidence on record demonstrating that the relevant scientific evidence "[was] and remains sufficient" to conduct a risk assessment for the five hormones.¹³⁷³

666. Finally, the United States argues that the Panel did not fail to make an objective assessment of the facts as required by Article 11 of the DSU in reaching its findings under Article 5.7 of the *SPS Agreement*. The United States asserts that the Panel acted within the bounds of its discretion as the trier of the facts by attributing to the different pieces of evidence a different weight and significance than the one attributed by the European Communities. The United States reiterates that "there was plentiful evidence in the record demonstrating that the relevant scientific evidence"¹³⁷⁴ remains sufficient to conduct a risk assessment for these five hormones, and therefore the Panel's consideration of whether there was a "'critical mass of new evidence' was proper and well-supported."¹³⁷⁵

667. Canada also argues that the Panel properly found that the relevant scientific evidence on the five hormones subject to the provisional ban was not "insufficient" within the meaning of Article 5.7 of the *SPS Agreement*.

668. Canada submits that the Panel correctly found that the existence of international standards "implies" that sufficient evidence has existed to complete a risk assessment, in light of the presumption of compliance that applies to measures that conform with international standards under Article 3.2.¹³⁷⁶ According to Canada, the Panel accepted that this presumption could be rebutted, as it subsequently recognized that previously sufficient evidence could subsequently become "insufficient" within the meaning of Article 5.7 when it is "unsettled"¹³⁷⁷ by new studies. Canada considers that the Panel properly excluded from the scope of its analysis under Article 5.7 the level of protection chosen by the European Communities. Canada asserts that the European Communities' argument that the "sufficiency" of scientific evidence depends on the acceptable level of risk adopted by a Member¹³⁷⁸ undermines the "basic logic" of the *SPS Agreement*, according to which Article 5.7 operates as a

¹³⁷³United States' appellee's submission, para. 81.

¹³⁷⁴*Ibid.* (referring to comments by the United States on the replies of the scientific experts, Codex, JECFA, and the IARC to questions posed by the Panel, Panel Reports, Annex F, paras. 47 and 48).

¹³⁷⁵*Ibid.*, para. 82.

¹³⁷⁶Canada's appellee's submission, para. 118 (quoting Panel Report, *Canada – Continued Suspension*, para. 7.622).

¹³⁷⁷*Ibid.*, para. 119 (quoting Panel Report, *Canada – Continued Suspension*, para. 7.598).

¹³⁷⁸*Ibid.*, para. 121 (referring to European Communities' appellant's submission, para. 397).

"temporary 'safety valve'"¹³⁷⁹ in situations where there is insufficient scientific evidence to allow a Member to conduct a risk assessment that fulfils the requirements of Articles 2.2 and 5.1.

669. Canada maintains that the Panel did not err in allocating to the European Communities the burden of proving the insufficiency of the scientific evidence under Article 5.7. Canada additionally considers that the Panel correctly characterized Article 5.7 as a "qualified exemption"¹³⁸⁰ from the obligation under Article 2.2 not to maintain SPS measures without sufficient scientific evidence and only shifted the burden of proof under Article 5.7 to the European Communities once it was satisfied that Canada had sufficiently refuted the European Communities' allegation of compliance through positive evidence of a breach of Article 5.7. Canada posits further that this allocation of the burden of proof is consistent with the Appellate Body's ruling in *US – Wool Shirts and Blouses*, because it was for the European Communities, as the party alleging a breach of Article 22.8 of the DSU, to demonstrate that its implementing measure complied with Article 5.7 of the *SPS Agreement*.¹³⁸¹

670. Moreover, Canada argues that the Panel did not err in finding that, in situations where international risk assessments have been conducted for the substances at issue, a "critical mass" of new evidence would be required to render the relevant scientific evidence "insufficient" for the purposes of Article 5.7. Canada dismisses the European Communities' argument that the "critical mass" standard excludes *a priori* the possibility that a WTO Member base its risk assessment on respectable minority views, because in such situations there is "inherently"¹³⁸² sufficient evidence to perform a risk assessment that provides a basis for the SPS measure. Canada asserts that Article 5.7 only applies to situations where there is insufficient scientific evidence so that it is not possible to conduct a risk assessment "at all", regardless of whether a measure is based on minority or mainstream scientific opinions.¹³⁸³ Canada adds that the notion of "critical mass" used by the Panel does not specify how much evidence would be needed to make insufficient scientific evidence that was previously sufficient, and does not "exclude the possibility that a new study or series of studies could call into question the scientific assumptions underpinning the current understanding of a scientific issue."¹³⁸⁴ Thus, Canada submits, the Panel's "critical mass" standard "correctly sets a high threshold"¹³⁸⁵ reflecting the presumption in this dispute that the available scientific evidence had been sufficient to adopt the relevant international standards.

¹³⁷⁹Canada's appellee's submission, para. 122.

¹³⁸⁰*Ibid.*, para. 114 (quoting Appellate Body Report, *Japan – Agricultural Products II*, para. 80).

¹³⁸¹*Ibid.*, para. 115 (referring to Appellate Body Report, *US – Wool Shirts and Blouses*, p. 14, DSR 1997:I, 323, at 335).

¹³⁸²*Ibid.*, para. 127.

¹³⁸³*Ibid.*, para. 128.

¹³⁸⁴*Ibid.*

¹³⁸⁵*Ibid.*

671. Canada also asserts that the Panel did not fail to conduct an objective assessment of the facts under Article 11 of the DSU in reaching its findings under Article 5.7 of the *SPS Agreement*. Canada observes that, as the trier of facts, the Panel had the discretion to determine what weight to attach to the statements made by the experts in the course of the proceedings, and assess their expertise and credibility. Canada rejects the European Communities' allegations that the Panel "systematically downplay[ed]"¹³⁸⁶ the expert opinions indicating that the scientific evidence was insufficient to carry out a risk assessment. Such allegations fail to take into account the fact that, in addition to reviewing the written answers by the experts to the Panel's questions, the Panel was able to "observe these experts" during the meetings with them and was able to "arrive at an assessment of their respective expertise and their credibility in particular areas".¹³⁸⁷ Therefore, Canada considers that the Panel's reliance on the views of these experts was commensurate with its function as the trier of facts, and consequently was consistent with Article 11 of the DSU.

672. Australia agrees with the European Communities that the existence of international standards cannot be determinative of whether there is sufficient evidence to conduct a risk assessment under the first requirement of Article 5.7 of the *SPS Agreement*.¹³⁸⁸ Australia also considers that the Panel's interpretation of Article 5.7 failed to attribute significance to a Member's right under Article 3.3 of the *SPS Agreement* to adopt measures that result in a higher level of protection than would be achieved by measures based on the relevant international standards.¹³⁸⁹

673. New Zealand disagrees with the European Communities' claims that the Panel erred in its assessment of Directive 2003/74/EC under Article 5.7 of the *SPS Agreement*. New Zealand argues that it was incumbent upon the European Communities, as the Member invoking Article 5.7, to demonstrate that the requirements of that provision have been met.¹³⁹⁰ New Zealand submits that the Panel correctly concluded that the European Communities has failed to meet this burden.¹³⁹¹

E. *The Panel's Finding that the Relevant Scientific Evidence in Relation to the Five Hormones Was Not "Insufficient" Within the Meaning of Article 5.7 of the SPS Agreement*

674. Under Article 2.2 of the *SPS Agreement*, WTO Members are required to "ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific

¹³⁸⁶Canada's appellee's submission, para. 130 (referring to European Communities' appellant's submission, paras. 427 and 429).

¹³⁸⁷*Ibid.*, para. 130.

¹³⁸⁸Australia's third participant's submission, para. 55.

¹³⁸⁹*Ibid.*, para. 56.

¹³⁹⁰New Zealand's third participant's submission, para. 3.58.

¹³⁹¹*Ibid.*, para. 3.60.

evidence, except as provided in paragraph 7 of Article 5." This requirement is made operative in other provisions of the *SPS Agreement*, including Article 5.1, which requires SPS measures to be "based on" a risk assessment. At the same time, Article 2.2 excludes from its scope of application situations in which the relevant scientific evidence is insufficient. In such situations, the applicable provision is Article 5.7 of the *SPS Agreement*. Thus, the applicability of Articles 2.2 and 5.1, on the one hand, and of Article 5.7, on the other hand, will depend on the sufficiency of the scientific evidence. The Appellate Body has explained that the relevant scientific evidence will be considered "insufficient" for purposes of Article 5.7 "if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A to the *SPS Agreement*."¹³⁹² This means that where the relevant scientific evidence is sufficient to perform a risk assessment, as defined in Annex A of the *SPS Agreement*, a WTO Member may take an SPS measure only if it is "based on" a risk assessment in accordance with Article 5.1 and that SPS measure is also subject to the obligations in Article 2.2. If the relevant scientific evidence is insufficient to perform a risk assessment, a WTO Member may take a provisional SPS measure on the basis provided in Article 5.7, but that Member must meet the obligations set out in that provision.

675. Having discussed the relationship between Articles 2.2, 5.1 and 5.7, we now focus on the conditions for the application of a provisional SPS measure pursuant to the latter provision. Article 5.7 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.

676. The Appellate Body has explained that Article 5.7 sets out four obligations. Two of these obligations set conditions that must be met before a provisional SPS measure is adopted. The other two obligations are conditions for maintaining the provisional SPS measure once it has been taken. These four obligations are:

(1) [the measure is] imposed in respect of a situation where "relevant scientific information is insufficient";

¹³⁹² Appellate Body Report, *Japan – Apples*, para. 179.

(2) [the measure is] adopted "on the basis of available pertinent information";

(3) [the Member that adopted the measure] "seek[s] to obtain the additional information necessary for a more objective assessment of risk"; and

(4) [the Member that adopted the measure] "review[s] the ... measure accordingly within a reasonable period of time."¹³⁹³

677. Article 5.7 begins with the requirement that the "relevant scientific evidence" be "insufficient". As explained earlier, the relevant scientific evidence is "insufficient" where "the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A to the *SPS Agreement*."¹³⁹⁴ Under Article 5.1, WTO Members are allowed to base SPS measures on divergent or minority views provided they are from a respected and qualified source.¹³⁹⁵ Thus the existence of scientific controversy in itself is not enough to conclude that the relevant scientific evidence is "insufficient". It may be possible to perform a risk assessment that meets the requirements of Article 5.1 even when there are divergent views in the scientific community in relation to a particular risk. By contrast, Article 5.7 is concerned with situations where deficiencies in the body of scientific evidence do not allow a WTO Member to arrive at a sufficiently objective conclusion in relation to risk. When determining whether such deficiencies exist, a Member must not exclude from consideration relevant scientific evidence from any qualified and respected source. Where there is, among other opinions, a qualified and respected scientific view that puts into question the relationship between the relevant scientific evidence and the conclusions in relation to risk, thereby not permitting the performance of a sufficiently objective assessment of risk on the basis of the existing scientific evidence, then a Member may adopt provisional measures under Article 5.7 on the basis of that qualified and respected view.

678. WTO Members' right to take provisional measures in circumstances where the relevant scientific information is "insufficient" is also subject to the requirement that such measures be adopted "on the basis of available pertinent information". Such information may include information from "the relevant international organizations" or deriving from SPS measures applied by other WTO Members. Thus, Article 5.7 contemplates situations where there is some evidentiary basis indicating the possible existence of a risk, but not enough to permit the performance of a risk assessment. Moreover, there must be a rational and objective relationship between the information concerning a certain risk and a Member's provisional SPS measure. In this sense, Article 5.7 provides a "temporary

¹³⁹³ Appellate Body Report, *Japan – Agricultural Products II*, para. 89.

¹³⁹⁴ Appellate Body Report, *Japan – Apples*, para. 179.

¹³⁹⁵ See *supra*, section VI.E.

