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CANADA – CONTINUED SUSPENSION OF OBLIGATIONS IN THE EC – HORMONES DISPUTE

Report of the Panel

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Argentina – Footwear (EC)	Appellate Body Report, *Argentina – Safeguard Measures on Imports of Footwear*, WT/DS121/AB/R, adopted 12 January 2000, DSR 2000:I, 515
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Australia – Salmon	Appellate Body Report, *Australia – Measures Affecting Importation of Salmon*, WT/DS18/AB/R, adopted 6 November 1998, DSR 1998:VIII, 3327
Australia – Salmon	Panel Report, *Australia – Measures Affecting Importation of Salmon*, WT/DS18/R and Corr.1, adopted 6 November 1998, as modified by Appellate Body Report, WT/DS18/AB/R, DSR 1998:VIII, 3407
Australia – Salmon (Article 21.5 – Canada)	Panel Report, *Australia – Measures Affecting Importation of Salmon – Recourse to Article 21.5 of the DSU by Canada*, WT/DS18/RW, adopted 20 March 2000, DSR 2000:IV, 2031
Canada – Aircraft (Article 21.5 – Brazil)	Appellate Body Report, *Canada – Measures Affecting the Export of Civilian Aircraft – Recourse by Brazil to Article 21.5 of the DSU*, WT/DS70/AB/RW, adopted 4 August 2000, DSR 2000:IX, 4299
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Canada – Aircraft Credits and Guarantees	Panel Report, *Canada – Export Credits and Loan Guarantees for Regional Aircraft*, WT/DS222/R and Corr.1, adopted 19 February 2002, DSR 2002:III, 849
Canada – Dairy (Article 21.5 – New Zealand and US II)	Appellate Body Report, *Canada – Measures Affecting the Importation of Milk and the Exportation of Dairy Products – Second Recourse to Article 21.5 of the DSU by New Zealand and the United States*, WT/DS103/AB/RW2, WT/DS113/AB/RW2, adopted 17 January 2003, DSR 2003:I, 213
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Canada – Periodicals	Appellate Body Report, *Canada – Certain Measures Concerning Periodicals*, WT/DS31/AB/R, adopted 30 July 1997, DSR 1997:I, 449
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Canada – Wheat Exports and Grain Imports	Appellate Body Report, *Canada – Measures Relating to Exports of Wheat and Treatment of Imported Grain*, WT/DS276/AB/R, adopted 27 September 2004, DSR 2004:VI, 2739
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Chile – Alcoholic Beverages	Appellate Body Report, *Chile – Taxes on Alcoholic Beverages*, WT/DS87/AB/R, WT/DS110/AB/R, adopted 12 January 2000, DSR 2000:I, 281

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EC – Asbestos	Appellate Body Report, *European Communities – Measures Affecting Asbestos and Asbestos-Containing Products*, WT/DS135/AB/R, adopted 5 April 2001, DSR 2001:VII, 3243
EC – Asbestos	Panel Report, *European Communities – Measures Affecting Asbestos and Asbestos-Containing Products*, WT/DS135/R and Add.1, adopted 5 April 2001, as modified by Appellate Body Report, WT/DS135/AB/R, DSR 2001:VIII, 3305
EC – Bananas III	Appellate Body Report, *European Communities – Regime for the Importation, Sale and Distribution of Bananas*, WT/DS27/AB/R, adopted 25 September 1997, DSR 1997:II, 591
EC – Bananas III (Article 21.5 – EC)	Panel Report, *European Communities – Regime for the Importation, Sale and Distribution of Bananas – Recourse to Article 21.5 of the DSU by the European Communities*, WT/DS27/RW/EEC and Corr.1, 12 April 1999, unadopted, DSR 1999:II, 783
EC – Bananas III (US) (Article 22.6 – EC)	Decision by the Arbitrators, *European Communities – Regime for the Importation, Sale and Distribution of Bananas – Recourse to Arbitration by the European Communities under Article 22.6 of the DSU*, WT/DS27/ARB, 9 April 1999, DSR 1999:II, 725
EC – Bed Linen (Article 21.5 – India)	Appellate Body Report, *European Communities – Anti-Dumping Duties on Imports of Cotton-Type Bed Linen from India – Recourse to Article 21.5 of the DSU by India*, WT/DS141/AB/RW, adopted 24 April 2003, DSR 2003:III, 965
EC – Bed Linen (Article 21.5 – India)	Panel Report, *European Communities – Anti-Dumping Duties on Imports of Cotton-Type Bed Linen from India – Recourse to Article 21.5 of the DSU by India*, WT/DS141/RW, adopted 24 April 2003, as modified by Appellate Body Report, WT/DS141/AB/RW, DSR 2003:IV, 1269
EC – Commercial Vessels	Panel Report, *European Communities – Measures Affecting Trade in Commercial Vessels*, WT/DS301/R, adopted 20 June 2005
EC – Hormones	Appellate Body Report, *EC Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998, DSR 1998:I, 135
EC – Hormones (Canada)	Panel Report, *EC Measures Concerning Meat and Meat Products (Hormones), Complaint by Canada*, 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
EC – Hormones (US)	Panel Report, *EC Measures Concerning Meat and Meat Products (Hormones), Complaint by the United States*, 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
EC – Hormones	Award of the Arbitrator, *EC Measures Concerning Meat and Meat Products (Hormones) – Arbitration under Article 21.3(c) of the DSU*, WT/DS26/15, WT/DS48/13, 29 May 1998, DSR 1998:V, 1833

Short Title	Full Case Title and Citation
EC – Hormones (Canada) (Article 22.6 – EC)	Decision by the Arbitrators, *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*, WT/DS48/ARB, 12 July 1999, DSR 1999:III, 1135
EC – Hormones (US) (Article 22.6 – EC)	Decision by the Arbitrators, *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*, WT/DS26/ARB, 12 July 1999, DSR 1999:III, 1105
EC – Tube or Pipe Fittings	Appellate Body Report, *European Communities – Anti-Dumping Duties on Malleable Cast Iron Tube or Pipe Fittings from Brazil*, WT/DS219/AB/R, adopted 18 August 2003, DSR 2003:VI, 2613
EC – Tube or Pipe Fittings	Panel Report, *European Communities – Anti-Dumping Duties on Malleable Cast Iron Tube or Pipe Fittings from Brazil*, WT/DS219/R, adopted 18 August 2003, as modified by Appellate Body Report, WT/DS219/AB/R, DSR 2003:VII, 2701
India – Patents (US)	Appellate Body Report, *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/AB/R, adopted 16 January 1998, DSR 1998:I, 9
India – Patents (US)	Panel Report, *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products, Complaint by the United States*, WT/DS50/R, adopted 16 January 1998, as modified by Appellate Body Report, WT/DS50/AB/R, DSR 1998:I, 41
Japan – Agricultural Products II	Appellate Body Report, *Japan – Measures Affecting Agricultural Products*, WT/DS76/AB/R, adopted 19 March 1999, DSR 1999:I, 277
Japan – Agricultural Products II	Panel Report, *Japan – Measures Affecting Agricultural Products*, WT/DS76/R, adopted 19 March 1999, as modified by Appellate Body Report, WT/DS76/AB/R, DSR 1999:I, 315
Japan – Alcoholic Beverages II	Appellate Body Report, *Japan – Taxes on Alcoholic Beverages*, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, adopted 1 November 1996, DSR 1996:I, 97
Japan – Apples	Appellate Body Report, *Japan – Measures Affecting the Importation of Apples*, WT/DS245/AB/R, adopted 10 December 2003, DSR 2003:IX, 4391
Japan – Apples	Panel Report, *Japan – Measures Affecting the Importation of Apples*, WT/DS245/R, adopted 10 December 2003, upheld by Appellate Body Report, WT/DS245/AB/R, DSR 2003:IX, 4481
Japan – Apples (Article 21.5 – US)	Panel Report, *Japan – Measures Affecting the Importation of Apples – Recourse to Article 21.5 of the DSU by the United States*, WT/DS245/RW, adopted 20 July 2005
Korea – Dairy	Appellate Body Report, *Korea – Definitive Safeguard Measure on Imports of Certain Dairy Products*, WT/DS98/AB/R, adopted 12 January 2000, DSR 2000:I, 3
Korea – Dairy	Panel Report, *Korea – Definitive Safeguard Measure on Imports of Certain Dairy Products*, WT/DS98/R and Corr.1, adopted 12 January 2000, as modified by Appellate Body Report, WT/DS98/AB/R, DSR 2000:I, 49
Korea – Procurement	Panel Report, *Korea – Measures Affecting Government Procurement*, WT/DS163/R, adopted 19 June 2000, DSR 2000:VIII, 3541
US – Carbon Steel	Appellate Body Report, *United States – Countervailing Duties on Certain Corrosion-Resistant Carbon Steel Flat Products from Germany*, WT/DS213/AB/R and Corr.1, adopted 19 December 2002, DSR 2002:IX, 3779

Short Title	Full Case Title and Citation
US – Carbon Steel	Panel Report, *United States – Countervailing Duties on Certain Corrosion-Resistant Carbon Steel Flat Products from Germany*, WT/DS213/R and Corr.1, adopted 19 December 2002, as modified by Appellate Body Report, WT/DS213/AB/R and Corr.1, DSR 2002:IX, 3833
US – Certain EC Products	Appellate Body Report, *United States – Import Measures on Certain Products from the European Communities*, WT/DS165/AB/R, adopted 10 January 2001, DSR 2001:I, 373
US – Certain EC Products	Panel Report, *United States – Import Measures on Certain Products from the European Communities*, WT/DS165/R and Add.1, adopted 10 January 2001, as modified by Appellate Body Report, WT/DS165/AB/R, DSR 2001:II, 413
US – FSC	Appellate Body Report, *United States – Tax Treatment for "Foreign Sales Corporations"*, WT/DS108/AB/R, adopted 20 March 2000, DSR 2000:III, 1619
US – FSC	Panel Report, *United States – Tax Treatment for "Foreign Sales Corporations"*, WT/DS108/R, adopted 20 March 2000, as modified by Appellate Body Report, WT/DS108/AB/R, DSR 2000:IV, 1675
US – Gambling	Appellate Body Report, *United States – Measures Affecting the Cross-Border Supply of Gambling and Betting Services*, WT/DS285/AB/R and Corr.1, adopted 20 April 2005, DSR 2005:XII, 5663
US – Gambling	Panel Report, *United States – Measures Affecting the Cross-Border Supply of Gambling and Betting Services*, WT/DS285/R, adopted 20 April 2005, as modified by Appellate Body Report, WT/DS285/AB/R, DSR 2005:XII, 5797
US – Hot-Rolled Steel	Appellate Body Report, *United States – Anti-Dumping Measures on Certain Hot-Rolled Steel Products from Japan*, WT/DS184/AB/R, adopted 23 August 2001, DSR 2001:X, 4697
US – Hot-Rolled Steel	Panel Report, *United States – Anti-Dumping Measures on Certain Hot-Rolled Steel Products from Japan*, WT/DS184/R, adopted 23 August 2001 modified by Appellate Body Report, WT/DS184/AB/R, DSR 2001:X, 4769
US – Line Pipe	Appellate Body Report, *United States – Definitive Safeguard Measures on Imports of Circular Welded Carbon Quality Line Pipe from Korea*, WT/DS202/AB/R, adopted 8 March 2002, DSR 2002:IV, 1403
US – Line Pipe	Panel Report, *United States – Definitive Safeguard Measures on Imports of Circular Welded Carbon Quality Line Pipe from Korea*, WT/DS202/R, adopted 8 March 2002, as modified by Appellate Body Report, WT/DS202/AB/R, DSR 2002:IV, 1473
US – Offset Act (Byrd Amendment)	Appellate Body Report, *United States – Continued Dumping and Subsidy Offset Act of 2000*, WT/DS217/AB/R, WT/DS234/AB/R, adopted 27 January 2003, DSR 2003:I, 375
US – Offset Act (Byrd Amendment)	Panel Report, *United States – Continued Dumping and Subsidy Offset Act of 2000*, 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
US – Section 211 Appropriations Act	Appellate Body Report, *United States – Section 211 Omnibus Appropriations Act of 1998*, WT/DS176/AB/R, adopted 1 February 2002, DSR 2002:II, 589
US – Section 211 Appropriations Act	Panel Report, *United States – Section 211 Omnibus Appropriations Act of 1998*, WT/DS176/R, adopted 1 February 2002, as modified by Appellate Body Report, WT/DS176/AB/R, DSR 2002:II, 683
US – Section 301 Trade Act	Panel Report, *United States – Sections 301-310 of the Trade Act of 1974*, WT/DS152/R, adopted 27 January 2000, DSR 2000:II, 815