'safety valve' in situations where some evidence of a risk exists but not enough to complete a full risk assessment, thus making it impossible to meet the more rigorous standards set by Articles 2.2 and 5.1."¹³⁹⁶

679. The second sentence of Article 5.7 requires that the available pertinent information which provides a basis for a Member's provisional SPS measure be supplemented with "the additional information necessary for a more objective assessment of risk" within a "reasonable period of time". As the Appellate Body noted, these two conditions "relate to the *maintenance* of a provisional [SPS] measure and highlight the *provisional* nature of measures adopted pursuant to Article 5.7."¹³⁹⁷ The requirement that the WTO Member "shall seek to obtain the additional information necessary for a more objective assessment of risk" implies that, as of the adoption of the provisional measure, a WTO Member must make best efforts to remedy the insufficiencies in the relevant scientific evidence with additional scientific research or by gathering information from relevant international organizations or other sources.¹³⁹⁸ Otherwise, the provisional nature of measures taken pursuant to Article 5.7 would lose meaning. The "insufficiency" of the scientific evidence is not a perennial state, but rather a transitory one, which lasts only until such time as the imposing Member procures the additional scientific evidence which allows the performance of a more objective assessment of risk. The Appellate Body has noted that Article 5.7 does not set out "explicit prerequisites regarding the additional information to be collected or a specific collection procedure".¹³⁹⁹ Nevertheless, the WTO Member adopting a provisional SPS measure should be able to identify the insufficiencies in the relevant scientific evidence, and the steps that it intends to take to obtain the additional information that will be necessary to address these deficiencies in order to make a more objective assessment and review the provisional measure within a reasonable period of time. The additional information to be collected must be "germane" to conducting the assessment of the specific risk.¹⁴⁰⁰ A Member is required under Article 5.7 to seek to obtain additional information but is not expected to guarantee specific results. Nor is it expected to predict the actual results of its efforts to collect additional information at the time when it adopts the SPS measure. Finally, the Member taking the provisional SPS measure must review it within a reasonable period of time.¹⁴⁰¹

¹³⁹⁶Canada's appellee's submission, para. 114.

¹³⁹⁷Appellate Body Report, *Japan – Apples*, footnote 318 to para. 176. (original emphasis)

¹³⁹⁸Pursuant to Article 10.1 of the *SPS Agreement*, due account shall be taken of the special needs of developing country Members in respect of their ability to procure the additional information for a more objective assessment of risk.

¹³⁹⁹Appellate Body Report *Japan – Agricultural Products II*, para. 92.

¹⁴⁰⁰*Ibid.*

¹⁴⁰¹"[W]hat constitutes a 'reasonable period of time' ... depends on the specific circumstances of each case, including the difficulty of obtaining additional information necessary for the review *and* the characteristics of the provisional SPS measure." (*Ibid.*, para. 93) (original emphasis)

680. These four conditions set out in Article 5.7, however, must be interpreted keeping in mind that the precautionary principle finds reflection in this provision.¹⁴⁰² As the Appellate Body has emphasized:

a panel charged with determining, for instance, whether "sufficient scientific evidence" exists to warrant the maintenance by a Member of a particular SPS measure may, of course, and should, bear in mind that responsible, representative governments commonly act from the perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned.¹⁴⁰³

In emergency situations, for example, a WTO Member will take a provisional SPS measure on the basis of limited information and the steps it takes to comply with its obligations to seek to obtain additional information and review the measure will be assessed in the light of the exigencies of the emergency.

681. The European Communities argues that SPS measures are either "based on" a risk assessment under Article 5.1, or otherwise the relevant scientific evidence will be "insufficient" within the meaning of Article 5.7, so that provisional SPS measures may be justified. We do not agree. There may be situations where the relevant scientific evidence is sufficient to perform a risk assessment, a WTO Member performs such a risk assessment, but does not adopt an SPS measure either because the risk assessment did not confirm the risk, or the risk identified did not exceed that Member's chosen level of protection. Also, there may be situations where there is no pertinent scientific information available indicating a risk such that an SPS measure would be unwarranted even on a provisional basis.

1. Insufficiency and the Acceptable Level of Protection

682. The European Communities argues that the Panel failed to take into account that the European Communities had chosen a higher level of protection when determining whether the relevant scientific evidence is "insufficient" within the meaning of Article 5.7 of the *SPS Agreement*.¹⁴⁰⁴ According to the European Communities, the context provided by Article 3.3 of the *SPS Agreement*, and the cross-reference to Article 5 contained therein, compels a panel to consider a Member's chosen level of protection in examining whether the requirements of Article 5.7 have been met. As we noted earlier, Article 3.3 permits that WTO Members adopt measures which result in a higher level of protection than the one achieved by measures based on the relevant international standards.

¹⁴⁰² Appellate Body Report, *EC – Hormones*, para. 124.

¹⁴⁰³ *Ibid.*

¹⁴⁰⁴ See European Communities' appellant's submission, paras. 397 and 398.

683. In their appellee's submissions, both the United States and Canada emphasize that risk assessment is an "objective" process aimed at identifying and evaluating a certain risk, and that a Member's appropriate level of protection is therefore entirely separate from the question of whether scientific evidence is "insufficient" to perform a risk assessment.¹⁴⁰⁵ At the oral hearing, however, the United States and Canada recognized that the chosen level of protection may have a role to play in framing the scope and methods of a risk assessment in the particular circumstances where a WTO Member chooses a higher level of protection than that which would be achieved by a measure based on the international standard.

684. The Panel noted that the terms of Article 5.1 and Annex A of the *SPS Agreement* "do not indicate that a Member's level of protection is pertinent to determine whether a risk assessment can be performed or not."¹⁴⁰⁶ The Panel quoted approvingly the reasoning of the panel in *EC – Approval and Marketing of Biotech Products*, which stated that "[t]he protection goals of a legislator may have a bearing on the question of which risks a Member decides to assess [a]nd are certainly relevant to the determination of the measure ... to be taken for achieving a Member's level of protection against risk. Yet there is no apparent link between a legislator's protection goals and the task of assessing the existence and magnitude of potential risks."¹⁴⁰⁷ The Panel concluded that:

The assessment [of] whether there is sufficient scientific evidence or not to perform a risk assessment should be an objective process. The level of protection defined by each Member may be relevant to determine the measure to be selected to address the assessed risk, but it should not influence the performance of the risk assessment as such.

Indeed, whether a Member considers that its population should be exposed or not to a particular risk, or at what level, is not relevant to determining whether a risk exists and what its magnitude is. *A fortiori*, it should have no effect on whether there is sufficient evidence of the existence and magnitude of this risk.

A risk-averse Member may be inclined to take a protective position when considering the measure to be adopted. However, the determination of whether scientific evidence is sufficient to assess the existence and magnitude of a risk must be disconnected from the intended level of protection.¹⁴⁰⁸

¹⁴⁰⁵ See United States' appellee's submission, paras. 72 and 73; and Canada's appellee's submission, paras. 121 and 122.

¹⁴⁰⁶ Panel Report, *US – Continued Suspension*, para. 7.609; Panel Report, *Canada – Continued Suspension*, para. 7.587.

¹⁴⁰⁷ *Ibid.* (quoting Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.3238).

¹⁴⁰⁸ Panel Report, *US – Continued Suspension*, paras. 7.610-7.612; Panel Report, *Canada – Continued Suspension*, paras. 7.588-7.590.

685. A WTO Member that adopts an SPS measure resulting in a higher level of protection than would be achieved by measures based on international standards must nevertheless ensure that its SPS measure complies with the other requirements of the *SPS Agreement*, in particular Article 5.¹⁴⁰⁹ This includes the requirement to perform a risk assessment.¹⁴¹⁰ At the same time, we recognize that, in order to perform a risk assessment, a WTO Member may need scientific information that was not examined in the process leading to the adoption of the international standard. We see no basis in Articles 3.3 and 5.1 of the *SPS Agreement* to conclude that WTO Members choosing a higher level of protection than would be achieved by a measure based on an international standard must frame the scope and methods of its risk assessment, including the scientific information to be examined, in the same manner as the international body that performed the risk assessment underlying the international standard. Thus, where the chosen level of protection is higher than would be achieved by a measure based on an international standard, this may have some bearing on the scope or method of the risk assessment.¹⁴¹¹ In such a situation, the fact that the WTO Member has chosen to set a higher level of protection may require it to perform certain research as part of its risk assessment that is different from the parameters considered and the research carried out in the risk assessment underlying the international standard.

686. For these reasons, we disagree with the Panel's finding that "the determination of whether scientific evidence is sufficient to assess the existence and magnitude of a risk must be disconnected from the intended level of protection."¹⁴¹² We emphasize, however, that whatever level of protection a WTO Member chooses does not pre-determine the outcome of its determination of the sufficiency of the relevant scientific evidence. The determination as to whether available scientific evidence is sufficient to perform a risk assessment must remain, in essence, a rigorous and objective process.¹⁴¹³

687. The European Communities refers to the chosen level of protection to support its argument that the existence of JECFA risk assessments for the five hormones does not necessarily mean that the relevant scientific evidence was sufficient for the European Communities to perform its own risk assessment. Before the Panel, the European Communities explained that "the evidence which served as the basis for the 1988 and 1999-2000 JECFA evaluations is not sufficient 'to perform a definitive risk assessment within the meaning of Article 5.7, in particular by the WTO Members applying a high

¹⁴⁰⁹Article 3.3 of the *SPS Agreement*.

¹⁴¹⁰Appellate Body Report, *EC – Hormones*, paras. 176 and 177.

¹⁴¹¹We noted earlier that, at the oral hearing, the United States and Canada recognized that the acceptable level of risk may sometimes play a role, albeit a limited one, in respect of the risk assessment.

¹⁴¹²Panel Report, *US – Continued Suspension*, para. 7.612; Panel Report, *Canada – Continued Suspension*, para. 7.590.

¹⁴¹³The Appellate Body has held in relation to risk assessments under Article 5.1 that the assessment "should not be distorted by preconceived views on the nature and the content of the measure to be taken; nor should it develop into an exercise tailored to and carried out for the purpose of justifying decisions *ex post facto*." (Appellate Body Report, *Japan – Apples*, para. 208)

level of health protection of no risk from exposure to unnecessary additional residues in meat of animals treated with hormones for growth promotion'.¹⁴¹⁴ We turn to this issue next.

2. Relevance of International Standards under Article 5.7 of the *SPS Agreement*

688. The European Communities claims that the Panel erred in finding that the existence of international standards demonstrates "sufficiency" of scientific evidence to perform a risk assessment within the meaning of Article 5.1 of the *SPS Agreement*, and thereby precludes adoption of provisional measures under Article 5.7. According to the European Communities, the Panel considered that the existence of international standards established an "irrebuttable presumption"¹⁴¹⁵ that the relevant scientific evidence in this case is not "insufficient" for the purposes of Article 5.7.

689. After recalling that international standards, guidelines or recommendations existed with respect to progesterone, testosterone, trenbolone acetate, and zeranol, the Panel observed "the important role given"¹⁴¹⁶ to international standards by the *SPS Agreement*, and recalled that Article 3.2 of the *SPS Agreement* provides that measures which conform to international standards, guidelines or recommendations shall be presumed to be consistent with the relevant provisions of the *SPS Agreement*. On this basis, the Panel concluded that:

The presumption of consistency of measures conforming to international standards, guidelines and recommendations with the relevant provisions of the *SPS Agreement* implies that these standards, guidelines or recommendations, particularly those referred to in this case, are based on risk assessments that meet the requirements of the *SPS Agreement*. This means, therefore, that there was sufficient evidence for JECFA to undertake the appropriate risk assessments.¹⁴¹⁷

690. In relation to MGA, the Panel noted that, even though Codex has not adopted a standard for this substance, "intensive work"¹⁴¹⁸ has been performed at the international level. The Panel observed that JECFA has conducted two risk assessments of MGA in 2000 and 2004, and that MGA is currently at Step 7 of the Codex international standards elaboration procedure. The Panel concluded

¹⁴¹⁴Panel Report, *US – Continued Suspension*, para. 7.604; Panel Report, *Canada – Continued Suspension*, para. 7.579 (quoting European Communities' second written submission, para. 149, and reply of the European Communities to Question 31 posed by the Panel after the first substantive meeting, Panel Reports, Annex B-1, paras. 167-172).

¹⁴¹⁵European Communities' appellant's submission, para. 406.

¹⁴¹⁶Panel Report, *US – Continued Suspension*, para. 7.643; Panel Report, *Canada – Continued Suspension*, para. 7.621.

¹⁴¹⁷Panel Report, *US – Continued Suspension*, para. 7.644; Panel Report, *Canada – Continued Suspension*, para. 7.622.

¹⁴¹⁸Panel Report, *US – Continued Suspension*, para. 7.813; Panel Report, *Canada – Continued Suspension*, para. 7.799.

that "the role of JECFA in the international risk assessment process is such that some degree of relevance should be given to that work."¹⁴¹⁹

691. On appeal, the European Communities argues that, under the Panel's interpretation, "the mere existence of an international standard would *ipso jure* make it impossible for a Member to adopt measures under Article 5.7 of the *SPS Agreement*."¹⁴²⁰ According to the European Communities, the presumption of consistency that applies to measures that conform to international standards under Article 3.2 of the *SPS Agreement*¹⁴²¹ does not necessarily lead to the conclusion that the risk assessment underlying the international standards is consistent with the *SPS Agreement*; nor does this presumption establish that scientific evidence underlying the international standards is sufficient to conduct a risk assessment under Article 5.1. This is so particularly where a Member chooses not to conform to such international standards pursuant to Article 3.2 and introduces measures that result in a higher level of SPS protection than would be achieved by measures based on international standards pursuant to Article 3.3.

692. As the preamble of the *SPS Agreement* recognizes, one of the primary objectives of the *SPS Agreement* is to "further the use of harmonized sanitary and phytosanitary measures between Members, on the basis of international standards, guidelines and recommendations developed by the relevant international organizations".¹⁴²² This objective finds reflection in Article 3 of the *SPS Agreement*, which encourages the harmonization of SPS measures on the basis of international standards, while at the same time recognizing the WTO Members' right to determine their appropriate level of protection.¹⁴²³ Article 3.1 of the *SPS Agreement* establishes that Members shall "base their

¹⁴¹⁹Panel Report, *US – Continued Suspension*, para. 7.813; Panel Report, *Canada – Continued Suspension*, para. 7.799.

¹⁴²⁰European Communities' appellant's submission, para. 393.

¹⁴²¹Article 3.2 provides:

Sanitary or phytosanitary measures which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994.

¹⁴²²See also Appellate Body Report, *EC – Hormones*, para. 165.

¹⁴²³As the Appellate Body explained in *EC – Hormones*:

In generalized terms, the object and purpose of Article 3 is to promote the harmonization of the SPS measures of Members on as wide a basis as possible, while recognizing and safeguarding, at the same time, the right and duty of Members to protect the life and health of their people. The ultimate goal of the harmonization of SPS measures is to prevent the use of such measures for arbitrary or unjustifiable discrimination between Members or a disguised restriction on international trade, without preventing Members from adopting or enforcing measures which are both "necessary to protect" human life or health and "based on scientific principles", and without requiring them to change their appropriate level of protection.

(*Ibid.*, para. 177)

[SPS] measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided in this Agreement, and in particular in paragraph 3."

693. The relevant "international standards, guidelines or recommendations" that are referred to in Articles 3.1 and 3.2 are those set by the international organizations listed in Annex A, paragraph 3 of the *SPS Agreement*, which includes Codex as the relevant standard-setting organization for matters of food safety.¹⁴²⁴ As we noted above, Codex adopts international standards for veterinary drug residues based on evaluations performed by JECFA. In this case, Codex has adopted international standards for testosterone, progesterone, trenbolone acetate, and zeranol, on the basis of evaluation performed by JECFA.¹⁴²⁵ In addition, Codex has initiated a standard-setting process for MGA, also on the basis of JECFA's evaluation, but this process has not yet been concluded.

694. It is therefore undisputed that JECFA has performed risk assessments for the six hormones at issue and that Codex has adopted international standards for five of these hormones on the basis of JECFA's risk assessments. The fact that JECFA has performed risk assessments for all six hormones means that the relevant scientific evidence was in its estimation sufficient to do so. Article 3.2 provides that SPS measures which conform to international standards shall be deemed necessary to protect human, animal or plant life or health, and shall be presumed to be consistent with the relevant provisions of the *SPS Agreement* and of the GATT 1994. This presumption, however, does not apply where a Member has not adopted a measure that conforms with an international standard. Article 3.2 is inapplicable where a Member chooses a level of protection that is higher than would be achieved by a measure based on an international standard. The presumption in Article 3.2 cannot be interpreted to imply that there is sufficient scientific evidence to perform a risk assessment where a Member chooses a higher level of protection.

695. This is borne out by Article 5.7, which provides that WTO Members may adopt provisional SPS 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". There is no indication in Article 5.7 that a WTO Member may not take a provisional SPS measure wherever a relevant international organization or another Member has performed a risk assessment. Information from relevant international organizations may not necessarily be considered "sufficient" to perform a risk assessment, as it may be part of the "available pertinent information"

¹⁴²⁴Paragraph 3(a) of Annex A of the *SPS Agreement* reads:

... for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice.

¹⁴²⁵See *supra*, footnote 933.

which provides the basis for a provisional SPS measure under Article 5.7. Moreover, scientific evidence that may have been relied upon by an international body when performing the risk assessment that led to the adoption of an international standard at a certain point in time may no longer be valid, or may become insufficient in the light of subsequent scientific developments. Therefore, the existence of a risk assessment performed by JECFA does not mean that scientific evidence underlying it must be considered to be sufficient within the meaning of Article 5.7.

696. In our view, it is reasonable for a WTO Member challenging the consistency with Article 5.7 of a provisional SPS measure adopted by another Member to submit JECFA's risk assessments and supporting studies leading to the adoption of international standards as evidence that the scientific evidence is not insufficient to perform a risk assessment. However, such evidence is not dispositive and may be rebutted by the Member taking the provisional SPS measure.

697. The European Communities argues that the Panel considered the existence of international standards as establishing an "irrebuttable presumption"¹⁴²⁶ that the relevant scientific evidence in this case is not "insufficient" for the purposes of Article 5.7. As we pointed out above, the existence of an international standard does not create a legal presumption of sufficiency for purposes of Article 5.7. The Panel recognized that "[i]t cannot be excluded that new scientific evidence or information call into question existing evidence", and acknowledged the possibility that "different risk assessments reach different interpretations of the same scientific evidence."¹⁴²⁷ The Panel examined the specific points raised by the European Communities concerning the insufficiencies it saw in the scientific evidence considered in JECFA's risk assessment. There would not have been a need for the Panel to undertake such an assessment if it had considered that the existence of international standards established an irrebuttable presumption that the relevant scientific evidence was not insufficient within the meaning of Article 5.7. Thus we find no fault with the Panel to the extent that it treated the evidence underlying JECFA's risk assessment as having probative value for determining whether the relevant scientific evidence was insufficient. In our view, the existence of risk assessments conducted by JECFA in relation to the five hormones at issue has probative value, but is not dispositive, of the question of whether the relevant scientific evidence on those hormones is "insufficient" within the meaning of Article 5.7.

698. The Panel relied on the existence of international standards to adopt a "critical mass" test for determining when scientific information that was previously considered sufficient becomes

¹⁴²⁶European Communities' appellant's submission, para. 406.

¹⁴²⁷Panel Report, *US – Continued Suspension*, para. 7.645; Panel Report, *Canada – Continued Suspension*, para. 7.623.

insufficient for purposes of Article 5.7 of the *SPS Agreement*. The European Communities also challenges this test on appeal. We examine this issue in the section that follows.

3. The Panel's "Critical Mass" Standard for Determining "Insufficiency" under Article 5.7 of the *SPS Agreement*

699. The European Communities asserts that the Panel's "critical mass" standard imposed an excessively "high quantitative and qualitative threshold" with respect to the new evidence that is required to render "insufficient" scientific evidence that was previously considered sufficient.¹⁴²⁸ According to the European Communities, the quality of the scientific evidence is more important than the quantity, and therefore even a single study could be considered *a priori* sufficient to question the sufficiency of previous scientific evidence.¹⁴²⁹ The European Communities adds that the Panel's "critical mass" standard effectively precluded the application of the precautionary principle in the interpretation of Articles 5.1 and 5.7, because the scientific evidence would pass immediately from a state of insufficiency under Article 5.7 to a state of sufficiency under Article 5.1.¹⁴³⁰

700. Both the United States and Canada accept that evidence which at some point in time was sufficient to perform a risk assessment could become insufficient at a later point in time.¹⁴³¹ The United States said this could happen, for example, if there was new pathway for a risk for which the information was insufficient.¹⁴³² Canada gave as an example the situation in which there is new scientific data that identifies new adverse effects or adverse effects at lower exposure levels.¹⁴³³ Another example given by Canada is the identification of new sources of exposure.¹⁴³⁴ The Panel also recognized that:

... there could be situations where existing scientific evidence can be put in question by new studies and information. There could even be situations where evidence which supported a risk assessment is unsettled by new studies which do not constitute sufficient relevant scientific evidence as such to support a risk assessment but are sufficient to make the existing, previously relevant scientific evidence insufficient.¹⁴³⁵ (footnote omitted)

¹⁴²⁸European Communities' appellant's submission, para. 412.

¹⁴²⁹*Ibid.*, para. 413.

¹⁴³⁰*Ibid.*, para. 427.

¹⁴³¹Panel Report, *US – Continued Suspension*, para. 7.617; Panel Report, *Canada – Continued Suspension*, para. 7.593.

¹⁴³²Panel Report, *US – Continued Suspension*, para. 7.617.

¹⁴³³Panel Report, *Canada – Continued Suspension*, para. 7.593.

¹⁴³⁴In addition, Canada mentioned the situation where there is a change in the basic understanding of a biological event that is triggered by the chemical under assessment. (Panel Report, *Canada – Continued Suspension*, para. 7.593)

¹⁴³⁵Panel Report, *US – Continued Suspension*, para. 7.620; Panel Report, *Canada – Continued Suspension*, para. 7.598.

701. We agree that scientific progress may lead a WTO Member and international organizations to reconsider the risk assessment underlying an SPS measure. In some cases, new scientific developments will permit a WTO Member to conduct a new risk assessment with the sufficient degree of objectivity. There may be situations, however, where the new scientific developments themselves do not permit the performance of a new risk assessment that is sufficiently objective. Such a situation would fall within the scope of Article 5.7 of the *SPS Agreement*.

702. The Appellate Body has explained that "'relevant scientific evidence' will be 'insufficient' within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A to the *SPS Agreement*."¹⁴³⁶ The body of scientific evidence underlying a risk assessment can always be supplemented with additional information. Indeed, the nature of scientific inquiry is such that it is always possible to conduct more research or obtain additional information. The possibility of conducting further research or of analyzing additional information, by itself, should not mean that the relevant scientific evidence is or becomes insufficient.

703. Moreover, as the Panel noted, science continuously evolves.¹⁴³⁷ It may be useful to think of the degree of change as a spectrum. On one extreme of this spectrum lies the incremental advance of science. Where these scientific advances are at the margins, they would not support the conclusion that previously sufficient evidence has become insufficient. At the other extreme lie the more radical scientific changes that lead to a paradigm shift. Such radical change is not frequent. Limiting the application of Article 5.7 to situations where scientific advances lead to a paradigm shift would be too inflexible an approach. WTO Members should be permitted to take a provisional measure where new evidence from a qualified and respected source puts into question the relationship between the pre-existing body of scientific evidence and the conclusions regarding the risks. We are referring to circumstances where new scientific evidence casts doubts as to whether the previously existing body of scientific evidence still permits of a sufficiently objective assessment of risk.