Short Title	Full Case Title and Citation
US – Shrimp	Appellate Body Report, *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, WT/DS58/AB/R, adopted 6 November 1998, DSR 1998:VII, 2755
US – Shrimp	Panel Report, *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, WT/DS58/R and Corr.1, adopted 6 November 1998, as modified by Appellate Body Report, WT/DS58/AB/R, DSR 1998:VII, 2821
US – Softwood Lumber VI	Panel Report, *United States – Investigation of the International Trade Commission in Softwood Lumber from Canada*, WT/DS277/R, adopted 26 April 2004, DSR 2004:VI, 2485
US – Upland Cotton	Appellate Body Report, *United States – Subsidies on Upland Cotton*, WT/DS267/AB/R, adopted 21 March 2005
US – Upland Cotton	Panel Report, *United States – Subsidies on Upland Cotton*, WT/DS267/R, and Corr.1, adopted 21 March 2005, as modified by Appellate Body Report, WT/DS267/AB/R
US – Wool Shirts and Blouses	Appellate Body Report, *United States – Measure Affecting Imports of Woven Wool Shirts and Blouses from India*, WT/DS33/AB/R and Corr.1, adopted 23 May 1997, DSR 1997:I, 323
US – Wool Shirts and Blouses	Panel Report, *United States – Measure Affecting Imports of Woven Wool Shirts and Blouses from India*, WT/DS33/R, adopted 23 May 1997, upheld by Appellate Body Report, WT/DS33/AB/R, DSR 1997:I, 343

I. INTRODUCTION

A. REQUEST FOR CONSULTATIONS AND REQUEST FOR THE ESTABLISHMENT OF A PANEL

1.1 On 8 November 2004, the European Communities requested consultations with Canada pursuant to Article XXII:1 of the General Agreement on Tariffs and Trade 1994 ("GATT 1994") and Article 4 of the Understanding on Rules and Procedures Governing the Settlement of Disputes ("DSU") regarding the Canada's continued suspension of concessions and other obligations under the covered agreements, after the European Communities' adoption of Directive 2003/74/EC on 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. The European Communities has notified this Directive to the DSB and stated that it has fully implemented the recommendations and rulings of the DSB in the dispute *European Communities – Measures Concerning Meat and Meat Products (Hormones)* (*EC – Hormones)*. The consultation request was circulated in document WT/DS321/1 dated 10 November 2004. The consultations were held on 16 December 2004 but the parties failed to reach a mutually satisfactory resolution of the dispute.

1.2 On 14 January 2005, the European Communities requested the establishment of a Panel pursuant to Articles 4.7 and 6 of the DSU, as well as Article XXIII of the GATT 1994.[1]

B. ESTABLISHMENT AND COMPOSITION OF THE PANEL

1.3 At its meeting on 17 February 2005, the DSB established a Panel pursuant to the request of the European Communities in document WT/DS321/6, in accordance with Article 6 of the DSU (WT/DSB/M/183), with standard terms of reference as below:

> "To examine, in the light of the relevant provisions of the covered agreements cited by the European Communities in document WT/DS321/6, the matter referred to the DSB by the European Communities in that document, and to make such findings as will assist the DSB in making the recommendations or in giving the rulings provided for in those agreements."[2]

1.4 On 27 May 2005, the European Communities requested the Director-General to determine the composition of the Panel, pursuant to paragraph 7 of Article 8 of the DSU. On 6 June 2005, the Director-General accordingly composed the Panel as follows:

Chairman: Mr. Tae-yul Cho

Members: Mr. William Ehlers
Ms. Claudia Orozco

1.5 Australia, Brazil, China, India, Mexico, New Zealand, Norway, Chinese Taipei and the United States have reserved their rights to participate in the Panel proceedings as a third party.

C. PANEL PROCEEDINGS

1.6 At the joint request of the parties, and on 1 August 2005, the Panel decided that its meetings at which the parties were invited to appear, would be open for observation by the public through closed-circuit broadcast, provided satisfactory logistical arrangements could be maintained by the Secretariat. The Panel, however, after consulting the third parties, also decided that the session with

[1] WT/DS321/6.
[2] WT/DS321/7.

the third parties would remain closed.[3] The Panel notified the DSB Chairman of this decision on the same day.[4] The Panel held its first joint substantive meeting with the parties to this dispute and the parties to the dispute on *United States – Continued Suspension of Obligations in the EC – Hormones Dispute* (WT/DS320) on 12-15 September 2005. The meeting with the parties was open for public observation through closed-circuit broadcast. It also met with the third parties in a closed special session on 14 September 2005.

1.7 The Panel in this dispute also decided to seek advice from scientific and technical experts after consultation with parties on 20 October 2005.[5] After consulting the parties, it finalized its Working Procedures for Consultations with Scientific and/or Technical Experts on 25 November 2005.[6] It selected six scientific and technical experts in consultation with the parties, sought their advice as well as advice from the Codex Alimentarius Commission (Codex), the Joint FAO/WHO Expert Committee on Food Additives (JECFA), and the International Agency for Research on Cancer (IARC) on scientific and technical questions in writing. The Panel also met with the six experts and four representatives from Codex, JECFA and IARC in the presence of the parties to this dispute and the parties to the dispute on *United States – Continued Suspension of Obligations* (WT/DS320) dispute on 27-28 September 2006. The expert from IARC served both as an individual expert to the Panel and as the representative of the IARC during the meeting. The Panel held its joint second substantive meeting with the parties on 2-3 October 2006. These meetings were also open for public observation through a closed-circuit broadcast.

1.8 On 31 July 2007, the Panel issued its interim report to the parties. On 28 September and 19 October 2007, the Panel received comments from the parties on the interim report. Neither of the parties requested an interim review meeting. On 21 December 2007, the Panel issued its final report to the parties.

II. FACTUAL ASPECTS

A. HISTORY OF THE DISPUTE

2.1 On 13 February 1998, the DSB adopted the Panel and Appellate Body reports in *EC – Hormones*. In doing so, the DSB recommended that the European Communities bring the measures at issue into conformity with WTO rules. The Arbitrator appointed pursuant to Article 21.3(c) of the DSU determined that the European Communities should have a "reasonable period of time" until 13 May 1999 to comply with the recommendations. On 26 July 1999, Canada obtained from the DSB the authorization to suspend obligations up to the level of 11.3 million Canadian Dollars per year. The arbitrators acting pursuant to Article 22.6 of the DSU had previously determined this level to be equivalent to the level of nullification or impairment (Article 22.4 of the DSU) suffered by Canada at the time of its recourse to arbitration in May 1999. On 1 August 1999 and pursuant to the DSB's authorization, Canada introduced import duties in excess of bound rates to imports from the European Communities by imposing a 100% *ad valorem* rate of duty on a list of articles that are the products of certain EC Member States.[7]

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[3] See Annex A-1, Letter to the Parties dated 1 August 2005 on the Panel Decision on Open Hearings for Public Observation. Annex A-2, Working Procedures for the Panel.

[4] WT/DS321/8.

[5] Annex A-3, Letter to the Parties dated 20 October 2005 on the Panel Decision on Consulting Scientific and Technical Experts.

[6] Annex A-4, Letter to the Parties dated 25 November 2005 on the Panel Decision on Certain Issues concerning the Experts' Working Procedures; Annex A-5, Working Procedures for Consultations with Scientific and/or Technical Experts.

[7] The measures were adopted as the "European Union Surtax Order", P.C. 1999-1323, 28 July 1999, published in Canada Gazette Part II, Vol. 133, No. 17, SOR/99-317.

2.2 The original measures in the *EC – Hormones (Canada)* dispute were provided in Directive 96/22/EC, which prohibited the administering to farm animals of substances having a *thyrostatic* action or substances having an *oestrogenic, androgenic,* or *gestagenic* action as well as the placing on market of meat from such animals.[8] On 22 September 2003, the European Communities adopted Directive 2003/74/EC of the European Parliament and of the Council 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. The Directive was published and entered into force on 14 October 2003. It provides for a permanent prohibition on oestradiol-17β and a provisional prohibition on testosterone, progesterone, trenbolone acetate, zeranol and melengestrol acetate.

2.3 Prior to the adoption of the Directive 2003/74/EC, and in order to comply with the recommendations and rulings of the DSB and the covered agreements, the European Communities initiated and funded a number of specific scientific studies and research projects for the purpose of conducting risk assessment(17 in total). The Scientific Committee on Veterinary Measures relating to Public Health (SCVPH), an independent experts committee established under EC legislation, reviewed the results of these studies and other publicly available information as well as the data it collected from various sources including CODEX/JECFA, and published its opinion entitled "Assessment of Potential Risks to Human Health from Hormones Residues in Bovine meat and Meat Products" ("the 1999 SCVPH Opinion") on 30 April 1999. The SCVPH subsequently reviewed this Opinion on two occasions and adopted review reports on 3 May 2000 (" the 2000 SCVPH Opinion") and on 10 April 2002 (the 2002 SCVPH Opinion"). The SCVPH Opinions address six hormonal substances: *oestradiol-17β, testosterone, progesterone, trenbolone acetate, zeranol and melengestrol acetate*.[9]

2.4 In light of these Opinions, which the European Communities contends are risk assessments, the European Communities prohibited the placing on the market of meat and meat products from animals that have been treated with oestradiol-17β for growth promotion purposes on the grounds that there was a substantial body of evidence showing that its residues are both carcinogenic and genotoxic. With respect to testosterone, progesterone, trenbolone acetate, zeranol and melengestrol acetate, the European Communities introduced the same measure on a provisional basis on the grounds that the available pertinent scientific information reflected in the above-mentioned SCVPH Opinions showed the existence of risks, but all the information and data necessary to conduct a more objective and complete risk assessment were insufficient or missing.[10]

2.5 On 27 October 2003, the European Communities notified to the DSB the adoption, publication and entry into force of the Directive. In the same communication, 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 as a consequence, it considers the Canada's suspension of concessions vis-à-vis the European Communities to be no longer justified.[11]

2.6 Canada disagreed in the DSB meeting held on 7 November 2003 that the new Directive was based on science and stated that it would not remove the retaliatory measures vis-à-vis the European Communities.[12]

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[8] WT/DS48/R/CAN, paras. 2.1-2.5.

[9] See, Request for the Establishment of a Panel by the European Communities, WT/DS321/6.

[10] Ibid. S*ee also* the EC's second written submission, para. 134.

[11] *European Communities – Measures Concerning Meat and Meat Products (Hormones)*, Communication from the European Communities, WT/DS26/22, WT/DS48/20, 28 October 2003.

[12] DSB, Minutes of Meeting held on 7 November 2003, WT/DSB/M/157, 18 December 2003, para.31; See also the Request for the Establishment of a Panel by the European Communities, WT/DS321/6.

B. MEASURE AT ISSUE

2.7 The measure challenged by the European Communities is the suspension of concessions and other obligations under the covered agreements, continued without recourse to the procedures under the DSU, after the European Communities' adoption of Directive 2003/74/EC on 22 September 2003 amending Council Directive 96/22/EC concerning the prohibition on the use in stock-farming of certain substances having a hormonal or thyrostatic action and of beta-agonists. The measure is provided in Canada's *European Union Surtax Order* and is enforced as of 1 August 1999. The EC's Directive was published and entered into force on 14 October 2003. The EC stated in its notification to the Dispute Settlement Body (DSB) that it has fully implemented the recommendations and rulings of the DSB in the dispute *European Communities – Measures Concerning Meat and Meat Products (Hormones)* (WT/DS48/AB/R ,WT/DS48/R/CAN).[13]

III. PARTIES' REQUESTS FOR FINDINGS AND RECOMMENDATIONS

3.1 The European Communities requests the Panel to find that Canada's unilateral conduct:

(a) violates Article 23 of the DSU and, more specifically, Article 23.2(a), read in conjunction with Article 21.5 and Article 23.1 of the DSU;

(b) violates Article 23.1 of the DSU read in conjunction with Articles 22.8 and 3.7 of the DSU; and

(c) violates Articles I and II of the GATT 1994.[14]

3.2 In the alternative, should the Panel find no violation of Article 23 of the DSU, the European Communities requests the Panel to find that Canada's measure violates Article 22.8 of the DSU and Articles I and II of the GATT 1994.[15]

3.3 Canada requests the Panel to reject the European Communities' claims and find that Canada has not maintained its suspension of concessions with regard to the European Communities in contravention of Articles 3.7, 21.5, 23.1, 23.2(a) and 22.8 of the DSU, and Articles I and II of the GATT 1994.[16]

IV. ARGUMENTS OF THE PARTIES

A. INTRODUCTION

4.1 The arguments of the parties are set out in their written submissions to the Panel and in their oral statements made during Panel meetings, as well as in their written replies to questions from the Panel. This Section presents a summary of the arguments of parties based on the executive summaries prepared by the parties where such summaries were made available to the Panel.