704. The Panel next discussed its understanding of "insufficiency" in the specific circumstances where international standards exist for the particular substance. It concluded:

We therefore conclude that if relevant evidence already exists, not any degree of insufficiency will satisfy the criterion under Article 5.7 that "relevant scientific evidence is insufficient". Having regard to our reasoning above, particularly with respect to scientific uncertainty and the existence of international standards, we consider

¹⁴³⁶ Appellate Body Report, *Japan – Apples*, para. 179.

¹⁴³⁷ Panel Report, *US – Continued Suspension*, para. 7.645; Panel Report, *Canada – Continued Suspension*, para. 7.623.

that, depending on the existing relevant evidence, there must be a *critical mass* of new evidence and/or information that calls into question the fundamental precepts of previous knowledge and evidence so as to make relevant, previously sufficient, evidence now insufficient. In the present case where risk assessments have been performed and a large body of quality evidence has been accumulated, this would be possible only if it put into question existing relevant evidence *to the point that* this evidence is no longer sufficient to support the conclusions of existing risks assessments.¹⁴³⁸ (original emphasis; footnote omitted)

705. The Panel's statement that "there must be a *critical mass* of new evidence and/or information that calls into question the fundamental precepts of previous knowledge and evidence so as to make relevant, previously sufficient, evidence now insufficient" could be understood as requiring that the new scientific evidence lead to a paradigm shift. As we have said, such an approach is too inflexible. Although the new evidence must call into question the relationship between the body of scientific evidence and the conclusions concerning risk, it need not rise to the level of a paradigm shift.

706. Some of the Panel's statements intended to explain what it meant by "critical mass" similarly can be understood as requiring a paradigm shift, which is too high a threshold. At the interim review stage, the European Communities requested that the Panel identify the provenance of the "critical mass" standard and explain how it should be reconciled with the Appellate Body's findings in *EC – Hormones*. The Panel responded as follows:

The Panel used the term "critical mass" in full knowledge of its meaning.²⁹⁴ It used it in the sense of a situation where evidence becomes quantitatively and qualitatively sufficient to call into question the fundamental precepts of previous knowledge and evidence. The Panel does not mean that there must be sufficient evidence to perform a new risk assessment. Otherwise, Article 5.7 of the *SPS Agreement* would become meaningless. It used the term "critical mass" very much in its common scientific usage, i.e. 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. We do not see in what respect this approach by the Panel, which applies to the specific situation in this case (i.e. one where a party alleges that previously sufficient scientific evidence has become insufficient) would be contrary to the findings of the Appellate Body in *EC – Hormones*.¹⁴³⁹ (original emphasis)

²⁹⁴In mathematics and physics "critical" is defined as "constituting or relating to a point of transition from one state, etc. to another". "Critical size" or "critical mass" are defined as the minimum size or mass of a body of a given fissile material which is capable of sustaining a nuclear chain

¹⁴³⁸Panel Report, *US – Continued Suspension*, para. 7.648; Panel Report, *Canada – Continued Suspension*, para. 7.626.

¹⁴³⁹Panel Report, *US – Continued Suspension*, para. 6.141; Panel Report, *Canada – Continued Suspension*, para. 6.133.

reaction (Shorter Oxford English Dictionary, 5th edition (1993), p. 558). In other words, the Panel assessed whether it had been provided with the minimum evidence necessary to conclude that knowledge has become quantitatively and qualitatively sufficient to call into question the fundamental precepts of previous knowledge and evidence.

707. In the reasoning quoted above, the Panel again required that the scientific evidence be "sufficient to call into question the fundamental precepts of previous knowledge and evidence". The Panel's explanation that "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" also connotes a paradigm shift.

708. We earlier observed that the existence of an international standard for which a risk assessment was conducted could be offered as evidence in support of an assertion that the relevant scientific evidence is not insufficient within the meaning of Article 5.7 of the *SPS Agreement*. It is an evidentiary issue in the sense that the scientific information underlying the international standard has probative value as to the sufficiency of the scientific evidence needed for conducting a risk assessment at a discrete point in time. However, in circumstances where a Member adopts a higher level of protection than that reflected in the international standard, the legal test that applies to the "insufficiency" of the evidence under Article 5.7 is not made stricter. Thus, it is incorrect to use JECFA's risk assessments as a legal benchmark for assessing insufficiency as the Panel did in this case.

709. In the interim review, the Panel expressly recognized that it used JECFA's risk assessments as a "benchmark":

[I]t is correct that the Panel considered that, in order to determine whether relevant scientific evidence was insufficient within the meaning of Article 5.7 of the *SPS Agreement*, it had to take the results of the risk assessments made by JECFA as a "benchmark" of the existence of sufficient scientific evidence. This is in line with the findings of the Appellate Body in *Japan – Apples* that the relevant scientific evidence will be insufficient within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A to the *SPS Agreement*, as well as with the presumption of compliance under Article 3.2 of the *SPS Agreement*.¹⁴⁴⁰ (footnote omitted)

710. We recall that the presumption in Article 3.2 is inapplicable where a WTO Member adopts an SPS measure that results in a higher level of protection than that reflected in an international standard. For this reason, Article 3.2 did not provide a basis for the Panel's use of the JECFA risk assessments

¹⁴⁴⁰Panel Report, *US – Continued Suspension*, para. 6.60; Panel Report, *Canada – Continued Suspension*, para. 6.55.

as the legal benchmark against which the insufficiencies in the relevant scientific evidence identified by the European Communities had to be evaluated. As the Appellate Body explained in *EC – Hormones*:

The presumption of consistency with relevant provisions of the *SPS Agreement* that arises under Article 3.2 in respect of measures that conform to international standards may well be an *incentive* for Members so to conform their SPS measures with such standards. It is clear, however, that a decision of a Member not to conform a particular measure with an international standard does not authorize imposition of a special or generalized burden of proof upon that Member, which may, more often than not, amount to a *penalty*.¹⁴⁴¹ (original emphasis)

711. The particular insufficiencies in the relevant scientific evidence identified by the European Communities had to be evaluated on their own terms. As indicated earlier, the scientific evidence underlying the risk assessments conducted by JECFA has probative value as to the sufficiency of the scientific evidence needed to perform an assessment of risks in relation to the five hormones; however, it was by no means dispositive of that question, in particular where a WTO Member has elected to adopt an SPS measure that does not conform to the international standard.

712. For these reasons, we reverse the Panel's finding that, where international standards exist, "there must be a *critical mass* of new evidence and/or information that calls into question the fundamental precepts of previous knowledge and evidence so as to make relevant, previously sufficient, evidence now insufficient" within the meaning of Article 5.7.¹⁴⁴²

4. The Panel's Allocation of the Burden of Proof under Article 5.7 of the *SPS Agreement*

713. We turn now to the European Communities' claim that the Panel erred by allocating to the European Communities the burden of demonstrating that Directive 2003/74/EC met the requirements of Article 5.7 of the *SPS Agreement* in relation to the provisional ban on the five hormones at issue. The European Communities argues that, by limiting its review to the "insufficiencies" in the scientific evidence identified by the European Communities, the Panel erroneously shifted to the European Communities the burden of proof under Article 5.7 of the *SPS Agreement*.¹⁴⁴³ In doing so, the

¹⁴⁴¹ Appellate Body Report, *EC – Hormones*, para. 102.

¹⁴⁴² Panel Report, *US – Continued Suspension*, para. 7.648; Panel Report, *Canada – Continued Suspension*, para. 7.626. (original emphasis)

¹⁴⁴³ European Communities' appellant's submission, paras. 380-382.

European Communities submits that the Panel misconstrued Articles 5.1 and 5.7 to stand on a rule-exception relationship¹⁴⁴⁴, even though Article 5.7 confers to WTO Members a "qualified right"¹⁴⁴⁵ to take provisional measures under certain conditions. In such circumstances, the United States and Canada should have borne the onus of demonstrating that the conditions provided under Article 5.7 had not been met.¹⁴⁴⁶

714. In particular, the European Communities challenges the following statement by the Panel:

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 scientific evidence is insufficient, we consider that it is for the European Communities to identify the issues for which such evidence is insufficient.

Therefore, we do not consider that, as Panel, we have any obligation to go beyond the insufficiencies identified by the European Communities. ... we deem it appropriate to limit our review exclusively to the "insufficiencies" expressly identified by the European Communities in its submissions to the Panel.¹⁴⁴⁷ (footnotes omitted)

715. The United States and Canada assert that the Panel correctly allocated the burden of proof under Article 5.7 of the *SPS Agreement*.¹⁴⁴⁸ The United States and Canada point out that the Panel only shifted the burden of proof to the European Communities once it was satisfied that the United States and Canada had sufficiently refuted the European Communities' allegation of compliance through positive evidence of a breach of Article 5.7.¹⁴⁴⁹ Canada argues that the Panel correctly

¹⁴⁴⁴European Communities' appellant's submission, para. 362.

¹⁴⁴⁵*Ibid.*, para. 368.

¹⁴⁴⁶*Ibid.*, para. 379.

¹⁴⁴⁷Panel Report, *US – Continued Suspension*, paras. 7.652 and 7.653; Panel Report, *Canada – Continued Suspension*, paras. 7.629 and 7.630.

¹⁴⁴⁸United States' appellee's submission, para. 98; Canada's appellee's submission, para. 115.

¹⁴⁴⁹United States' appellee's submission, para. 93; Canada's appellee's submission, para. 115.

identified Article 5.7 as a "qualified exemption" to Article 2.2¹⁴⁵⁰, while the United States dismisses as speculative the European Communities' contention that the Panel treated Article 5.7 as an exception to Article 5.1.¹⁴⁵¹

716. In section IV.E, we explained how we see the allocation of the burden of proof in a post-suspension situation in which the parties disagree as to whether an implementing measure brings about substantive compliance. The European Communities had to provide a clear description of its implementing measure, and an adequate explanation regarding how this measure rectifies the inconsistencies found in the original proceedings. We recall that the definitive import ban that was the subject of *EC – Hormones* and found to be inconsistent with Article 5.1 has been replaced, under Directive 2003/74/EC, by a provisional ban relating to the five other hormones. The import ban applies to the same products: meat from cattle treated with progesterone, testosterone, trenbolone acetate, zeranol and MGA. The European Communities replaced the original definitive ban with a provisional ban and invoked Article 5.7 as an alternative justification to Article 5.1. Thus, the European Communities had to provide an adequate explanation of how the provisional ban taken under Article 5.7 rectifies the inconsistencies found in *EC – Hormones*. Such explanation had to include, *inter alia*, an identification of the insufficiencies in the relevant scientific evidence that precluded the European Communities from performing a sufficiently objective risk assessment. Accordingly, we do not consider that the Panel erred by limiting its review to the insufficiencies identified by the European Communities.

717. Having said that, we referred above¹⁴⁵² to the Panel's discussion of how it would allocate the burden of proof for purposes of its analysis under Articles 5.1 and 5.7 of the *SPS Agreement* and we identified several flaws in the Panel's approach, which we need not repeat here. We also explained how the Panel should have allocated the burden of proof in relation to the European Communities' contention that Directive 2003/74/EC meets the requirements of Articles 5.1 and 5.7 of the *SPS Agreement*. To the extent that the Panel did not allocate the burden of proof in its analysis of whether Directive 2003/74/EC met the requirements of Article 5.7 of the *SPS Agreement* according to the principles outlined above, we find that the Panel has erred.

718. Accordingly, we find that the Panel erred in the allocation of the burden of proof in its examination of the consistency of Directive 2003/74/EC with Article 5.7 of the *SPS Agreement*.

¹⁴⁵⁰Canada's appellee's submission, para. 112.

¹⁴⁵¹United States' appellee's submission, para. 96.

¹⁴⁵²See *supra*, para. 579.