B. PARTIES' REQUESTS AND ARGUMENTS ON OPENING THE PANEL MEETING FOR THE PUBLIC OBSERVATION

4.2 At the Panel's organizational meeting with the parties on 13 June 2005, the parties requested that the Panel hold open meetings with the parties in this dispute. The Panel posed written questions

[13] WT/DS321/6, WT/DS26/22, WT/DS48/20.
[14] EC's first written submission, para. 150.
[15] EC's first written submission, paras. 24 and 151.
[16] Canada's first written submission, para. 133.

to the parties and the third parties regarding this joint request after its organizational meeting. The parties answered these questions in writing on 20 June 2005 and on 7 July 2005.

1. Arguments of the European Communities

(a) Whether panels are permitted to open hearings under Article 12 (including Appendix 3), Articles 14.1 and 17.10 of the DSU

4.3 The European Communities argues that open hearings are permissible at the panel level. The European Communities submits that Appendix 3, second paragraph, first sentence of the DSU excludes public access to panel hearings, but this rule is not obligatory, as Article 12.1 of the DSU states: "Panels shall follow the Working Procedures in Appendix 3 unless the panel decides otherwise after consulting the parties to the dispute." In the European Communities' view, it is therefore permissible for a panel to adopt, under the procedure of Article 12.1 of the DSU, working procedures that foresee open hearings.

4.4 The European Communities also argues that this conclusion is not affected by Article 14.1 of the DSU. The term "deliberations" under Article 14.1 of the DSU designates the part of the panel's work where it internally discusses the case, including the decision it intends to pronounce in its report and the supporting reasoning. This is the ordinary meaning of this term, in which it is also used in other systems of adjudication, and the French ("délibérations") and Spanish versions ("deliberaciones") fully coincide with this meaning. These deliberations take place in the presence of the Secretariat team working on the dispute, but without the parties. The term "deliberations" does not cover the meetings with the parties, for which different terminology is used in Appendix 3 of the DSU. The context supports this reading because everything that is addressed in the three paragraphs of Article 14 of the DSU relates to the independent work which the panel conducts alone, in the absence of the parties. Had the drafters of the DSU wanted to exclude open panel hearings, they would have used a different language in Article 14.1 of the DSU. They would not have addressed this question solely in the Appendix 3 working procedures from which a panel may depart, as Article 12.1 expressly stipulates.

4.5 In the European Communities' view, this interpretation is also corroborated by the use of the term "proceedings" in Article 17.10 of the DSU which appears to be broader. Meaning must therefore be given to the DSU negotiators' deliberate choice of the term "deliberations" in Article 14.1 of the DSU.

4.6 The European Communities argues that such interpretation is the long-standing position of several Members and has never been rejected by any WTO Member in any dispute. WTO Members have repeatedly stated that the DSU rules on panel procedures are flexible and allow the provision of open hearings (Articles 14.1, 12.1, Appendix 3). Obviously, since a panel is obliged to consult the parties before departing from the working procedures suggested in Appendix 3, the parties' position carries significant weight for the panel's decision. The EC considers that in the present case where all the parties have agreed to open hearings, the Panel should accommodate the parties' request. Article 18.2 of the DSU also provides context and supports this position as it implies that parties are entitled to "waive" the confidentiality of their positions.

(b) Legal implications of open hearings on covered persons under the Rules of Conduct

4.7 The European Communities considers that no legal issues arise under the Rules of Conduct. These Rules state in Section II, paragraph 1 that each covered person "shall respect the confidentiality of proceedings" (see also Section VII, paragraph 1), and also that "[t]hese Rules shall in no way modify the rights and obligations of Members under the DSU nor the rules and procedures therein." In the European Communities view, the Rules of Conduct are and remain fully binding on all covered

persons in this dispute, even if the hearings are opened to the public. Simultaneously, the Rules of Conduct do not prevent the panel from fulfilling its task under the DSU and in accordance with the procedural rules contained therein, which permit public hearings. The Rules of Conduct expressly state that they do not modify these DSU rules.

4.8 The European Communities also considers that Article 18.2 of the DSU again provides context in that it shows that parties are entitled to "waive" the confidentiality of their positions. The Panel's deliberations will in any event not be affected by the opening and remain confidential, as required by Article 14.1 of the DSU.

(c) Systemic and political impact of opening hearings

4.9 The European Communities is of the view that there are no implications for WTO Members who are not parties to this dispute, notably the parties to another dispute remain able to adhere to their preference, if any, not to open the hearings in their dispute. Opening a hearing for observers who will remain completely passive during the session would not change anything about the intergovernmental character of the WTO, nor would it impair the chances to reach a mutually agreed solution, as preferred by the DSU (Article 3.7), if the parties jointly request the hearings to be open, in line with their general policy to apply transparency where the DSU rules allow (for instance by making public their submissions). Also, there are no implications for third parties and accordingly there is no need to consult them before the Panel adopts its working procedures because the parties have jointly requested that the public be excluded from the third parties' session during the presentation by a third party who prefers this. Thus, opening hearings to public observation will not affect third parties beyond the extent to which they themselves agree. The DSU is clear in that the panel must consult the parties, not the third parties, before adopting Working Procedures in departing from Appendix 3.

4.10 The European Communities also states that consulting the DSB and General Council Chairs or the Director-General before opening the hearing for public observation does not seem necessary because under the DSU the Panel has the power to take decisions regarding its Working Procedures and is required to fulfil its task in full independence. If all parties are in agreement on this question of working procedures, the Panel should accommodate their request if the parties consider that this is part of the best way to "secure a positive solution to the dispute", which is the aim of the dispute settlement mechanism (Article 3.7 of the DSU).

(d) What procedures can be adopted to protect confidential information in an open hearing

4.11 The European Communities indicates that it does not expect that confidential information will be submitted in this dispute. Should this nevertheless happen, one could easily apply appropriate means to close the portion of any meeting where confidential information is discussed.

4.12 The European Communities does not consider that there is any issue of confidentiality in relation to information submitted by other Members or non-Members (under Article 13 of the DSU), unless the confidentiality requirement of the last sentence of Article 13.1 of the DSU applies, in which case the corresponding portion of any meeting where this information is discussed could be closed.

4.13 With respect to the third party session, the European Communities considers that each third party should decide whether to open the part of the third party session dealing with that third party's statement.

2. Arguments of Canada

(a) Whether panels are permitted to open hearings under Article 12 (including Appendix 3), Articles 14.1 and 17.10 of the DSU

4.14 Canada argues that the DSU allows for open hearings of WTO panels. Article 14.1 of the DSU states that panel "deliberations" shall be confidential. The reference to "deliberations" indicates that this paragraph applies to the internal deliberations of panels, not to the panels' meetings with the parties. Furthermore, paragraph 2 of the Working Procedures in Appendix 3 of the DSU, which refers to closed panel meetings, is subject to DSU Article 12.1, which specifically allows a panel to deviate from the Working Procedures in Appendix 3 after consulting parties to the dispute. In cases such as this one, where all parties to the dispute have agreed to open hearings, Canada is of the view that the Panel should accommodate such a request. This position is consistent with the right of all parties to waive confidentiality as expressed in Article 18.2 of the DSU, which states that a party is not precluded from disclosing statements of its own positions to the public. In the present case, it is clear that all parties have agreed beforehand to waive their right to confidentiality during the panel hearings.

(b) Legal implications of open hearings on covered persons under the Rules of Conduct

4.15 Canada argues that the relevant provision in the Rules of Conduct is paragraph VII.1, which provides: "[e]ach covered person shall at all times maintain the confidentiality of dispute settlement deliberations and proceedings together with any information identified by a party as confidential. No covered person shall at any time use any information acquired during such deliberations and proceedings to gain personal advantage or advantage for others. "

4.16 This provision, in Canada's view, requires confidentiality on the part of members of a panel of deliberations and proceedings. However, in accordance with paragraph II:1 of the Rules of Conduct, which expressly states that these Rules do not modify the rules and procedures under the DSU, this provision is subject to a decision of the Panel to hold public hearings pursuant to Article 12.1 of the DSU. Therefore, Canada considers that the obligation of covered persons to maintain the confidentiality of a panel proceedings continues to apply but is modified to the extent that the Panel has decided to hold public hearings.

(c) Systemic and political impact of opening hearings

4.17 Canada considers that opening the panel meetings to the public can only contribute to the legitimacy, and perception of legitimacy, of the dispute settlement process. The desire of the disputing parties to hold open hearings in this case does not have any broader systemic or political implications – it merely serves the interests of the disputing parties in this case consistent with the institutional framework of the WTO and with Article 12.1 of the DSU.

4.18 Canada submits that Article 12.1 of the DSU requires that panels decisions on their working procedures be taken in view of consultation with parties. This provision does not require consultation with third parties. However, Canada recognizes that third parties may have requested third party status with the expectation of participating in closed proceedings. Therefore, Canada suggests that after the Panel decides to hold public hearings it should consult with third parties to (a) identify any concerns of third parties regarding their participation in the proceedings, and (b) explore possible steps to accommodate such concerns. Such accommodation measures may include turning off cameras during the delivery of oral statements of third parties that do not wish to deliver such an oral statement in a public hearing. Canada does not see a need for the Panel to consult with the Chairs of the DSB, of the General Council or of the DSB Special Sessions, or with the Director General.

(d) What procedures can be adopted to protect confidential information in an open hearing

4.19 Canada believe that a provision should be added to the Working Procedures that would provide a mechanism to protect business-confidential information that may become the subject of discussion during the public hearings. Canada recommends a procedure under which a party may request the Panel to suspend the public nature of the hearing for as long as such business-confidential information was being discussed.

4.20 As to the third parties, Canada submits that they will have to follow the provisions in the Working Procedures adopted by the Panel pursuant to DSU Article 12. Thus it is open to the Panel to decide that the oral statements by third parties will take place in public meeting. However, it is also within the Panel's discretion to leave it to the choice of individual third parties whether they wish to make their oral statements in a private or public session. Canada prefers giving third parties such a choice. Canada recommends the adoption of a practical procedural mechanism to suspend the public nature of the hearing as necessary.

4.21 The treatment of written materials presented by other WTO Members or by non-Members falls outside the scope of issues raised by the possible public nature of the hearing. None of the parties has proposed a modification to the Working Procedures that would expand the categories of participants in the hearing. Nevertheless, Canada recognizes that the written evidence provided by other WTO Members or non-Members may have been provided in confidence. To the extent that such confidential information is discussed during the hearings, there will be need to add to the Working Procedures a provision that would permit the Panel to interrupt the public nature of the hearing before a discussion of such confidential written materials takes place. In Canada's view, such a procedure should be similar to that outlined above in respect of business-confidential information.

C. FIRST WRITTEN SUBMISSION OF THE EUROPEAN COMMUNITIES

1. Introduction

4.22 This case is about procedural obligations under the DSU of Members that continue to apply the suspension of concessions or other obligations after almost two years despite the proper notification by the responding party that it has adopted the necessary measures to implement the DSB recommendations and rulings. In the alternative, the European Communities makes conditional substantive claims under Article 22.8 of the DSU and Articles I:1 and II of the GATT 1994.

2. Factual aspects

4.23 Following an authorization by the DSB, Canada suspended tariff concessions and other related obligations up to the level of Canadian $ 11.3 million. Subsequently, the European Communities implemented the original DSB recommendations and rulings by Council Directive 2003/74/EC. However, Canada continues to suspend concessions and related obligations against certain products originating in the European Communities based on a unilateral determination that the EC's implementation measure is insufficient to comply with the DSB recommendations and rulings.

3. Legal arguments: Part I – Violation of Articles 23, 21.5, 22.8 and 3.7 of the DSU and Articles I and II of the GATT 1994

(a) The structure of Article 23 of the DSU

4.24 Article 23 of the DSU lays down the fundamental principle that the dispute settlement system of the WTO is the exclusive means to redress any violation of any provision of the WTO Agreement.