5. The Panel's Application of Article 5.7 of the *SPS Agreement*

719. We turn finally to the European Communities' claim that the Panel incorrectly applied Article 5.7 of the *SPS Agreement*. On appeal, the European Communities asserts that the Panel "systematically downplay[ed]"¹⁴⁵³ and ignored "highly relevant scientific evidence"¹⁴⁵⁴ which "go[es] against the evaluations of the JECFA or support the position of the European Communities and that in fact the scientific evidence was indeed insufficient"¹⁴⁵⁵ to perform a risk assessment, particularly in the following areas: (a) effects of hormones on certain population groups; (b) dose response; (c) bioavailability; (d) long latency periods for cancer and confounding factors; and (e) adverse effects on growth and reproduction.¹⁴⁵⁶ The European Communities also points to several errors committed by the Panel when determining whether the evidence concerning the risks posed by each of the five hormones individually was insufficient to conduct a risk assessment under Article 5.7.¹⁴⁵⁷

720. The United States responds that the scientific evidence on record, including the statements of the experts, support the conclusion that the relevant scientific evidence on the five hormones is and remains sufficient to conduct a risk assessment.¹⁴⁵⁸ Canada argues that the European Communities' allegations are without merit, and considers that the Panel properly weighed the scientific evidence before it.¹⁴⁵⁹

721. As we noted in subsection 3, the Panel's "critical mass" test imposed an excessively high threshold in terms of the change in the scientific evidence that would make previously sufficient evidence insufficient. Rather than requiring that the new evidence call into question the relationship between the body of scientific evidence and the conclusions concerning risk, the Panel's test required a paradigm shift to the extent the evidence needed to call into question the "fundamental precepts of previous knowledge and evidence" on the five hormones. This erroneous threshold led the Panel to fail to attribute significance to evidence that could cast doubt as to whether the relevant scientific evidence still permits of a sufficiently objective assessment of risk. One such example is the Panel's analysis of the European Communities' contention that the relevant scientific evidence concerning the effects of the hormones on certain categories of the population, in particular pre-pubertal children, was "insufficient" within the meaning of Article 5.7 of the *SPS Agreement*.

¹⁴⁵³European Communities' appellant's submission, para. 427.

¹⁴⁵⁴*Ibid.*, para. 447.

¹⁴⁵⁵*Ibid.*, para. 427.

¹⁴⁵⁶*Ibid.*, paras. 430-436.

¹⁴⁵⁷*Ibid.*, paras. 437-447.

¹⁴⁵⁸United States' appellee's submission, para. 81.

¹⁴⁵⁹Canada's appellee's submission, para. 130.

722. Before the Panel, the European Communities argued that the development of more sensitive detection methods had identified lower endogenous levels of oestradiol in pre-pubertal children than previously assumed by the detection method referred to in JECFA's risk assessments. According to the European Communities, this suggested that individuals that have the lowest endogenous levels of sex hormones, such as pre-pubertal children and post-menopausal women, might be at an increased risk for adverse health effects that might be associated with exposure to exogenous sources of both oestrogens and testosterone.¹⁴⁶⁰

723. The new detection method was examined in a scientific study conducted by Klein et al. (1994), and was reviewed by the European Communities in the 1999 Opinion. The Panel described the Klein study, and the conclusions the European Communities derived from it, as follows:

The 1999 Opinion specifies that the hormone levels on which it relies were determined by radio-immunoassays (RIA) and that the use of these assays has frequently been associated with production of variable results, particularly when used to detect low levels of endogenous hormones. The 1999 Opinion notes that Klein et al. (1994) developed an ultrasensitive assay (100-fold more sensitive than RIAs) which identified values of oestradiol considerably lower than the range of oestradiol levels found through RIAs for prepubertal children.¹⁴⁶¹ (footnote omitted)

724. In its analysis, the Panel recalled its earlier finding that, in order to determine that the evidence on the five hormones was "insufficient" within the meaning of Article 5.7, there must be "a critical mass of new evidence and/or information that calls into question the fundamental precepts of knowledge and evidence so as to make relevant, previously sufficient, evidence now insufficient."¹⁴⁶² On this basis the Panel concluded that its task was to examine "whether the more sensitive detection methods which identified lower hormonal levels in prepubertal children than thought until now are such as to call into question the range of physiological levels of the sex hormones in humans currently believed to exist."¹⁴⁶³ The Panel referred to Dr. Sippell's testimony, which characterized the development of ultra-sensitive detection methods as a "quantum leap in [oestrogen] assay methodology"¹⁴⁶⁴ The Panel noted Dr. Sippell's statement that "[t]he risk to children arising from hormones that are naturally present in meat as compared to residues of hormonal growth promoters

¹⁴⁶⁰See Panel Report, *US – Continued Suspension*, para. 7.664; and Panel Report, *Canada – Continued Suspension*, para. 7.641.

¹⁴⁶¹Panel Report, *US – Continued Suspension*, para. 7.665; Panel Report, *Canada – Continued Suspension*, para. 7.642.

¹⁴⁶²Panel Report, *US – Continued Suspension*, para. 7.666; Panel Report, *Canada – Continued Suspension*, para. 7.643.

¹⁴⁶³*Ibid.*

¹⁴⁶⁴Panel Report, *US – Continued Suspension*, para. 7.667; Panel Report, *Canada – Continued Suspension*, para. 7.644 (quoting replies of the scientific experts to Question 40 posed by the Panel, Panel Reports, Annex D, para. 328).

has, to my knowledge, been estimated for [oestradiol-17 β] only".¹⁴⁶⁵ The Panel then observed that the 2000 Opinion stated that such new detection methods had not been validated¹⁴⁶⁶, and quoted Dr. Boobis' opinion questioning the validity of the new study presented by the European Communities.¹⁴⁶⁷ On this basis, the Panel concluded that:

We note that the evidence presented relates only to oestradiol, but that the claim we are examining with regard to the insufficiencies of the evidence are with respect to the five other hormones at issue, not oestradiol. We note furthermore that the 2002 Opinion concludes that these more sensitive detection methods have not yet been validated.

On the basis of the above, we are not convinced that the studies discussed by the experts call into question the fundamental precepts of previous knowledge and evidence so as to make relevant, previously sufficient evidence now insufficient in relation to the effect of the five hormones on pre-pubertal children. Particularly, it has not been established that the data regarding the effects of hormones on which the JECFA assessments are based are insufficient in light of new evidence relating to the other five hormones at issue.¹⁴⁶⁸

725. In concluding that it is "not convinced" that the ultra-sensitive assay study referred to by the European Communities "call[s] into question the fundamental precepts of previous knowledge" in relation to the effect of the five hormones on pre-pubertal children, the Panel applied an excessively high threshold in relation to the new scientific evidence which is required to render previously sufficient scientific evidence "insufficient" within the meaning of Article 5.7. Irrespective of whether the Panel was itself persuaded by the Klein study, the Panel erred to the extent that it considered that a paradigmatic shift in the scientific knowledge was required in order to render the scientific evidence relied by JECFA now "insufficient" within the meaning of Article 5.7. The "insufficiency" requirement in Article 5.7 does not imply that new scientific evidence must entirely displace the scientific evidence upon which an international standard relies. It suffices that new scientific developments call into question whether the body of scientific evidence still permits of a sufficiently objective assessment of risk.

¹⁴⁶⁵Panel Report, *US – Continued Suspension*, para. 7.668; Panel Report, *Canada – Continued Suspension*, para. 7.645 (quoting replies of the scientific experts to Question 41 posed by the Panel, Panel Reports, Annex D, para. 335).

¹⁴⁶⁶Panel Report, *US – Continued Suspension*, para. 7.669; Panel Report, *Canada – Continued Suspension*, para. 7.646 (referring to 2000 Opinion, p. 3).

¹⁴⁶⁷*Ibid.* (referring to replies of the scientific experts to Question 40 posed by the Panel, Panel Reports, Annex D, paras. 325 and 326).

¹⁴⁶⁸Panel Report, *US – Continued Suspension*, paras. 7.670 and 7.671; Panel Report, *Canada – Continued Suspension*, paras. 7.647 and 7.648.

726. The Panel seemed to rely on two pieces of evidence in coming to the conclusion that the ultra-sensitive detection method discussed in the Klein study had not yet been validated: a statement to that effect in the 2002 Opinion¹⁴⁶⁹, and the testimony of Dr. Boobis, who questioned the validity of the Klein study.¹⁴⁷⁰ However, the Panel record shows that at least some of the scientific experts considered that the Klein study could possibly cast doubt as to whether the body of scientific evidence relied on by JECFA still permitted of a sufficiently objective assessment of risks posed by the five hormones in relation to pre-pubertal children.

727. Dr. Sippell seemed to agree with the European Communities' position that the relevant scientific evidence on the effects of hormones in pre-pubertal children was not "sufficient" to conduct a risk assessment under Article 5.1. Dr. Sippell observed that "[w]e just don't have yet everywhere where it would be necessary the methodology, the analytical tools to measure as sensitively as we should do it, and therefore I think that the data available are insufficient."¹⁴⁷¹ Dr. Sippell also explained that:

... it is difficult to calculate the exact [hormone] production rates in prepubertal children. ... [JECFA values] have been based on the, so to speak, traditional levels measured by radio immuno assays, and usually by radio immuno assays without prior extraction. We all know that the sensitivity of such procedures is not enough compared with more modern techniques ... the extractive procedures involving radio immuno assays, but even more modern molecular base techniques like recombinant cell bioassays, of oestrogen, oestradiol or oestrogen activity. And these ... are significantly below the levels previously thought, and by that the production rate is now significantly lower. And this of course implies that any risk from exogenous sources, for example, beef treated with hormones, treated with oestradiol-17 β , is much higher.¹⁴⁷²

728. Dr. De Brabander concurred, stating that "I cannot say that the [JECFA] data are bad ... I just say you don't know that they are good, and you have to check them with modern analytical methods."¹⁴⁷³ Dr. Guttenplan espoused a similar view, noting that "more accurate methods of analysis could now be used to measure the effect of eating hormone-treated beef on blood levels of estrogen in children and post-menopausal women."¹⁴⁷⁴ He also observed that "in boys the [oestrogen]

¹⁴⁶⁹Panel Report, *US – Continued Suspension*, para. 7.670; Panel Report, *Canada – Continued Suspension*, para. 7.647 (referring to 2002 Opinion, para. 4.4.1, para. 9).

¹⁴⁷⁰Panel Report, *US – Continued Suspension*, para. 7.669; Panel Report, *Canada – Continued Suspension*, para. 7.646 (quoting replies of the scientific experts to Question 40 posed by the Panel, Panel Reports, Annex D, paras. 325 and 326).

¹⁴⁷¹Transcript of the Panel's joint meeting with scientific experts on 27-28 September 2006, Panel Reports, Annex G, para. 891.

¹⁴⁷²*Ibid.*, para. 557.

¹⁴⁷³*Ibid.*, para. 675.

¹⁴⁷⁴Replies of the scientific experts to Question 52 posed by the Panel, Panel Reports, Annex D, para. 413.

levels are even lower, and there I think we have to worry about developmental effects ... I still think that these could be investigated epidemiologically or in or some type of study. We might ... need a surrogate, perhaps saliva or urine, but I think it is perhaps the most important issue to address is the sensitivity of children."¹⁴⁷⁵

729. Dr. Boobis, who as the Panel noted questioned the validity of the ultra-sensitive recombinant assay used in the Klein study, also testified that the levels of oestradiol endogenously produced in pre-pubertal children may be lower than previously thought. In response to direct questioning by the United States, Dr. Boobis explained that:

.... having looked at these data is that, first of all, the recombinant assay has not yet been validated adequately, but secondly there is evidence, when one looks at these data, to suggest that the circulating levels of oestradiol in male children are lower than previously thought, I would accept that, but I would not think they are as low as in the original publication by Klein *et al*, because there have been numerous publications since then using a variety of assays which suggest that the levels are certainly higher than those very low levels first reported.¹⁴⁷⁶

730. Although the Panel was correct in observing that the Klein study only examined endogenous levels of oestradiol, lower levels of endogenous production of hormones in humans played a key role in the European Communities' conclusion that no safe threshold level or ADI could be established for any of the six hormones assessed. The 1999 Opinion states that, in the light of "uncertainties in the estimates of endogenous hormone production rates and metabolic clearance capacity, particularly in prepubertal children, no threshold level and therefore no ADI can be established for any of the [six] hormones."¹⁴⁷⁷ For this reason, the Panel should have explored further the question of what relevance, if any, the study relied on by the European Communities examining endogenous levels of oestradiol could have in relation to potential adverse health effects relating to the other five hormones. During the course of the oral hearing, the European Communities argued that some scientists agree with its position that measurements of the endogenous levels of natural hormones are relevant for synthetic hormones that share similar toxicological properties and effects.