Any attempt to seek "redress" can take place only in the institutional framework of the WTO and pursuant to the rules and procedures of the DSU. This has been confirmed in *US – Section 301 Trade Act* and *US – Certain EC Products.*

4.25 Article 23.1 of the DSU contains a general obligation to follow the rules and procedures of the DSU whereas Article 23.2 of the DSU lists a number of "specific and clearly-defined forms of prohibited unilateral action." The relationship between the two paragraphs has two distinguishing features. First, Article 23.2 of the DSU has to be read in the context of the first Paragraph ("in such cases"), that is, it has to be established that the Member's action is performed with a view to redressing a WTO violation. Second, the specific forms described in Paragraph 2 do not exhaust the list of prohibited unilateral action. There is a relationship of *lex specialis* and *lex generalis* which implies, on the one hand, that whenever there is a violation of a specific case in Paragraph 2 of Article 23, there always is also a violation of Paragraph 1 of that provision; and on the other hand, that a particular conduct that may not come under the specific cases listed in paragraph 2 of Article 23, may still constitute a violation under paragraph 1 of that provision.

(b) Applicability of Article 23 – Article 23.1 of the DSU: Seeking the redress of a WTO Violation

4.26 The meaning of "seeking the redress of a violation" under Article 23.1 of the DSU has been extensively discussed by previous panels, i.e. *US – Section 301 Trade Act* and *US – Certain EC Products*. The "violation" with regard to which redress is sought need not be one that has been identified as such by the relevant WTO bodies. It suffices if it is perceived as being one by the Member in question. The suspension of concessions or other obligations is a means of "redress." Indeed it is the very means the WTO system envisages as a last resort remedy to WTO violations according to Articles 3.7 and 22.1 of the DSU.

4.27 It is obvious that when it suspended concessions in August 1999, Canada was seeking to redress a (WTO-determined) violation. Back then, Canada reacted to the European Communities' failure to implement, within the reasonable period of time, the DSB recommendations in the *EC – Hormones* case. It requested and obtained a DSB authorization under Article 22.2 (respectively 22.7) of the DSU, following which Canada decided on the imposition of 100% additional duties. Canada's way of proceeding back then is the very example of "seeking to redress a WTO violation" in line with the rules and procedures of the DSU.

4.28 There can equally be no doubt that, if Canada is continuing the suspension of concessions to this day despite the European Communities' adoption of an implementation measure, it does so because it still is seeking to redress a WTO violation. This can already be deduced from the fact that the August 1999 measure of applying duties in excess of bound rates is being continued without there being any modification to it. Since that measure is motivated to be imposed as "a result of the EC's failure to implement the recommendations and rulings of the WTO," and since Canada has neither abolished nor changed the measure, nor modified its reason, Canada is obviously of the view that the EC's failure to implement the recommendations and rulings of the WTO still persists. Indeed, the continuation of the suspension of concessions is an unequivocal indication that Canada believes that there continues to be a violation. Otherwise it would have ended the suspension of concessions in accordance with its obligations under Article 22.8 of the DSU. Moreover, this is the explicit view Canada has formally taken in the DSB and in various official statements.

(c) Violation of Articles 23.2(a) and 21.5 and of Article 23.1 of the DSU

4.29 Canada's conduct is contrary to the specific prohibition of unilateral conduct set out in Article 23.2(a) of the DSU. Instead of seeking redress of the perceived continued failure of the European Communities to implement the DSB's recommendations and rulings through the continued

suspension of concessions, Canada should have introduced a compliance procedure under Article 21.5 of the DSU. Because it has not done so, it has violated the specific prohibition of unilateral conduct set out in Article 23.2(a) of the DSU. This violation of Article 23.2(a) and 21.5 constitutes at the same time a violation of Article 23.1 of the DSU.

4.30 As the Panel in *US – Section 301 Trade Act* has noted, the following conditions need to be fulfilled in order to find a violation of Article 23.2(a) of the DSU. First, given the "chapeau" of Article 23.2, it needs to be established that there is "such a case", namely that a Member is seeking to redress a WTO violation. This is the case here.

4.31 Second, Article 23.2(a) of the DSU requires that a Member has made a "determination to the effect that a WTO violation has occurred." The ordinary meaning of the term "determination," has been noted by the Panels in *US – Section 301 Trade Act* and *US – Certain EC Products.* Such a decision need not have a specific form, and can be inferred from action. The suspension of concessions or other obligations is the very means (albeit of last resort) to react to a violation and therefore necessarily implies a decision that there is a violation. That such a decision bears consequences in WTO trade relations hardly requires any explanation. The present case is similar to the situation in *US – Certain EC Products*. Again, the action in question is the suspension of concessions and related obligations. In contrast to the above case, nevertheless, the suspension here had initially been authorized by the DSB based on a multilateral determination that there was a violation. This multilateral determination, however, was made with respect to the measures applied by the European Communities at the time. Logically, it could not and did not apply to the measures subsequently adopted and properly notified to the WTO by the European Communities. With regard to the current legislative situation in the European Communities, no multilateral determination has been made by the time at which this Panel was established. If Canada nevertheless continues to apply the suspension of concessions and related obligations, it necessarily implies that it has unilaterally determined that there continues to be a violation. It has, in addition, explicitly said so.

4.32 Third, Article 23.2(a) of the DSU is violated if the determination is not made in accordance with the rules and procedures of the DSU, or is not consistent with the findings of a dispute settlement organ. The DSU provides for a specific procedure, namely Article 21.5 of the DSU, to address the situation that Members disagree over the existence or consistency of measures taken to comply with the recommendations and rulings of the DSB.

4.33 There exists obviously a disagreement as to whether or not, by adopting Directive 2003/74/EC, the European Communities has implemented the recommendations and rulings from the DSB in the *EC – Hormones* case. Article 21.5 of the DSU requires that disagreement *shall* be decided through recourse to dispute settlement. The European Communities has invited several times Canada, but, to date, it refuses to initiate a compliance procedure under Article 21.5 (or, for that matter, any other dispute settlement procedure under the DSU). Instead, it simply continues to apply the suspension of concessions and related obligations as if no "measure to comply" had been taken or the non-compliance of the new directive of the European Communities had already been established.

4.34 As the determination in the present case has been made *before* the commencement, let alone the exhaustion of the Article 21.5 procedure, it is necessarily not one that has been made consistent with the findings contained in an adopted panel or Appellate Body report.

(d) Canada's continued suspension of concessions and related obligations is in violation of Article 23.1, read together with Articles 22.8 and 3.7 of the DSU

4.35 Under Article 23.1 of the DSU, Canada is obliged to have recourse to, and abide by, the rules and procedures of this Understanding. This encompasses, *inter alia*, Articles 22.8 and 3.7 of the DSU. In this respect, the following should be noted.

4.36 The suspension of concessions or other obligations is limited in time. This temporal limitation is the very foundation of the retaliation system under the DSU. The importance of this principle is already demonstrated by the fact that the "temporary nature" of countermeasures appears contextually at two places in Article 22 of the DSU, in Paragraph 8 and in Paragraph 1. The temporal limitation is a practical consequence of the fact that suspension of concessions should only be applied as "a last resort", Article 3.7 of the DSU. This means that the suspension of concessions should only apply where justified and necessary.

4.37 The temporary nature of the suspension of concessions or other obligations has been recurrently interpreted by arbitrators to indicate that one of the main objects and purposes of sanctions is to induce compliance by the violating WTO member with its obligations. Indeed, in reaching this conclusion the arbitrators followed a suggestion by Canada (see *EC – Bananas III (US) (Article 22.6 – EC)*). The objective of inducing compliance entails, however, that once a Member has adopted compliance measures which are not properly challenged by the complaining Member, the suspension of concessions or other obligations can not be applied any longer. Indeed, in such a scenario the suspension of concessions or other obligations would be deprived of one of its main objectives, i.e. to achieve implementation of a DSB decision, for the simple reason that the WTO Member has already taken measures to implement the DSB recommendation. In this case, the objective to induce compliance can only revive after it has been properly established that the implementing measure has been insufficient to remedy a WTO violation.

4.38 Article 22.8 of the DSU prohibits the continued unilateral application of the suspension of concessions or other obligations when the measure which has been found inconsistent is removed. The term "removed" thereby refers to the compliance by a WTO Member because this provision is based on the respect of the WTO obligations by the Member concerned (see Article XVI:4 of the WTO Agreement and Article 19.1 of the DSU). The scope of the compliance obligation is determined by the DSB recommendations and rulings following the adoption of the Panel and/or Appellate Body report (Articles 21.5, 22.2 of the DSU).

4.39 Article 22.8 of the DSU does not specify how the removal of the WTO inconsistency is determined. However, in the light of its context, i.e. Articles 21.5 and 23.2(a) of the DSU, and given the exceptional nature of countermeasures, i.e. their temporal limitation, it is clear that a Member can not unilaterally determine that the WTO inconsistency persists despite the notification of a compliance measure. In very much the same vein, a Member can not decide to continue to suspend concessions or other obligations unilaterally. The WTO inconsistency of the implementing measure can only be determined in accordance with the appropriate procedure, namely Article 21.5 of the DSU. Unless such a procedure concludes that the compliance measure does not fully implement the DSB recommendations and rulings, it cannot be presumed that this is the case.

4.40 This also follows from the general principle of good faith as it applies in international State relations, under which States are normally considered to act in conformity with their obligations. This principle has been widely confirmed in the international (trade) jurisprudence (see ICJ *Corfu Channel*, *EC – Hormones (Article 22.6)*, *Chile – Alcoholic Beverages*, *Canada – Aircraft (Article 21.5 – Brazil)* and it also applies for implementing measures (*Canada – Dairy (Article 21.5 – New Zealand and US II), EC – Bed Linen (Article 21.5 –India))*.

4.41 Therefore, it is clear that Canada could not unilaterally determine that the European Communities implemented the DSB recommendations and rulings in a WTO inconsistent way. To the contrary, the European Communities must be presumed to have complied with its WTO obligations, if Canada refuses to establish the contrary.

4.42 Once the inconsistency of the measure has been removed, Article 22.8 of the DSU provides that "the suspension of concessions or other obligations shall be temporary and shall only be applied

until such time as the measure found to be inconsistent with a covered agreement has been removed." This provision is mandatory. It does not leave any margin of discretion to the retaliating Member, thereby corroborating the exceptional nature of the imposition of countermeasures. As explained above, a Member which contests the removal of the inconsistency of the measure has to abide by the rules and procedures under the DSU, i.e. Article 21.5 of the DSU. Only if it is established in such a procedure that the WTO inconsistency persists is the application of the suspension of concessions or other obligations permissible under Article 22.8 of the DSU.

4.43 Under the same logic, Article 22.8 of the DSU does not allow for the application of countermeasures on the basis of a *unilateral* determination regarding the WTO inconsistency of the measure. Rather, Article 22.8 of the DSU, read in its context with Articles 21.5 and 23.2(a) of the DSU, requires that in the absence of an adverse finding, the suspension of concessions or other obligations shall not "be applied" any longer. This language is open in, at least, three directions:

4.44 Firstly, it indicates that the suspension of concessions or other obligations must be terminated in case a compliance measure is not challenged, the measure thus being accepted as being in full accordance with the WTO agreements.

4.45 Secondly, Article 22.8 of the DSU shows that the suspension of concessions or other obligations must not be applied any longer if the complaining Member delays, postpones or refuses the initiation of an Article 21.5 proceeding. As a WTO Member is presumed to act in conformity with its obligations, it follows necessarily that through the compliance measure it is presumed to have removed the WTO inconsistency of the measure at least when the following three conditions are fulfilled: (1) the Member has followed its internal decision-making procedures that are normally applied for the purpose of adopting compliance measures of that kind; (2) the elaboration, deliberation and adoption of the compliance measure is done in an open and transparent manner, and (3) the compliance measure is notified properly to the WTO. Therefore, the suspension of concessions or other obligations should not apply any longer. This case is particularly relevant in the present dispute where Canada has been refusing for almost two years to initiate the compliance procedure under Article 21.5 and to cease the suspension of concessions and related obligations against the European Communities. Thus, Canada continues the suspension of concessions and related obligations on the basis of a unilateral determination regarding the WTO-inconsistency of the notified compliance measure.

4.46 In the light of the two first conclusions, it would also be appropriate to infer from Article 22.8 read together with Article 23.1 of the DSU that the suspension of concessions or other obligations should not continue to be applied until the WTO inconsistency of the properly notified measure has been positively determined by the DSB.

4.47 This result is also corroborated by the system and overall thrust of Article 23 of the DSU, which is to strengthen the multilateral system. If a WTO Member were allowed to continue the application of suspension of concessions without challenging the implementing measure, it would necessarily have to base its assessment on a unilateral determination of the WTO inconsistency of the new measure. This would be in plain contradiction to Article 23.2(a), in conjunction with Article 21.5 of the DSU, as explained above.