¹⁴⁷⁵ Transcript of the Panel's joint meeting with scientific experts on 27-28 September 2006, Panel Reports, Annex G, para. 1061.

¹⁴⁷⁶ *Ibid.*, para. 572.

¹⁴⁷⁷ 1999 Opinion, pp. 72 and 73. The 1999 Opinion also concludes that: "For all six hormones endocrine, developmental, immunological, neurobiological, immunotoxic, genotoxic, and carcinogenic effects could be envisaged. Of the various susceptible risk groups, prepubertal children is the group of greatest concern. Again the available data do not enable a quantitative estimate of the risk".

731. In sum, the Panel erred in its interpretation and application of Article 5.7 of the *SPS Agreement* by adopting an incorrect legal test to assess the European Communities' explanations concerning the insufficiencies in the relevant scientific evidence.

732. The European Communities argues further that the Panel failed to conduct an objective assessment of the facts of the case, as required by Article 11 of the DSU, in its analysis under Article 5.7. Having determined that the Panel incorrectly interpreted and applied Article 5.7 of the *SPS Agreement*, we do not find it necessary to address the European Communities' claim that the Panel acted inconsistently with Article 11 of the DSU.

F. *Conclusions*

733. We found above that the Panel drew too rigid a distinction between the chosen level of protection and the "insufficiency" of the relevant scientific evidence under Article 5.7 of the *SPS Agreement*.¹⁴⁷⁸ We also reversed the Panel's finding that, where international standards exist, a "critical mass of new evidence and/or information that calls into question the fundamental precepts of previous knowledge and evidence" is required to render the relevant scientific evidence "insufficient" within the meaning of Article 5.7.¹⁴⁷⁹ We found, moreover, that the Panel erred in the allocation of the burden of proof.¹⁴⁸⁰ Finally, we found that the Panel incorrectly interpreted and applied Article 5.7 in determining whether the relevant scientific evidence in relation to the five hormones was "insufficient" within the meaning of that provision.¹⁴⁸¹ In addition, we have found that the Panel's analysis was compromised because its consultations with Drs. Boisseau and Boobis infringed the European Communities' due process rights.¹⁴⁸²

734. In the light of these errors, we reverse the Panel's finding that "it has not been demonstrated that relevant scientific evidence was insufficient, within the meaning of Article 5.7 of the *SPS Agreement*, in relation to any of the five hormones with respect to which the European Communities applies a provisional ban."¹⁴⁸³ As a consequence of its finding, the Panel also concluded that "the [European Communities'] compliance measure does not meet the requirements of Article 5.7 of the *SPS Agreement* as far as the provisional ban on progesterone, testosterone, zeranol, trenbolone acetate and melengestrol acetate is concerned."¹⁴⁸⁴ Because it is premised on the Panel's

¹⁴⁷⁸See *supra*, para. 686.

¹⁴⁷⁹See *supra*, para. 712.

¹⁴⁸⁰See *supra*, para. 718.

¹⁴⁸¹See *supra*, para. 731.

¹⁴⁸²See *supra*, section V.

¹⁴⁸³Panel Report, *US – Continued Suspension*, para. 7.835; Panel Report, *Canada – Continued Suspension*, para. 7.821.

¹⁴⁸⁴Panel Report, *US – Continued Suspension*, para. 7.836; Panel Report, *Canada – Continued Suspension*, para. 7.822.

earlier finding concerning the "insufficiency" of the relevant scientific information, which we have reversed, the Panel's conclusion cannot stand.

735. Given the numerous flaws that we identified in the Panel's analysis, and the highly contested nature of the facts, we do not consider it possible to complete the analysis. Thus, we make no findings on the consistency or inconsistency of the European Communities' provisional SPS measure relating to progesterone, testosterone, zeranol, trenbolone acetate and MGA.

VIII. Findings and Conclusions

736. For the reasons set out in this Report, the Appellate Body:

- (a) As regards the DSU:
 - (i) finds that the Panel did not err in stating that proceedings under Article 21.5 of the DSU are open to not only the original complainant¹⁴⁸⁵, because they may be initiated by original complainants and original respondents;
 - (ii) upholds the Panel's finding that "it has jurisdiction to consider the compatibility of the [European Communities'] implementing measure with the *SPS Agreement* as part of its review of the claim raised by the European Communities with respect to Article 22.8 of the DSU"¹⁴⁸⁶;
 - (iii) because it has not been established that the measure found to be inconsistent with the *SPS Agreement* in the *EC – Hormones* dispute has been removed¹⁴⁸⁷, upholds the Panel's finding that "the European Communities has not established a violation of Articles 23.1 and 3.7 of the DSU *as a result of a breach of Article 22.8*"¹⁴⁸⁸;
 - (iv) reverses the Panel's finding that, "by maintaining its suspension of concessions even after the notification of [Directive 2003/74/EC]", the United States is "seeking redress of a violation with respect to [this Directive], within the meaning of Article 23.1 of the DSU"¹⁴⁸⁹; and

¹⁴⁸⁵Panel Report, *US – Continued Suspension*, para. 7.355.

¹⁴⁸⁶*Ibid.*, para. 7.379.

¹⁴⁸⁷See subparagraphs (c) and (d) *infra*.

¹⁴⁸⁸Panel Report, *US – Continued Suspension*, para. 7.857(b). (original emphasis)

¹⁴⁸⁹*Ibid.*, para. 7.215. See also *ibid.*, para. 7.856(a).

- (v) reverses the Panel's findings that the United States "made a 'determination' within the meaning of Article 23.2(a) in relation to Directive 2003/74/EC" on the basis of statements made at DSB meetings and the fact that the suspension of concessions continued subsequent to the notification of Directive 2003/74/EC¹⁴⁹⁰, and that the United States "failed to make any such determination consistent with the findings contained in the panel or Appellate Body report adopted by the DSB or an arbitration award rendered under the DSU", in breach of Article 23.2(a).¹⁴⁹¹
- (b) As regards the Panel's consultations with the scientific experts, finds that the Panel infringed the European Communities' due process rights, because the institutional affiliation of Drs. Boisseau and Boobis compromised their appointment and thereby the adjudicative independence and impartiality of the Panel. Accordingly, the Panel failed to comply with its duties under Article 11 of the DSU.
- (c) As regards the consistency with Article 5.1 of the *SPS Agreement* of the European Communities' import ban on meat from cattle treated with oestradiol-17 β for growth-promotion purposes, which is applied pursuant to Directive 2003/74/EC:
- (i) finds that the Panel erred in its interpretation and application of Article 5.1 in relation to risks of misuse and abuse in the administration of hormones to cattle for growth-promotion purposes;
- (ii) finds that the Panel did not err in requiring the European Communities to evaluate specifically the risks arising from the presence of residues of oestradiol-17 β in meat or meat products from cattle treated with the hormone for growth-promotion purposes;
- (iii) finds that the Panel did not err in its interpretation of Article 5.1 and paragraph 4 of Annex A of the *SPS Agreement* as regards quantification of risk;
- (iv) finds that the Panel erred in the allocation of the burden of proof in its assessment of the consistency of Directive 2003/74/EC with Article 5.1 of the *SPS Agreement*;

¹⁴⁹⁰Panel Report, *US – Continued Suspension*, para. 7.239. See also *ibid.*, para. 7.856(b).

¹⁴⁹¹*Ibid.*, para. 7.244. (emphasis omitted) See also *ibid.*, para. 7.856(b).

- (v) finds that the Panel applied an incorrect standard of review in examining whether the European Communities' risk assessment satisfied the requirements of Article 5.1 and paragraph 4 of Annex A of the *SPS Agreement*, and thereby failed to comply with its duties under Article 11 of the DSU; and
- (vi) reverses the Panel's finding that the European Communities' import ban relating to oestradiol-17 β is not based on a risk assessment as required by Article 5.1 of the *SPS Agreement*¹⁴⁹²; however, the Appellate Body is unable to complete the analysis and therefore makes no findings as to the consistency or inconsistency of the import ban relating to oestradiol-17 β with Article 5.1 of the *SPS Agreement*.
- (d) As regards the consistency with Article 5.7 of the *SPS Agreement* of the European Communities' provisional import ban on meat from cattle treated with testosterone, progesterone, trenbolone acetate, zeranol, and MGA, for growth-promotion purposes, which is applied pursuant to Directive 2003/74/EC:
- (i) reverses the Panel's finding that "the determination of whether scientific evidence is sufficient to assess the existence and magnitude of a risk must be disconnected from the intended level of protection"¹⁴⁹³;
- (ii) reverses the Panel's finding that, where international standards exist, "there must be a *critical mass* of new evidence and/or information that calls into question the fundamental precepts of previous knowledge and evidence so as to make relevant, previously sufficient, evidence now insufficient"¹⁴⁹⁴;
- (iii) finds that the Panel erred in the allocation of the burden of proof in its examination of the consistency of Directive 2003/74/EC with Article 5.7 of the *SPS Agreement*;
- (iv) finds that the Panel erred in its interpretation and application of Article 5.7 of the *SPS Agreement* by adopting an incorrect legal test in determining whether the relevant scientific evidence was "insufficient";

¹⁴⁹²Panel Report, *US – Continued Suspension*, paras. 7.573, 7.578, and 7.579.

¹⁴⁹³*Ibid.*, para. 7.612.

¹⁴⁹⁴*Ibid.*, para. 7.648. (original emphasis; footnote omitted)

- (v) does not find it necessary to address the European Communities' claim that the Panel acted inconsistently with Article 11 of the DSU; and
- (vi) reverses the Panel's finding that the provisional import ban relating to testosterone, progesterone, trenbolone acetate, zeranol, and MGA does not meet the requirements of Article 5.7 of the *SPS Agreement*¹⁴⁹⁵; however, the Appellate Body is unable to complete the analysis and therefore makes no findings as to the consistency or inconsistency of the European Communities' provisional import ban with Article 5.7 of the *SPS Agreement*.

737. Because we have been unable to complete the analysis as to whether Directive 2003/74/EC has brought the European Communities into substantive compliance within the meaning of Article 22.8 of the DSU, the recommendations and rulings adopted by the DSB in *EC – Hormones* remain operative. In the light of the obligations arising under Article 22.8 of the DSU, we recommend that the Dispute Settlement Body request the United States and the European Communities to initiate Article 21.5 proceedings without delay in order to resolve their disagreement as to whether the European Communities has removed the measure found to be inconsistent in *EC – Hormones* and whether the application of the suspension of concessions by the United States remains legally valid.

¹⁴⁹⁵Panel Report, *US – Continued Suspension*, paras. 7.835 and 7.836.

Signed in the original in Geneva this 19th day of September 2008 by:

David Unterhalter
Presiding Member

Georges Abi-Saab
Member

Lilia Bautista
Member

ANNEX I

**WORLD TRADE
ORGANIZATION**

WT/DS320/12
WT/DS321/12
2 June 2008
(08-2559)

Original: English

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

**CANADA – CONTINUED SUSPENSION OF OBLIGATIONS IN THE
EC – HORMONES DISPUTE**

Notification of an Appeal by the European Communities
under Article 16.4 and Article 17 of the Understanding on Rules
and Procedures Governing the Settlement of Disputes (DSU),
and under Rule 20(1) of the *Working Procedures for Appellate Review*

The following notification, dated 29 May 2008, from the Delegation of the European Commission, is being circulated to Members.

Notification of an Appeal by the European Communities under Article 16.4 and Article 17 of the *Understanding on Rules and Procedures Governing the Settlement of Disputes* (DSU), and under Rule 20.1 of the *Working Procedures for Appellate Review*.

1. Pursuant to Article 16.4 and Article 17 of the DSU and to Rule 20.1 of the *Working Procedures for Appellate Review*, the European Communities submits its Notice of Appeal on certain issues of law covered in the Reports of the Panels in DS320, *United States – Continued Suspension of Obligations in the EC – Hormones Dispute* and DS321, *Canada – Continued Suspension of Obligations in the EC – Hormones Dispute* and certain legal interpretations developed by the Panels in those Reports.
2. The European Communities seeks review by the Appellate Body of the following errors of law and legal interpretation contained in the Reports of the Panels:
 - (a) The Panels incorrectly interpreted and applied the words "recourse to dispute settlement in accordance with the rules and procedures of this Understanding" in Article 23.2(a) of the DSU in the presence of an implementation measure in a post-retaliation situation. This is due principally to the Panels' incorrect interpretation of Article 21.5 of the DSU. The Panels' errors are contained in particular in paragraphs 7.246 to 7.249 and 7.346 to 7.359 of the Panel Report in DS320 and paragraphs 7.239 to 7.242 and 7.344 to 7.357 of the Panel Report in DS321.
 - (b) The Panels erred in failing to make a proper finding of violation of Article 23.1 read together with Article 22.8 and 3.7 of the DSU when stating that "to the extent the measure found to be

inconsistent with the *SPS Agreement* in the *EC – Hormones* dispute ... has not been removed by the European Communities, [the United States and Canada] have not breached Article 22.8 of the DSU; and to the extent that Article 22.8 has not been breached, the European Communities has not established a violation of Articles 23.1 and 3.7 of the DSU as a result of a breach of Article 22.8". This error is due to the Panels' incorrect interpretation of Article 22.8 of the DSU and in particular the words "the measure found to be inconsistent with a covered agreement has been removed" therein. The Panels' conclusion and the corresponding reasoning are contained in paragraphs 7.857 and 7.252 to 7.386 of the Panel Report in DS320 and paragraphs 7.842 and 7.245 to 7.383 of the Panel Report in DS321.

- (c) The Panels went beyond their terms of reference and assumed the function of Article 21.5 DSU panels contrary to Articles 7 and 21.5 of the DSU. This appears in particular in paragraph 8.3 of the two Panel Reports and paragraphs 7.150 to 7.182, 7.270 to 7.291 and 7.360 to 7.379 of the Panel Report in DS320 and paragraphs 7.137 to 7.164, 7.286 to 7.307 and 7.358 to 7.376 of the Panel Report in DS321.
- (d) The Panels failed to respect the fundamental principle of due process when selecting and taking the advice of scientific experts under Articles 13.2 of the DSU and 11.2 of the *SPS Agreement* with the result that the Panels failed to make an objective assessment of the matter before them in breach of Article 11 of the DSU. This appears in particular in paragraphs 7.55 to 7.99 and 6.21 to 6.25 and the subsequent analysis of the Panel under the *SPS Agreement* in paragraphs 7.387 to 7.846 of the Panel Report in DS320 and paragraphs 7.53 to 7.96 and the subsequent analysis of the Panel under the *SPS Agreement* in paragraphs 7.384 to 7.831 of the Panel Report in DS321.
- (e) The Panels failed to correctly determine and apply the standard of review under in particular Articles 5.1 and 5.7 of the *SPS Agreement* in breach thereof and in breach of Article 11 of the DSU. The Panels seriously mischaracterised and misinterpreted the evidence on which the European Communities based itself and conducted a *de novo* review of the matter before them and *inter alia* failed to take into account or properly evaluate the scientific basis of the European Communities' measure. They also failed to attach proper legal relevance to genuine uncertainties and scientific controversies on the matter before them and arbitrarily chose between the opinions of their experts and those presented by the other parties to the disputes. The Panels also relied incorrectly on the opinions of Codex Alimentarius and JECFA. This appears *inter alia* in paragraphs 7.412 to 7.427 and paragraphs 7.435 to 7.846 of the Panel Report in DS320 and paragraphs 7.403 to 7.418 and paragraphs 7.426 to 7.831 of the Panel Report in DS321.
- (f) The Panels failed to correctly determine and apply the burden of proof under the *SPS Agreement* and in particular Articles 5.1 and 5.7 thereof. The Panels imposed the burden of proof on the European Communities to prove the consistency of its measure with the *SPS Agreement* and in particular Articles 5.1 and 5.7 thereof. This appears in particular in paragraphs 7.380 to 7.386 and paragraphs 7.435 to 7.846 of the Panel Report in DS320 and paragraphs 7.377 to 7.383 and paragraphs 7.426 to 7.831 of the Panel Report in DS321.
- (g) The Panels incorrectly interpreted and applied Article 5.1 of the *SPS Agreement* and failed to make an objective assessment of the matter before them in breach of Article 11 of the DSU. The Panels erroneously adopted an overly restrictive notion of "an assessment, as appropriate to the circumstances, of the risk" under Article 5.1 of the *SPS Agreement* as informed by Article 5.2 thereof, ignored that the EC risk assessments had focussed on and addressed the particular risk at stake and required that the risk be quantified. The Panels' erroneous assessments arose out of its application of an inappropriate standard of review, as set out in paragraph (e) above. In particular, it arbitrarily chose between the opinions of their scientific experts in their review of the matter before them. This appears in particular in

paragraphs 7.435 to 7.579 of the Panel Report in DS320 and paragraphs 7.426 to 7.549 of the Panel Report in DS321.

- (h) The Panels incorrectly interpreted and applied Article 5.7 of the *SPS Agreement* and failed to make an objective assessment of the matter before them in breach of Article 11 of the DSU. The Panels incorrectly interpreted the relationship of Article 5.7 with the other provisions of the *SPS Agreement* and in particular Articles 3.2, 3.3 and 5.1 thereof and adopted and applied an erroneous criterion of critical mass of new scientific evidence and/or information for the purposes of applying Article 5.7. The Panels' erroneous assessments arose out of its application of an inappropriate standard of review, as set out in paragraph (e) above. In particular, it arbitrarily chose between the opinions of its scientific experts in their review of the matter before them. This appears in particular in paragraphs 7.580 to 7.837 of the Panel Report in DS320 and paragraphs 7.550 to 7.823 of the Panel Report in DS321.
 - (i) The Panels erred in making a suggestion that insufficiently clarifies the implications of their findings contrary to Article 3.7 and 19.1 of the DSU. This appears in particular in paragraphs 8.2 and 8.3 of the Panel Reports.
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ANNEX II

**WORLD TRADE
ORGANIZATION**

WT/DS320/13
16 June 2008

(08-2784)

Original: English

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

Notification of an Other Appeal by the United States
under Article 16.4 and Article 17 of the Understanding on Rules
and Procedures Governing the Settlement of Disputes (DSU),
and under Rule 23(1) of the *Working Procedures for Appellate Review*

The following notification, dated 10 June 2008, from the Delegation of the United States, is being circulated to Members.

Pursuant to Article 16 of the *Understanding on Rules and Procedures Governing the Settlement of Disputes* ("DSU") and Rule 23 of the *Working Procedures for Appellate Review*, the United States hereby notifies its decision to appeal to the Appellate Body certain issues of law covered in the Report of the Panel on *United States – Continued Suspension of Obligations in the EC – Hormones Dispute* (WT/DS320/R) ("Panel Report") and certain legal interpretations developed by the Panel.

1. The United States seeks review by the Appellate Body of the Panel's legal conclusion that the United States breached Article 23.1 of the DSU (e.g., Panel Report, paras. 7.250, 7.856(a)). This conclusion is in error and is based on erroneous findings on issues of law and legal interpretations, including the Panel's findings that, by maintaining its suspension of concessions after the notification by the European Communities ("EC") of Directive 2003/74/EC, the United States was seeking the redress of a violation of obligations under a covered agreement without having recourse to, and abiding by, the rules and procedures of the DSU (e.g., Panel Report, paras. 7.215, 7.856(a)), and the Panel's interpretation and understanding of the legal basis for the U.S. suspension of concessions (e.g., Panel Report, paras. 7.209-7.214).

2. The United States also seeks review of the Panel's conclusion that the United States breached DSU Article 23.2(a) (e.g., Panel Report, paras. 7.245, 7.856(b)). This conclusion is in error and is based on erroneous findings on issues of law and legal interpretations, including the Panel's findings that the United States made a determination to the effect that a violation had occurred without recourse to dispute settlement in accordance with the rules and procedures of the DSU (e.g., Panel Report, paras. 7.239, 7.856(b)), on the basis of U.S. statements made at the meetings of the Dispute Settlement Body on November 1 and December 7, 2003 (e.g., Panel Report paras. 7.223-7.230) and/or the continuation of the U.S. suspension of concessions after the EC's notification of Directive 2003/74/EC (e.g., Panel Report paras. 7.226, 7.230, 7.232).

3. The United States seeks review of the Panel's suggestion that the United States should have recourse to the rules and procedures of the DSU without delay (e.g., Panel Report paras. 6.45, 8.3) and the Panel's conclusion that it was restricted from a direct determination of the compatibility of Directive 2003/74/EC with the covered agreements (e.g., Panel Report paras. 7.162-7.164, 7.360, 7.855, 8.3). The suggestion and conclusion are in error and based on erroneous findings on issues of law and related legal interpretations. However, the Appellate Body would not need to review the suggestion and conclusion if it reverses the Panel's findings and conclusions on DSU Articles 23.1 and 23.2(a).

ANNEX III

**WORLD TRADE
ORGANIZATION**

WT/DS321/13
16 June 2008

(08-2783)

Original: English

**CANADA – CONTINUED SUSPENSION OF OBLIGATIONS IN THE
EC – HORMONES DISPUTE**

Notification of an Other Appeal by Canada
under Article 16.4 and Article 17 of the Understanding on Rules
and Procedures Governing the Settlement of Disputes (DSU),
and under Rule 23(1) of the *Working Procedures for Appellate Review*

The following notification, dated 10 June 2008, from the Delegation of Canada, is being circulated to Members.

Pursuant to paragraph 4 of Article 16 of the *Understanding on Rules and Procedures Governing the Settlement of Disputes* (the "DSU") and paragraph 1 of Rule 23 of the *Working Procedures for Appellate Review*, the Government of Canada hereby submits its Notice of Other Appeal concerning certain other issues of law covered in the Panel Report on *Canada – Continued Suspension of Obligations in the EC – Hormones Dispute* (WT/DS321/R) and certain legal interpretations developed by the Panel.

In the view of the Government of Canada, the Panel erred in interpreting Article 23 of the DSU in isolation from Article 22.8 of the DSU and committed an error in law by applying, in particular, Article 23.1 and 23.2(a) of the DSU to the situation of post-retaliation in this case. These errors are contained in paragraphs 7.162 to 7.164, 7.189 to 7.244 and 7.841 of the Panel Report.

The Government of Canada is also of the view that the Panel erred in finding that by continuing to suspend concessions *vis-à-vis* the European Communities following its notification to the Dispute Settlement Body of Directive 2003/74/EC Canada was: (i) seeking the redress of a violation of obligations under a covered agreement without having recourse to, and abiding by, the rules and procedures of the DSU in violation of Article 23.1 of the DSU; and (ii) making a determination to the effect that a violation had occurred without having recourse to dispute settlement in accordance with the rules and procedures of the DSU, in violation of Article 23.2(a) of the DSU. These errors are due to the Panel's misinterpretation of the legal basis for Canada's suspension of concessions. The Panel's findings and corresponding reasoning are contained in paragraphs 7.841 and 7.189 to 7.244 of its report.

In the alternative, should the Appellate Body confirm the findings of the Panel in respect of DSU Article 23.1 and 23.2(a) in relation to Canada, the Government of Canada submits that the Panel erred in stating that it did not have jurisdiction to determine the compatibility of Directive 2003/74/EC with the covered agreements and by making the suggestion that Canada should have recourse to the

rules and procedures of the DSU without delay in order to implement its findings under Article 23 of the DSU. These statements are contained in paragraph 8.3 of the Panel Report and are contrary to Articles 3.3, 3.7, 19.2 and 22.8 of the DSU.