4.48 The scenario described above follows the same *ratio legis* that applies for the initial imposition of suspension of concessions or other obligations. Thus, whether a Member suspends for the first time concessions or other obligations or wishes to maintain the suspension despite an implementation act does not make a difference. In both cases, a Member must not substitute unilaterally its assessment of a WTO inconsistency of an implementation measure to the procedures under the DSU.

4.49 In the case of the initial imposition of suspension of concessions or other obligations, the DSU implies first a determination that the Member concerned has not implemented the DSB recommendations and rulings. The DSB would not authorize the suspension of concessions or other obligations, if a WTO Member has taken implementing measures. It is established practice that the Member which intends to suspend concessions or other obligations first obtains a DSB decision regarding the insufficiency of the implementing measure following an Article 21.5 of the DSU proceeding. This normal course of events and legal steps in the case of the imposition of suspension of concessions or other obligations is in full accordance with the overarching principle set out in Article 23 of the DSU prohibiting Members from making unilateral determinations that another Member has violated its obligations.

4.50 Regarding the question of the conditions under which the suspension of concessions or other obligations could be *maintained,* there is no reason to assume that this fundamental logic should change in any way whatsoever. In fact, the legal situation is identical where the implementing Member has taken the necessary measures to comply with its WTO obligations in accordance with its internal rules and procedures and notified the measures in question to the WTO.

4.51 This comparability is even more striking if one focuses on the timing of an implementation measure. In the case of the initial *imposition* of the suspension of concessions or other obligations, a WTO Member has not implemented its obligations *before* the DSB's authorization to suspend concessions or other obligations. In the case of the *maintenance* of suspension of concessions or other obligations, a WTO Member implements its obligations *after* the DSB's authorization to suspend concessions or other obligations. This difference in timing, however, does not alter the normal legal sequencing between the multilateral review of the compliance measure and the application of suspension of concessions or other obligations. Indeed, the sole difference in timing does not give the retaliating Member all of a sudden the substantive right to make *unilateral* decisions as to whether or not the implementing measure is appropriate and sufficient and, if it is not considered sufficient, to continue applying the countermeasures as if nothing had happened.

4.52 In light of the above, there is an absolute need to refrain from continuing to apply the suspension of concessions or other obligations in cases where the retaliating Member has not properly challenged the compliance measure in an Article 21.5 proceeding. In fact, if a Member were allowed to maintain the suspension of concessions or other obligations even in such a new legal situation, it could make the kind of unilateral determinations which Article 23 specifically outlaws. Also, it could continue to apply the suspension of concessions or other obligations even if the WTO violation has been objectively removed. The implementing Member would then have to suffer from the suspension of concessions or other obligations even though it has fully abided by its obligations. It goes without saying that such a result would be in plain contradiction to the DSU provisions governing the suspension of concessions or other obligations, in particular Articles 3.7 and 22.

4.53 These fundamental principles are not altered by the fact that there exists a DSB authorization under Article 22.7 of the DSU to suspend concessions or other obligations. The DSB authorization cannot change the fundamental rules under the DSU. Rather, the DSB implements these rules. Thus, as the DSU provides that the suspension of concessions or other obligations should not be applied unless a WTO violation by a Member's measure has been properly established, the DSB authorization cannot be interpreted to justify such a suspension if a WTO violation of a Member's (new) measures has not been properly determined.

4.54 The basis for a DSB authorization to suspend concessions or other obligations is a prior *multilateral* determination that the implementing WTO Member has failed to comply with its obligations. This is the case if an Article 21.5 proceeding concludes that the implementing measure was insufficient. This is also implicitly the case if a Member has not adopted any implementing measure at all at the time of the DSB decision under Article 22.7 of the DSU. On the contrary, if a

WTO Member implements properly its obligations after the DSB has authorized the suspension of concessions or other obligations the basis for this decision changes fundamentally. As the original DSB authorization was taken in view of the original measure, it cannot logically encompass the new implementing measure. Hence, the DSB authorization cannot cover the continued application of the suspension of concessions or other obligations, if a WTO Member subsequently implements its obligations in the absence of a multilateral review regarding the compliance (or not) of this new measure.

4.55 Regarding this DSB authorization it is once again useful to compare the two situations of the *imposition* and the *maintenance* of the suspension of concessions or other obligations. The DSB could not authorize the imposition of retaliatory measures under Article 22.7 of the DSU, if the implementing Member had undertaken measures to comply with its obligations and if those had not been found WTO inconsistent following an Article 21.5 proceeding. In the very same vein, the DSB authorization cannot justify the maintenance of suspension of concessions or other obligations if a Member properly complies with its obligations after the imposition of these measures and if its compliance measure is not challenged in an Article 21.5 proceeding. Again, the mere temporal difference of the new implementing measure does not mean that the DSB authorization, once received, serves as a blank authorization for a Member to continue the application of the suspension of concessions or other obligations indefinitely in the future and on the basis of unilateral determinations.

4.56 Furthermore, the European Communities would note that, from a systemic point of view, Article 22.8 of the DSU is subsequent to Article 22.7 of the DSU. This indicates that once the situation under Paragraph 8 occurs it overtakes the authorization granted under Paragraph 7. Paragraph 8 conditions Paragraph 7. As it must be assumed that the DSU negotiators followed a logical sequencing in the way they drafted Article 22, it is clear that Article 22.8 of the DSU was supposed to impact on the authorization under Article 22.7 of the DSU. Indeed, to assume that the removal of the inconsistency of the measure under Paragraph 8 has no impact on the DSB authorization under Paragraph 7 is not legally coherent or reasonable.

4.57 Moreover, this reading of the DSB authorization is corroborated if one takes a closer look at the substance of this authorization. The level of nullification or impairment has to be determined in relation to the violation determined for the existing measure (Article 3.8 of the DSU). Thus, assuming that a WTO Member has not undertaken any implementation steps, the level of nullification should be determined in relation to the original violation. But assuming, in a second scenario, that a Member has implemented partly or fully its WTO obligations, the level of nullification or impairment would have to be determined accordingly. Obviously, in the area where the Member implemented properly its obligations there would be no nullification or impairment. This logic had also been recognized by the arbitrators in *EC – Bananas III (US) (Article 22.6 – EC).*

4.58 Applying the same reasoning in the present case, it is clear that the level of suspension of concessions or other obligations as authorized by the DSB was based on a non-implementation by the European Communities. However, this level and, therefore, the scope of the authorization may not be justified any longer once the European Communities has properly implemented its obligations.

4.59 Finally, following the jurisprudence by the Appellate Body, once a Member violates Article 23.1 read in conjunction with Article 22.8 of the DSU, it necessarily also acts contrary to Article 3.7 of the DSU.

(e) Canada is in violation of Article I:1 of the GATT1994 because of the continued suspension of concessions and related obligations

4.60 Canada is acting inconsistently with Article I:1 of the GATT 1994 by imposing import duties in excess of bound rates on products originating in certain EC Member States.

(f) Canada is acting inconsistently with Article II of the GATT 1994 by the continued application of countermeasures on products originating in the European Communities.

4.61 Canada is violating its obligations under Article II:1(a) and Article II:1(b) of the GATT by suspending concessions and related obligations against the European Communities.

4. Legal arguments: Part II – Conditional claim in the event that the Panel does not find any violation of Article 23 of the DSU as set out in Part I

(a) Canada is violating Article 22.8 of the DSU because the measure found to be inconsistent has been removed by the European Communities

4.62 Canada is violating Article 22.8 of the DSU by continuing to suspend concessions and related obligations even though the measure found to be inconsistent has been removed. Consequently, Canada is under an obligation not to apply the suspension of concessions any longer. In the following, the European Communities will set out in more detail why the new measure is not only in presumed compliance as argued above but in actual compliance with the recommendations and rulings of the DSB.

4.63 The rulings of both the Panel and the Appellate Body had essentially turned on the reading of Article 5.1 of the *SPS Agreement*, and in particular, the requirement that a measure be based on a risk assessment. The Appellate Body upheld the Panel's finding that the EC measures at issue were inconsistent with the requirements of Article 5.1 of the *SPS Agreement*. At the same time, the report contains an important clarification as to how the European Communities could bring its regime for hormones-treated meat in accordance with its obligations under the covered agreements. As seen above in relation to Part I, the Appellate Body held "that Article 5.1, read in conjunction with Article 2.2, requires that the results of the risk assessment must sufficiently warrant the SPS measure at stake."

4.64 On the basis of the scientific data presented by the European Communities, the Appellate Body found that that data did not sufficiently warrant or reasonably support the import prohibition. The Appellate Body found, in particular, that the scientific reports and studies submitted by the European Communities did not rationally support the EC import prohibition or were too general, i.e. relevant but not sufficiently specific to the case. It is important to understand, therefore, that the Appellate Body did not find that an import prohibition for beef from hormone treated cattle was *per se* in violation of the *SPS Agreement.* Rather it found that the EC import prohibition was not sufficiently warranted, that is to say reasonably supported, by the specific risk assessment relied upon at that time by the European Communities.

4.65 In order to comply with the above findings the European Communities conducted a comprehensive risk assessment. The risk assessment focussed on potential risks to human health from hormone residues in bovine meat and meat products, in particular such risks arising from residues of the six hormonal substances (oestradiol-17β, testosterone, progesterone, trenbolone acetate, zeranol and melengestrol acetate). In carrying out the risk assessment, the European Communities initiated and during 1998-1999 funded altogether 17 specific scientific studies and research projects in order to obtain as much as possible of the missing scientific information as identified in the above rulings. Moreover, the European Communities addressed in 1998 specific requests for the submission of

scientific data to the United States, Canada, Australia and New Zealand which all authorize the use of these six hormones for animal growth promotion. It also published an open call for documentation requesting any interested party, including the industry, to provide any relevant and recent scientific data and information in their possession to be taken into account in the complementary risk assessment.

4.66 The data collected was submitted to the *Scientific Committee on Veterinary Measures relating to Public Health* (SCVPH), an independent expert Committee established under EC legislation to evaluate this kind of substances on the EC legal system. This scientific body was the one responsible for scientific and technical questions concerning consumer health and food safety related to production, processing and supply of food of animal origin. The SCVPH reviewed all the old and new data and issued its opinion on 30 April 1999, which it reviewed and confirmed again in 2000 and once more in 2002 on the basis of additional and new information submitted subsequently.

4.67 Based on this comprehensive risk assessment, the European Communities adopted Directive 2003/74/EC. In accordance with the above scientific conclusions the Directive provides for a definite import prohibition on meat and meat products from animals treated for growth promotion purposes with oestradiol-17β. Furthermore, on the basis of the available but still incomplete data, the Directive provides for a provisional ban on meat and meat products from animals treated for growth promotion purposes with testosterone, progesterone, trenbolone acetate, zeranol and melengestrol acetate. The Directive provides for an obligation on the Commission to seek more complete scientific information from any source which could shed light and clarify gaps in the present state of knowledge on these substances.

4.68 Article 22.8 of the DSU obliges Canada to cease applying the suspension of concessions, once an inconsistent measure has been removed. However, even though the inconsistent measure has been removed, Canada continues to apply the suspension of concessions. Canada, therefore, is in violation of Article 22.8 of the DSU.

(b) Canada is in violation of Articles I and II of the GATT 1994 following the continued application of suspension of Concessions

4.69 The illegal continued suspension of concessions and related obligations automatically entails a violation of Articles I and II of the GATT 1994. This has been explained above to which the European Communities would refer to.

D. FIRST WRITTEN SUBMISSION OF CANADA

1. Introduction

4.70 This case involves three issues. First, it is about whether the DSB authorization permitting Canada to suspend concessions with respect to the EC – in response to the EC's failure to comply with the recommendations and rulings of the DSB in the *EC – Hormones* dispute – remains in effect. Second, it is about whether the EC bears the burden of demonstrating that it has complied with those recommendations and rulings in order to have the DSB authorization terminated. And third, it is about whether the EC has actually complied with those recommendations and rulings. The first two issues must be answered in the affirmative; the third issue must be answered in the negative.