The Government of Canada respectfully requests the Appellate Body to reverse the findings and conclusions of the Panel referred to above and to modify accordingly the recommendations of the Panel.

ANNEX IV –

PROCEDURAL RULING OF 10 JULY TO ALLOW
PUBLIC OBSERVATION OF THE ORAL HEARING

10 July 2008

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

AB-2008-5

Canada – Continued Suspension of Obligations in the EC – Hormones Dispute

AB-2008-6

Procedural Ruling

1. On 3 June 2008, Canada, the European Communities, and the United States each filed a request to allow public observation of the oral hearing in these proceedings.¹ The participants argued that nothing in the *Understanding on Rules and Procedures Governing the Settlement of Disputes* (the "DSU") or the *Working Procedures for Appellate Review* (the "*Working Procedures*") precludes the Appellate Body from authorizing public observation of the oral hearing. On 4 June 2008, we invited the third participants to comment in writing on the requests of Canada, the European Communities, and the United States. In particular, we asked third parties to provide their views on the permissibility of opening the hearing under the DSU and the Working Procedures, and, if they so wished, on the specific logistical arrangements proposed in the requests. We received comments on 12 June 2008 from Australia, Brazil, China, India, Mexico, New Zealand, Norway, and the Separate Customs Territory of Taiwan, Penghu, Kinmen, and Matsu. Australia, New Zealand, Norway, and the Separate Customs Territory of Taiwan, Penghu, Kinmen, and Matsu expressed their support for the request of the participants. Brazil, China, India, and Mexico requested the Appellate Body to deny the participants' request. According to these third participants, the oral hearing forms part of the proceedings of the Appellate Body and, therefore, is subject to the requirement of Article 17.10 of the DSU that "[t]he proceedings of the Appellate Body shall be confidential." On 16 June 2008, we invited Canada, the European Communities, and the United States to comment on the submissions made by the third participants. We also invited third participants who wished to do so to submit comments on the submissions made by the other third participants. Additional comments from Canada, the European Communities, and the United States were received on 23 June 2008. We held an oral hearing with the participants and third participants on 7 July 2008 exclusively dedicated to exploring the issues raised by the request of the participants. The participants and third participants were invited to submit by close of business, 8 July 2008, additional comments relating specifically to the technical modalities proposed by the participants for public observation. Comments were received from Brazil, China, India, and Mexico, as well as Canada, the European Communities, and the United States.

2. We consider it necessary that a ruling is made by us on the request of the participants without delay. Accordingly, we give a ruling with concise reasons. These reasons may be further elaborated in the Appellate Body report.

¹The participants expressed a preference for simultaneous, closed-circuit television broadcast to another room. As alternatives, they mentioned delayed television broadcast and having a separate session for the third participants who elect not to participate in the open hearing.

3. The participants have different views on the scope of the term "proceedings" in Article 17.10 of the DSU. The European Communities argues that the term "proceedings" in Article 17.10 should be interpreted narrowly as referring to the Appellate Body's internal work and does not include its oral hearing.² The United States refers to the Recommendations by the Preparatory Committee for the WTO. The United States contends that the Preparatory Committee viewed Article 17.10 as focused on the deliberations of the Appellate Body.³ Canada concedes that the term "proceedings" covers the oral hearing. A similar view has been put forward by Brazil, China, India, and Mexico. We consider the term "proceedings" to mean the entire process by which an appeal is prosecuted, from the initiation of an appeal to the circulation of the Appellate Body report, including the oral hearing. This is also how the Appellate Body understood the term in *Canada – Aircraft*.⁴ Having agreed with this broad interpretation of the term "proceedings", we now consider the precise meaning and scope of the confidentiality requirement in Article 17.10.

4. The third participants that object to the request to allow public observation argue that the confidentiality requirement in Article 17.10 is absolute and permits of no derogation. We disagree with this interpretation because Article 17.10 must be read in context, particularly in relation to Article 18.2 of the DSU. The second sentence of Article 18.2 expressly provides that "[n]othing in this Understanding shall preclude a party to a dispute from disclosing statements of its own positions to the public". Thus, under Article 18.2, the parties may decide to forego confidentiality protection in respect of their statements of position. With the exception of India, the participants and third participants agreed that the term "statements of its own positions" in Article 18.2 extends beyond the written submissions referred to in the first sentence of Article 18.2, and includes oral statements and responses to questions posed by the Appellate Body at the oral hearing. The third sentence of Article 18.2 states that "Members shall treat as confidential information submitted by another Member to the panel or the Appellate Body which that Member has designated as confidential." This provision would be redundant if Article 17.10 were interpreted to require absolute confidentiality in respect of all elements of appellate proceedings. There would be no need to require, pursuant to Article 18.2, that a Member designate certain information as confidential. The last sentence of Article 18.2 ensures that even such designation by a Member does not put an end to the right of another Member to make disclosure to the public. Upon request, a Member must provide a non-confidential summary of the information contained in its written submissions that it designated as confidential, which can then be disclosed to the public. Thus, Article 18.2 provides contextual support for the view that the confidentiality rule in Article 17.10 is not absolute. Otherwise, no disclosure of written submissions or other statements would be permitted during any stage of the proceedings.

5. In practice, the confidentiality requirement in Article 17.10 has its limits. Notices of Appeal and Appellate Body reports are disclosed to the public. Appellate Body reports contain summaries of the participants' and third participants' written and oral submissions and frequently quote directly from them. Public disclosure of Appellate Body reports is an inherent and necessary feature of our rules-based system of adjudication. Consequently, under the DSU, confidentiality is relative and time-bound.

²European Communities' request for an open hearing, para. 9. Norway also argued for a narrower understanding of the term "proceedings".

³United States' comments on the third participants' submissions regarding open hearings, paras. 5 and 6 (referring to Establishment of the Appellate Body: Recommendations by the Preparatory Committee for the WTO approved by the Dispute Settlement Body on 10 February 1995 (WT/DSB/1), para. 9).

⁴Appellate Body Report, *Canada – Aircraft*, para. 143. However, we note that that case did not involve a request to lift confidentiality; rather, that dispute concerned a request for additional confidentiality protection for business confidential information.

6. In our view, the confidentiality requirement in Article 17.10 is more properly understood as operating in a relational manner.⁵ There are different sets of relationships that are implicated in appellate proceedings. Among them are the following relationships. First, a relationship between the participants and the Appellate Body. Secondly, a relationship between the third participants and the Appellate Body. The requirement that the proceedings of the Appellate Body are confidential affords protection to these separate relationships and is intended to safeguard the interests of the participants and third participants and the adjudicative function of the Appellate Body, so as to foster the system of dispute settlement under conditions of fairness, impartiality, independence and integrity. In this case, the participants have jointly requested authorization to forego confidentiality protection for their communications with the Appellate Body at the oral hearing. The request of the participants does not extend to any communications, nor touches upon the relationship, between the third participants and the Appellate Body. The right to confidentiality of third participants vis-à-vis the Appellate Body is not implicated by the joint request. The question is thus whether the request of the participants to forego confidentiality protection satisfies the requirements of fairness and integrity that are the essential attributes of the appellate process and define the relationship between the Appellate Body and the participants. If the request meets these standards, then the Appellate Body would incline towards authorizing such a joint request.

7. We note that the DSU does not specifically provide for an oral hearing at the appellate stage. The oral hearing was instituted by the Appellate Body in its *Working Procedures*, which were drawn up pursuant to Article 17.9 of the DSU. The conduct and organization of the oral hearing falls within the authority of the Appellate Body (*compétence de la compétence*) pursuant to Rule 27 of the *Working Procedures*. Thus, the Appellate Body has the power to exercise control over the conduct of the oral hearing, including authorizing the lifting of confidentiality at the joint request of the participants as long as this does not adversely affect the rights and interests of the third participants or the integrity of the appellate process. As we observed earlier, Article 17.10 also applies to the relationship between third participants and the Appellate Body. Nevertheless, in our view, the third participants cannot invoke Article 17.10, as it applies to their relationship with the Appellate Body, so as to bar the lifting of confidentiality protection in the relationship between the participants and the Appellate Body. Likewise, authorizing the participants' request to forego confidentiality, does not affect the rights of third participants to preserve the confidentiality of their communications with the Appellate Body.

8. Some of the third participants argued that the Appellate Body is itself constrained by Article 17.10 in its power to authorize the lifting of confidentiality. We agree that the powers of the Appellate Body are themselves circumscribed in that certain aspects of confidentiality are incapable of derogation—even by the Appellate Body—where derogation may undermine the exercise and integrity of the Appellate Body's adjudicative function. This includes the situation contemplated in the second sentence of Article 17.10, which provides that "[t]he reports of the Appellate Body shall be drafted without the presence of the parties to the dispute and in the light of the information provided and the statements made." As noted by the participants, the confidentiality of the deliberations is necessary to protect the integrity, impartiality, and independence of the appellate process. In our view, such concerns do not arise in a situation where, following a joint request of the participants, the Appellate Body authorizes the lifting of the confidentiality of the participants' statements at the oral hearing.

9. The Appellate Body has fostered the active participation of third parties in the appellate process in drawing up the *Working Procedures* and in appeal practice. Article 17.4 provides that third participants "may make written submissions to, and be given an opportunity to be heard by, the Appellate Body." In its *Working Procedures*, the Appellate Body has given full effect to this right by providing for participation of third participants during the entirety of the oral hearing, while third

⁵This relational view of rights and obligations of confidentiality is consistent with the approach followed in domestic jurisdictions with respect to similar issues, such as privilege.

parties meet with panels only in a separate session at the first substantive meeting. Third participants, however, are not the main parties to a dispute. Rather, they have a systemic interest in the interpretation of the provisions of the covered agreements that may be at issue in an appeal. Although their views on the questions of legal interpretation that come before the Appellate Body are always valuable and thoroughly considered, these issues of legal interpretation are not inherently confidential. Nor is it a matter for the third participants to determine how the protection of confidentiality in the relationship between the participants and the Appellate Body is best dealt with. In order to sustain their objections to public observation of the oral hearing, third participants would have to identify a specific interest in their relationship with the Appellate Body that would be adversely affected if we were to authorize the participants' request—in this case, we can discern no such interests.

10. The request for public observation of the oral hearing has been made jointly by the three participants, Canada, the European Communities, and the United States. As we explained earlier, the Appellate Body has the power to authorize a joint request by the participants to lift confidentiality, provided that this does not affect the confidentiality of the relationship between the third participants and the Appellate Body, or impair the integrity of the appellate process. The participants have suggested alternative modalities that allow for public observation of the oral hearing, while safeguarding the confidentiality protection enjoyed by the third participants. The modalities include simultaneous or delayed closed-circuit television broadcasting in a room separate from the room used for the oral hearing. Finally, we do not see the public observation of the oral hearing, using the means described above, as having an adverse impact on the integrity of the adjudicative functions performed by the Appellate Body.

11. For these reasons, the Division authorizes the public observation of the oral hearing in these proceedings on the terms set out below. Accordingly, pursuant to Rule 16(1) of the *Working Procedures*, we adopt the following additional procedures for the purposes of these appeals:

- (a) The oral hearing will be open to public observation by means of simultaneous closed-circuit television. The closed-circuit television signal will be shown in a separate room to which duly-registered delegates of WTO Members and members of the general public will have access.
 - (b) Oral statements and responses to questions by third participants wishing to maintain the confidentiality of their submissions will not be subject to public observation.
 - (c) Any third participant that has not already done so may request authorization to disclose its oral statements and responses to questions on the basis of paragraph (a), set out above. Such requests must be received by the Appellate Body Secretariat no later than 5:30 p.m. on 18 July 2008.
 - (d) An appropriate number of seats will be reserved for delegates of WTO Members in the room where the closed-circuit broadcast will be shown.
 - (e) Notice of the oral hearing will be provided to the general public through the WTO website. WTO delegates and members of the general public wishing to observe the oral hearing will be required to register in advance with the WTO Secretariat.
 - (f) Should practical considerations not allow simultaneous broadcast of the oral hearing, deferred showing of the video recording will be used in the alternative.
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