2. Background to the dispute

4.71 The EC has had in place since the 1980s a ban on the importation of meat and meat products derived from cattle treated with any of six growth-promoting hormones. In the *EC – Hormones* dispute, the DSB ruled that EC legislation implementing the ban (*i.e.* Directive 96/22/EC) was not

based on a risk assessment as required by the *SPS Agreement*. The DSB, in February 1998, recommended that the EC bring its measure into compliance and was subsequently granted fifteen months to do so. The EC failed to comply within that time and as a result the DSB, in July 1999, authorized Canada to suspend concessions to the EC to the amount of Can$11.3 million. On the basis of that authorization, Canada adopted the *European Union Surtax Order*, a measure which remains unchanged and in force to this day.

4.72 After having been found non-compliant in the *EC – Hormones* dispute, the EC commissioned a series of scientific studies and mandated the SCVPH to review these studies along with other available scientific evidence. The SCVPH produced three opinions, in which it concluded that a "risk to the consumer has been identified with different levels of conclusive evidence for the 6 hormones in question." The opinions concluded that oestradiol-17β is a "complete carcinogen", that the current state of knowledge does not allow a quantitative estimate of the risk for the other five hormones, and that no ADI could be established for any of the six hormones.

4.73 On the basis of the three SCVPH opinions, the EC adopted Directive 2003/74/EC in September 2003. This Directive simply amended Directive 96/22/EC by making the ban on oestradiol-17β permanent, on the ground that it was now based on a risk assessment, and by making the ban on the other five substances provisional, on the ground that there was insufficient information to complete a proper risk assessment.

4.74 Upon notifying its amended Directive to the DSB, the EC stated that it considered itself in compliance with the recommendations and rulings in the *EC – Hormones* dispute and, as a result, Canada's suspension of concessions was no longer justified. Canada responded that it was for the EC to obtain multilateral confirmation of its claim of compliance, and explained that Canada's continued suspension of concessions was pursuant to the original and continuing DSB authorization. Canada further questioned how the EC's notification to the DSB of its unilateral assertion of compliance could terminate Canada's multilateral authorization.

4.75 The EC did not initiate WTO compliance proceeding or otherwise seek confirmation from the DSB of the compliance of its measure. Instead, it requested the establishment of this Panel, alleging that it was Canada's continued suspension of concessions that was inconsistent with Articles I and II of GATT 1994 and Articles 23.1, 23.2(a) and (c), 3.7, 22.8 and 21.5 of the DSU.

3. Legal arguments

4.76 This dispute concerns the respective rights and obligations under the DSU of the EC and Canada in the context of Canada's adoption of WTO-authorized suspension of concessions to the EC. This dispute also concerns the obligations of the EC under the *SPS Agreement*, in particular, whether the EC has actually complied with the recommendations and rulings of the DSB in the *EC – Hormones* disputes.

(a) Canada has not acted inconsistently with Articles 22.8 and 3.7 of the DSU

4.77 In alleging that Canada has acted inconsistently with Articles 22.8 and 3.7 of the DSU, the EC fails to acknowledge that: 1) the DSB authorization permitting Canada to suspend concessions remains in effect; 2) it is the EC, and not Canada, that now bears the burden of demonstrating that its measure now complies; and 3) the EC measure does not benefit from a presumption of compliance in these circumstances.

(i) The DSB authorization remains in effect

4.78 The EC's claim that its unilateral assertion of its own compliance has resulted in the automatic termination of Canada's authorization to suspend concessions must fail. That authorization remains unchanged and in effect to this day. The EC remains subject to an ongoing obligation to comply with its WTO obligations. Moreover, the *EC – Hormones* dispute has remained at all times under the surveillance of the DSB, including the EC's obligation to comply as well as the suspension of concessions by Canada that was authorized to induce this compliance.

4.79 Canada's measure is therefore by definition WTO consistent and only the DSB can terminate the authorization of that measure. Any mechanism for terminating the authorization that is not under the authority and surveillance of the DSB undermines the ability of the dispute settlement system to achieve one of its central objectives, that of ensuring the security and predictability of the multilateral trading system.

(ii) The EC bears the burden of demonstrating its compliance

4.80 It is the EC, and not Canada, that bears the burden of demonstrating that it has complied with the recommendations and rulings of the DSB. As explicitly recognized by the panel in *US – Certain EC Products*, this proposition flows from the general rules on burden of proof. That is, since it is the EC that seeks to have Canada's authorized and WTO-consistent measure "de-authorized", it is the EC that bears the burden of demonstrating that the measure should no longer be authorized on the basis of the actual compliance of its own measure.

4.81 It is therefore incumbent upon the EC to avail itself of the avenues available to it under the DSU to demonstrate that it has complied with the recommendations and rulings of the DSB, with a view to having the DSB authorization revoked. The EC may have recourse to proceedings initiated under Article 21.5 or it may initiate new proceedings in which it requests the Panel to deliver findings on the actual compliance of the EC measure. Under either scenario, Canada's continued suspension of concessions remains WTO-authorized, WTO-consistent and unchallengeable until such time as the EC successfully demonstrates the compliance of its own measure, and consequently the DSB terminates the authorization concerned.

(iii) The EC measure does not benefit from a presumption of compliance

4.82 Relying upon an unfounded assertion that its measure benefits from a presumption of compliance, the EC claims that it has satisfied the first condition of Article 22.8 of the DSU by "removing" its measure. As a result, according to the EC, the temporary period provided for in Article 22.8 has passed and Canada's DSB authorization has been automatically terminated. Canada does not challenge the existence and correctness of a presumption of good faith in many circumstances, nor does it disagree that authorized suspension of concessions is meant to be temporary. However, neither of these principles is relevant in the circumstances of this dispute.

4.83 Underlying this dispute is neither an EC measure taken as part of its day-to-day business of governing, nor one that the EC has taken to comply prior to the adoption of DSB authorization to suspend concessions. Rather, this dispute concerns the failure of the EC to correct a measure that had been found by the DSB to be inconsistent with the EC's WTO obligations, and as a result the DSB authorized Canada to suspend concessions. The existence of DSB authorization, and the adoption by Canada of a measure based on that authorization, distinguishes this case from those situations in which a presumption of compliance might apply to the EC measure.

4.84 The DSU does not explicitly address how a DSB authorization of suspension of concessions, once granted, is to be terminated. What is clear is that the EC's unilateral claim of compliance cannot,

in itself, terminate that authorization. Any presumed compliance the EC measure might enjoy prior to the adoption of the DSB authorization must yield to the actual compliance of Canada's WTO–authorized measure. Any other interpretation of the DSU would undermine the objective of the dispute settlement system to ensure the security and predictability of the multilateral trading system.

4.85 If the EC's claims were to be accepted, both meritorious and purely illusory claims of compliance would result in the immediate termination of the suspension of concessions, even if the assertions of compliance were patently unreasonable. An otherwise WTO-consistent measure (*i.e.* suspending concessions) of one Member would be automatically rendered WTO-inconsistent by the simple adoption and notification of a "compliance measure" by another Member. The self-proclaimed "complying" Member could buy itself considerable periods of relief through the announcement of a measure that barely differed from the one originally found to be non-compliant. This scenario would clearly not contribute to the objectives of inducing prompt compliance and ensuring the security and predictability of the multilateral trading system.

4.86 The EC's claims under Article 3.7 of the DSU – which are coincidental to its claims under Article 22.8 – also fail as Canada has demonstrated that it has not acted inconsistently with Article 22.8.

(b) Canada has not acted inconsistently with Articles 23.1, 23.2(a) and 21.5 of the DSU

4.87 The EC also claims that: 1) Canada is seeking to redress a perceived WTO violation without recourse to the rules and procedures of the DSU, contrary to Article 23.1 of the DSU; 2) Canada has made a unilateral determination that the EC's current measure is not in compliance with the recommendation and rulings of the DSB, contrary to Article 23.2(a) of the DSU; and 3) Canada's failure to initiate compliance proceedings to determine the WTO consistency of the EC's current measure is contrary to Article 21.5 of the DSU. These claims are unsustainable.

(i) Canada is not seeking redress of a perceived WTO violation

4.88 The EC's claim that Canada has sought to redress a perceived violation without recourse to the rules and procedures of the DSU is based on a misunderstanding of the basis for Canada's continued suspension of concessions. The panel in *EC – Commercial Vessels* found that a necessary precondition to the application of Article 23 of the DSU is that a Member must be acting in response to the perceived WTO-inconsistent behaviour of another Member. In the circumstances before this Panel, Canada is not seeking the redress of a perceived WTO violation; it has already sought and obtained redress pursuant to the rules and procedures of the DSU.

4.89 In the *EC – Hormones* dispute, Canada sought and obtained DSB authorization to suspend concessions to the EC after the EC failed to bring itself into compliance with the recommendations and rulings of the DSB within the reasonable period of time. Canada's impugned measures were adopted and continue to be applied pursuant to this validly obtained authorization from the DSB, and not on the basis of any views it has subsequently developed on the consistency of the EC's current measure. In other words, Canada's assessment of the consistency of the EC's current measure is unrelated to, and irrelevant to, Canada's continued suspension of concessions.

(ii) Canada has not made a unilateral determination

4.90 The EC is simply wrong to suggest that Canada's continued suspension of concessions necessarily implies that it has made a unilateral determination that the EC measure does not comply. According to the text of Article 23.2 itself, as well as the Appellate Body in *US – Certain EC Products,* that provision simply sets out certain specific and clearly-defined forms of unilateral action

already prohibited "in such cases" covered by Article 23.1. Since Canada is not seeking to redress a perceived violation, it cannot be said to have made a unilateral determination.

4.91 Moreover, the panel in *US – Section 301 Trade Act* found that a "determination" can only occur subsequent to a Member having decided that, in its preliminary view, there may be a WTO inconsistency. Mere opinions or views expressed before that stage is reached are not intended to be covered by Article 23.2(a). In the circumstances in this dispute Canada has not passed this threshold of having made a "determination" regarding the EC's current measure.

4.92 In support of its allegations that Canada has made such a determination, the EC has incorrectly interpreted statements made by Canada in the DSB. The reality is that Canada consistently stated that it is the EC's responsibility to establish that it has complied with the DSB's recommendations and rulings, and as result there was no reason for Canada to initiate WTO procedures or to take any other action. The views that Canada expressed on the WTO consistency of the EC's current measure are unrelated to, and irrelevant to, its continued suspension of concessions.

(iii) Canada has no obligation to initiate compliance proceedings

4.93 The EC's allegations that Canada was under an obligation to initiate compliance proceedings under Article 21.5 of the DSU must also fail, as these allegations are based on unfounded assertions that Canada is seeking redress of violation and that it has made a unilateral determination. The mechanism of Article 21.5 was available to either party to obtain a determination as to whether the EC's measure is in compliance. However, it is the responsibility of the EC to avail itself of this procedure if it wishes to have the ongoing DSB authorization terminated.

4.94 The EC's own failure to initiating proceedings under Article 21.5 of the DSU is not a legitimate basis for a claim that Canada acted unilaterally by not initiating such proceedings. Nor does it absolve the EC of its responsibility to demonstrate that it has brought itself into compliance. The EC's interpretation of the DSU on this point, were it to prevail, would negate a WTO Member's right to rely on a validly obtained DSB authorization to suspend concessions and would seriously undermine the proper functioning of the dispute settlement system in the WTO. Furthermore, the DSU cannot be interpreted to compel a Member to initiate proceedings to challenge another Member's measures.

4.95 The EC also incorrectly considers Canada's submission in *US – Section 301 Trade Act* as contradicting its position in these proceedings. The circumstances on which Canada was commenting in that case were very different from those before this Panel. That dispute concerned a US law allowing the US to impose retaliatory measures without having obtained multilateral authorization for such measures. Canada agrees that WTO Members should have recourse to the WTO dispute settlement system rather than their own unilateral determinations. In the current case, however, Canada's measure has been adopted pursuant to DSB authorization and the EC's unilateral and unconfirmed declaration of compliance cannot create a positive obligation for Canada to initiate proceedings under Article 21.5 of the DSU.

(c) The EC has failed to demonstrate its compliance with the recommendations and rulings of the DSB in *EC – Hormones*

4.96 Canada has demonstrated that the EC measure does not benefit from a presumption of compliance in these circumstances and that the EC bears the burden of demonstrating that it actually complies. It has failed to do so. What the EC has put forward in respect of its own measure is three paragraphs from the recitals of Directive 2003/74/EC that summarize the conclusions of the SCVPH. This falls far short of a prima facie case of compliance with the recommendations and rulings of the DSB in *EC – Hormones*.

4.97 The Appellate Body in *US – Gambling* found that a prima facie case must be based on "evidence *and* legal argument" put forward by the party making a claim. It is insufficient therefore for the EC to simply submit limited evidence and expect the Panel to divine from it the EC's claim of compliance. Nor can the EC simply allege facts without relating them to arguments about how they demonstrate compliance. When one assesses the EC's three paragraphs in the light of criteria established by the Appellate Body, it is clear that the EC has failed to establish even a prima facie case of compliance.

(d) Arguments and evidence concerning the non-compliance of the EC measure

4.98 The Panel should dismiss this case on the grounds that the EC has failed to make its case in respect of allegations that Canada has acted inconsistently with the DSU. Canada is nonetheless prepared to elaborate on arguments and scientific evidence that the EC measure does not comply with the recommendations and rulings of the DSB in *EC – Hormones*, an issue the EC is trying to avoid.

(i) The EC's permanent ban on oestradiol-17β is not based on a risk assessment

4.99 The EC has not met either of the two conditions required to demonstrate that its permanent ban on oestradiol-17β is based on a risk assessment. The EC must demonstrate that the SCVPH Opinions constitute a "risk assessment" and that the EC measure banning the use of oestradiol-17β for growth-promotion purposes is "based on" that risk assessment.

(e) The SCVPH Opinions do not constitute a risk assessment

4.100 With respect to the first condition, the Appellate Body in *EC – Hormones* set out a two-step process that the SCVPH Opinions must follow to be considered a risk assessment for the purposes of the *SPS Agreement*. The SCVPH Opinions must first identify the adverse effects on human health (if any) arising from the presence of the six hormones when used as growth promotants in meat and then, if any such adverse effects exist, they must evaluate the potential occurrence of these effects. They do neither.

4.101 First, the SCVPH opinions do not identify any adverse effects on human health that arise from the consumption of meat containing residues of oestradiol-17β that has been used as a growth promotant. The SCVPH opinions identify only in a speculative fashion potential adverse effects of oestradiol-17β in general, a substance available from many sources both internal (endogenous) and external (exogenous) to the human body.

4.102 None of the potential adverse effects identified by the SCVPH were said to arise specifically from the consumption of meat containing residues of oestradiol-17β when used as a growth promotant. In fact, the SCVPH specifically acknowledges the absence of such a link. As a result of the speculative nature of the identification of potential adverse effects in general and the absence of a specific link between such effects and the use of hormone growth promotants in particular, the SCVPH opinions cannot be seen to satisfy the first step in the conduct of a "risk assessment".

4.103 Second, the SCVPH Opinions do not evaluate the potential occurrence of the adverse effects they purport to identify. The three SCVPH opinions simply point to general concerns about possible adverse effects of oestradiol-17β, and do not evaluate the potential occurrence of such effects as a result of consumption of meat derived from hormone-treated animals. Moreover, the SCVPH has failed to conduct even the minimum steps of such an evaluation.

4.104 The Appellate Body found in *EC – Hormones* that the scientific evidence considered in a risk assessment had to be "sufficiently specific" to the substance at issue. Even those potential adverse effects that it does identify the SCVPH does not evaluate in a manner that is sufficiently specific to

the substances at issue, and as such the SCVPH has not completed the second step required of a risk assessment.

(f) The EC measure is not based on a risk assessment

4.105 With respect to the second condition, the EC measure is not based on a risk assessment. Since the EC has not even conducted a proper risk assessment, the measure cannot be said to be "based on" a risk assessment. However, even if the SCVPH opinions are considered to constitute a risk assessment, the EC still fails to satisfy this condition as its measure is not "based on" that risk assessment.

4.106 The Appellate Body in *EC – Hormones* found that the results of the risk assessment must "sufficiently warrant" an SPS measure, and there must be a "rational relationship" between the measure and the risk assessment. In order to satisfy this test, the EC must demonstrate that the conclusions of its so-called risk assessment (that oestradiol-17β in general may have adverse effects) sufficiently warrant the conclusions underlying its measure (that residues of oestradiol-17β consumed from meat derived from animals treated for growth-promoting purposes have adverse effects).

4.107 All that the SCVPH has arguably identified are some potential adverse effects associated with oestradiol-17β *per se*. It has not demonstrated that these adverse effects occur as a result of consumption of the quantity of oestradiol-17β that would be present in meat derived from treated animals. Even if the conclusions on the adverse effects of oestradiol-17β were correct, the rational response would be to ban oestradiol-17β, or at least to inform consumers of its various sources and the actions they should take to minimize exposure. The EC has instead chosen to respond to advice about the potential adverse effects of oestradiol-17β from all sources by banning only meat from animals treated with oestradiol-17β for certain purposes, while allowing others.

4.108 In *EC – Hormones,* the EC failed to convince either the panel or the Appellate Body that its measure – which was nearly identical to the present one – was "based on" on a risk assessment. The evidence that the EC now relies on remains as insufficient to establish a basis for its ban as it was in *EC – Hormones.* As a result, the conclusions of the SCVPH opinions do not support the conclusions underlying the measure, so the measure is not "based on" a risk assessment.

(i) The EC's ban on the five other hormones is not a provisional measure

4.109 The EC claims that its provisional ban on five other hormones – testosterone, progesterone, TBA, zeranol and MGA – is justified under Article 5.7 of the *SPS Agreement*, on the ground that there is insufficient scientific knowledge to conduct a risk assessment. As the EC has failed to present any evidence in support of this claim, it must also fail. In fact, the EC expressly stated in *EC – Hormones* that its ban on these hormones was not a provisional measure in the sense of Article 5.7, presumably because it concluded that there was sufficient scientific information on which to base its measure at the time. It strains credulity therefore for the EC to now assert, over seven years later, that the ban on these hormones is now being imposed on a "provisional" basis.

4.110 The burden of proof rests on the party invoking Article 5.7 to justify its provisional measure to make a prima facie case in support of that position. The EC has failed to present any case whatsoever in support of its provisional ban, choosing instead to merely cite Directive 2003/74/EC in support of its contention that its ban is a provisional measure. Regardless of where the burden lies, there is ample evidence to suggest that the EC has no grounds for justifying the ban on these five hormones on a provisional basis.

4.111 In interpreting the obligations under Articles 2.2 and 5.7 of the *SPS Agreement*, the Appellate Body in *Japan – Agricultural Products II* set out four cumulative requirements for a measure to be

justified as a provisional measure. A measure may be justified as "provisional" where: (1) it is imposed in a situation where relevant scientific evidence is insufficient; (2) it is adopted on the basis of available pertinent information; and such a provisional measure may only be maintained where: (3) the Member seeks to obtain additional information necessary for a more objective assessment; and (4) the Member reviews the measure accordingly within a reasonable period of time.

4.112 With respect to the sufficiency of the scientific evidence, the body of scientific evidence relating to these five hormones is such that the EC cannot plausibly argue that it is insufficient to conduct a proper assessment of risk. The five hormones have already been the subject of several risk assessments by reputable national regulatory agencies and international expert scientific committees, such as JECFA. In fact, the panel in *EC – Hormones* found that several scientific reports met the minimum requirements of a risk assessment.

4.113 JECFA's studies of these five hormones reveal the breadth and depth of the available scientific evidence. As early as 1981, JECFA evaluated the health effects of residue levels of progesterone and testosterone, concluding that residues from the use of these hormones according to good veterinary practices are unlikely to pose a hazard to human health. After its most comprehensive evaluation in 1999, JECFA recommended ADI levels for these two hormones. In 2000, JECFA published residue and toxicological monographs, in which it referenced a large number of available studies dealing with progesterone and testosterone. Zeranol and TBA were considered by JECFA in 1982 and again in 1983. JECFA ultimately recommended an ADI for zeranol in 1987 and one for TBA in 1989. JECFA then turned its attention to MGA in 2000 and again in 2004, at which time it recommended an ADI.

4.114 In the light of the available scientific evidence on which JECFA has based it recommendations, it is clear that JECFA does not consider that residues of these hormones have an adverse effect on human health, provided they are used in accordance with good veterinary practices. Faced with this conclusion from JECFA, the EC cannot substantiate its assertion that there is insufficient scientific information to perform an adequate risk assessment in respect of these five hormones.

4.115 With respect to the availability of pertinent information, the Panel would only need to consider this second requirement in the event that it accepted that there is insufficient scientific evidence to allow the EC to conduct an adequate risk assessment. If the Panel proceeds to this stage, the requirement that a measure be adopted "on the basis" of available pertinent information requires that there be a rational relationship between the EC measure and the available pertinent information. An objective analysis of the available pertinent information regarding the health risks associated with residues of these hormones does not reasonably support the EC's ban on these five hormones.

4.116 The EC's ban is inconsistent with the current position of JECFA and Codex – an organization specifically recognized in the *SPS Agreement* as an international standard-setting body – on the human safety of these hormones when used in accordance with good veterinary practices. JECFA concluded that there was no need to specify numerical MRLs for progesterone and testosterone when these substances are used in accordance with good veterinary practices. JECFA recommended MRLs for zeranol, TBA and MGA in 1987, 1989 and 2004, respectively. For its part, Codex indicated in 1995 that it was "unnecessary" to set numerical MRLs for progesterone and testosterone. It did set numerical MRLs for zeranol and TBA.

4.117 Finally, with respect to the third and fourth requirements under Article 5.7 – the collection of additional information for a more objective assessment and review within a reasonable period of time – the EC has not demonstrated that it is complying with these obligations. Although the EC Directive specifically indicates that the Commission shall seek additional information from all

possible sources, the EC has provided no evidence of its efforts to obtain the necessary information to conduct a proper risk assessment.

(g) Canada has not acted inconsistently with Articles I and II of the GATT 1994

4.118 Canada's suspension of obligations is authorized by the DSB and therefore fully justified under the DSU. Since the EC's claims under Articles I and II of the GATT 1994 are dependent on its DSU claims, these consequential claims must also fail.

E. ORAL STATEMENT OF THE EUROPEAN COMMUNITIES DURING THE FIRST SUBSTANTIVE MEETING

1. Introduction

4.119 The central provision on which the European Communities bases its claims is Article 23 of the DSU. Article 23 requires WTO Members to have recourse to the procedures set out in the *DSU* instead of resorting to any kind of "self-help." Article 23, in other words, prohibits a WTO Member from making itself the judge over other WTO Members. What is and what is not a violation of the covered agreements and what one can do to remedy it, are to be determined multilaterally, not unilaterally.

2. Seeking redress – Article 23.1

4.120 As to Article 23.1 all parties seem to agree that when, in 1999, the US and Canada requested, obtained and started using a DSB authorization to suspend concessions, they were seeking to redress a violation established at that time. The parties differ on what the US and Canada are doing right now. One should think that they are still seeking redress. After all, they are still applying their suspension of concessions stating explicitly that they fail to see how the European Communities' implementation measure achieves compliance. This can only mean that they still see a violation, especially given that Article 22.8 of the DSU would prohibit the continuation of sanctions in the opposite case.

4.121 The defending parties, however, flatly deny that what they are doing right now is seeking redress of a violation against an alleged WTO-inconsistency of the implementing measure. The United States states that it "has already sought and obtained redress through the multilateral dispute settlement system for a violation found by the DSB." Canada not only uses the same terms – "sought and obtained" – but also takes the trouble of underlining those words in its submission in order for everyone to understand the difference between the present tense ("seeking"), in Article 23.1 DSU, and the past tense of "sought and obtained". That difference seems obvious enough. What is much less obvious, however, is how, by referring to the past, the defending parties want to explain what they are doing right now. Applying sanctions is a form of seeking redress as the defending parties have admitted themselves. They are currently applying sanctions – present tense, not past tense – so how could they not be seeking redress?

4.122 They are not seeking redress, so the defending parties say, because they are acting under an authorization. An authorization, however, can neither deny facts nor derogate from a Member's obligations outside its scope. Thus, as regards specifically Article 23 of the DSU, it is clear that the mere existence of an authorization cannot simply do away with the obligation to abide by the rules and procedures of the DSU, when a Member is seeking redress of a violation.

3. Article 23.2(a) of the DSU in conjunction with Article 21.5 of the DSU

4.123 As regards specifically the EC's claim under Article 23.2(a) in conjunction with Article 21.5 the defending parties put forward a number of reasons as to why there is no determination by them.

Interestingly enough, they hardly deal with one of the main points the European Communities has raised, namely that their "unilateral determination" can be inferred from the fact that they continue to apply sanctions unilaterally. And how could it not be inferred from it? It is inconceivable – and indeed would be even worse than what we are discussing now – if they did so without any good reason. On the other hand, both spend considerable time in their first written submissions explaining – in a rather defensive manner – that their public statements do not constitute determinations, that they never alluded to a violation, that they have not yet concluded on non-compliance, etc. And finally, elsewhere in their submissions, they spend even more time explaining why the European Communities' implementing measure actually falls short of compliance.

4.124 Whether or not a specific statement reaches – as Canada puts it – the "threshold" of a determination is one thing. Yet, another thing is if that statement is accompanied by conduct that severely affects the EC's trade. We are not looking at statements made *in abstracto* here. A "determination" need not be pinned down to a specific statement in a specific form, it is the whole conduct a WTO Member is displaying that needs to be looked at.

4.125 The defending parties further claim that they do not have an obligation under Article 21.5 of the DSU to launch compliance proceedings. This Panel, however, is asked to find whether, under Article 23 of the DSU, in conjunction with Article 21.5, a Member has an obligation to launch a compliance procedure if and because it continues to apply sanctions against another Member, even though there is a new implementing measure. It is not relevant for this dispute what obligations can be found directly in 21.5 in the absence of such unilateral conduct.

4.126 Finally, the United States claims that there is no obligation for the complaining parties to *immediately* launch a compliance review. In the present context and circumstances, with almost one and a half years that have passed after the adoption of the European Communities' implementing measure at the moment when this Panel was established and with all the discussions that took place between the parties to this dispute regarding this implementing measure, both before and after it was adopted, the question of how quickly a retaliating complainant must react to an implementing measure does not pose itself. If anything, one could discuss the defendants' bad faith and their contradictory behaviour (*venire contra factum proprium)*.

4. Article 23.1 in conjunction with Articles 22.8 and 3.7 of the DSU

4.127 As regards the EC' claim under Article 23.1 in conjunction with Article 22.8, 3.7 of the DSU, the defending parties submit that the conditions of Article 22.8 are not fulfilled because the European Communities did not prove that it has "removed" the inconsistency of the measure. This argumentation overlooks the fact that dispute settlement proceedings are about a non-compliance review not a compliance review. Indeed, in all dispute settlement proceedings that have ever been adopted by the DSB it was for a complaining Member to prove the WTO *in*consistency of a measure by another Member. This is explicitly confirmed by Article 6 of the DSU, the provision under which panels are established.

4.128 The defending parties ignore that the European Communities makes its systemic claim under *Article 22.8, in conjunction with Article 23.1*. Thus, the Panel is called upon to decide whether or not the conditions under Article 22.8 are fulfilled *in view of* the prohibition under Article 23 to make unilateral determinations of non compliance. It is not possible for the defending parties to contest the removal by the EC of the inconsistency of our old measure (Article 22.8), without making a unilateral determination under Article 23.

4.129 Further, both defending parties submit that the European Communities cannot base itself on a presumption of good faith compliance. The European Communities bases itself on the same *rationale* as the Appellate Body in the *Byrd Amendment* case. Thus, even though the defending parties allege

that the European Communities is still in violation of the *SPS Agreement*, this does not in any event affect the presumption of good faith. As the Appellate Body has made clear, these are two completely different questions.

4.130 The defending parties claim that there is a reversed burden of proof in a compliance case. Contrary to what Canada believes, a reversal of presumption can also not be deduced from the DSB authorization granted in 1999. The DSB authorization is limited to giving a Member the right to apply sanctions. However, it does not go further than that. The DSB authorization cannot reverse the normal rules which apply for subsequent implementing measures.

4.131 If Canada's criterion of a "day-to-day business" conduct for the presumption of good faith should bear any relevance at all, the European Communities considers that in the present case it even supports the EC' reliance on good faith. Indeed, the European Communities prepared the implementation of the DSB recommendations and rulings with extraordinary carefulness. During the compliance process, the European Communities has made every effort to analyse the relevant scientific evidence in full transparency and with an open mind. All stakeholders – whether inside or outside the European Communities – had at every moment in time the opportunity to submit relevant information and to intervene in the whole process.

4.132 It is therefore also absurd, and indeed puts the reality on its head, to maintain that the European Communities in this case seeks to end the sanctions on the basis of a "mere declaration of compliance", and that this could be done also just "a week after" the DSB authorization. It insinuates that the European Communities abused its rights and it just waives its hand to claim compliance. In the light of the whole process, as just described, it is instead fully legitimate for the European Communities to rely on the presumption of good faith for its compliance.

4.133 As to the relevance of the DSB authorization for the continued application of sanctions in the context of Article 22.8, obviously, the defending parties and the European Communities have different views about the scope of the DSB authorization. For the United States and Canada, the DSB authorization operates like a sort of "absolute justification" which makes every behaviour *per se* WTO consistent, irrespective of any subsequent events and compliance acts. On the other hand, the European Communities considers that it is necessary to put the DSB authorization in its proper context under the DSU.

4.134 In this case, the DSB authorization has been granted under Article 22.7 following an arbitration procedure under Article 22.6 of the DSU. The subject-matter of this Article 22.6 arbitration was the level of nullification or impairment caused by the original EC's Hormones legislation. Thus, it is crucial to note that the very basis of the DSB authorization has been the WTO-inconsistency of the Member *before* the authorization was granted. On the other hand, the DSB authorization is not based on any (alleged) WTO inconsistency of a compliance measure that has been adopted *afterwards*.

4.135 What follows from this important and undisputable fact is that, first of all, in case of a subsequent compliance that is properly adopted and duly notified to the WTO, the basis on which the DSB has granted its authorization has fundamentally changed. The DSB only granted the authorization to suspend concessions precisely because a WTO Member had been found to be WTO inconsistent in the past and no implementation measure was taken within the reasonable period of time. The DSB's authorization was to induce compliance by the other Member and to rebalance temporarily the rights and obligations until the other Member has complied.

4.136 Second, the DSB authorization is even more fundamentally changed in case of a subsequent compliance measure which has never been found WTO-inconsistent, because the defending parties do not dare to challenge it under Article 21.5. In its first written submission, the European Communities

has referred to the "sequencing" discussion and practice of WTO Members in case of a compliance act before the DSB authorization is granted. Quite remarkably, in the *EC – Bananas III* dispute, the DSB Chairman explicitly stated that the sequencing of a determination of compliance or non-compliance and the suspension of concessions should be treated in a "logical way forward".[17]

4.137 As it happened, the logical way forward at the time was to assess first whether or not the compliance measure was sufficient before determining the nullification or impairment caused by the WTO-inconsistent measure. In stark contrast to this sequencing, the defending parties consider now that the logical way forward is to continue to apply sanctions even though the EC' compliance measure has not been challenged by them and not been found WTO-inconsistent. And what is more, they even refuse to challenge the EC' compliance measure pretending that this is not necessary since they have a DSB authorization.

4.138 But how can Canada and the United States know that the European Communities is still not in compliance with its obligations? They do so solely on the basis of a unilateral determination of the EC' compliance measure which is in obvious contradiction to Article 23 and Article 21.5 of the DSU.

4.139 One might argue that the DSU is not explicit on this question. However, the DSU contains several elements which indicate that the DSB authorization can not serve as a blank cheque for the continuous application of the sanctions even after a subsequent compliance measure has been adopted and notified properly to the DSB.

4.140 First, let us consider the wording of Article 22.8 of the DSU and what it does *not* say. Even in case of a removal of the inconsistency of the measure, Article 22.8 does *not* say that the "DSB authorization ceases to apply". Instead, it states that the suspension of concessions or other obligations shall not "be applied" any longer. Thus, Article 22.8 does not formally address the fate of the DSB authorization. In an Article 22.8 situation it is, therefore, perfectly conceivable that although the DSB authorization is not *formally* terminated or withdrawn, a WTO Member is not entitled to continue the application of suspension of concessions. Furthermore, Article 22.8 does *not* say that the removal of the inconsistency or the termination of the application of suspension requires whatever kind of DSB decision. Rather, Article 22.8 is self-executing. The use of the word "shall" supports this interpretation, which does not give any margin of manoeuvre and requires no additional acts.

4.141 Second, contextually, Article 22.8 describes the next procedural step in the course of a dispute after an authorization has been granted. Article 22.8, therefore, provides for the next logical step. Consequently, once the inconsistency of the measure has been removed, the application of suspension of concessions or other obligations is no longer permitted.

4.142 In addition, Article 22.8 should be interpreted in the context of Article 23 of the DSU, which prohibits WTO Members from judging unilaterally the properly adopted and notified compliance measures of other WTO members. According to the text, object, purpose and context of Articles 22.8 and 23, the defending parties must seek a determination of non-compliance under the normal DSU procedures. This general principle is not altered in whatever way under Article 22.8.

4.143 Another contextual element which should be taken into account is Articles 3.7 and 22.1 of the DSU, which underline the exceptional and temporal nature of the application of suspension of concessions or other obligations. Their exceptional and temporal nature effectively complements the principle of good faith. In case of a properly adopted and notified compliance measure, the exceptional and temporal justification of countermeasures is put into question. In the presence of a subsequent compliance measure, the "normal" situation revives and sanctions can no longer be applied as if nothing has changed.

[17] Minutes of the DSB Meetings held on 25, 28 and 29 January and 1 February 1999, WT/DSB/M/54.

4.144 Canada tries to draw contextual support for its position from Article 3.2, emphasizing the security and predictability given by the DSB authorization. The "security and predictability" under Article 3.2, also applies to the WTO Member who properly implements its obligations. Once this Member has removed the inconsistency of the measure it should have the reassurance that sanctions are no longer applied. At a minimum, the implementing Member must have the reassurance that its measure is properly challenged under the DSU by the retaliating Member, which does not agree with the compliance measure. But even this, Canada and the United States refuse to do despite the repeated requests by the European Communities to do so.

4.145 The European Communities would also recall the object and purpose of the trade sanctions, which is to induce compliance and to rebalance the rights and obligations under the WTO agreements. However, both objectives require that a Member's measure has been found first to be WTO-inconsistent in accordance with the DSU rules. And such a determination concerns logically not just any measure, but the measure that is currently in force in the Member concerned. Transposed in the present context, it means that Canada and the United States cannot simply argue that the "old" measure has been found to be WTO-inconsistent in 1998. This measure is not any longer in force, since the European Communities adopted and notified its compliance measure in 2003. It is simply not rational and credible to argue that the object and purpose of the suspension of concessions continues to exist, if its basic reason, i.e. the old WTO-inconsistency, has disappeared.

5. Concluding statement of the European Communities

4.146 The EC believes that allowing public observation of the debate during this hearing has been very beneficial for the public's understanding of the dispute settlement process as well as this particular dispute. The public observation has in no way hindered an efficient conduct of this hearing. On the contrary, the third parties have clearly benefited from their observation of this hearing during the first two days for the purpose of their participation in this dispute.

4.147 What we have heard from the defendants in the last few days is essentially that a retaliating Member has no obligation whatsoever under the DSU. Instead, the retaliating Member may continue to apply sanctions until the authorization is "revoked" by the DSB. The United States and Canada argue that by virtue of this authorization they can simply lean back and see what the complying Member comes up with. If eventually the complying Member adopts an implementation measure they do not even see a need to review it in due time. Let me remind that in this case the United States and Canada claim that they have even after two years (and I should add after an additional three years of preparation) not made up their mind whether the EC's measure is WTO consistent. Indeed there seems to be no prospect that the United States and Canada will ever make up their minds. Canada has stated that it would never make a determination about the EC's new measures and the United States gave even less cause for reassurance stubbornly refusing even to agree that there is a disagreement.

4.148 Whatever the defendants may mean by these statements, it is clear that the United States and Canada do not accept a responsibility to submit the EC's legislation to a multilateral review as it has been done in any other case by WTO Members which ended in an adopted WTO decision. And although they do not contest that the EC has acted in good faith, they do not even concede that the EC's measure can benefit from a presumption of good faith compliance.

4.149 This is a very easy going way for the United States and Canada. But it cannot be the correct one under the DSU.

4.150 The EC would recall some essential points which had been discussed by the parties:

4.151 First, the EC has advanced what would be the logical solution to this dispute, i.e. to follow its example in the *US – FSC* case (launching Article 21.5 compliance procedure by original complaining

party, suspension of sanctions in the meantime). Quite remarkably, the United States fully agreed with this EC' approach and considered it as "the appropriate solution" in the *US – FSC* dispute. Yet, the EC struggles to understand why in a reverse situation where the United States is retaliating, the United States does not follow this example if it considers it as "appropriate".

4.152 Second, there has been a lot of discussion about the presumption of good faith and the presumption of compliance, which is important for the EC claim under Article 22.8 and Article 23.1 of the DSU. Neither the United States nor Canada nor any of the Third Parties have contested that the EC has adopted its compliance measure in good faith. Yet, the United States and Canada refuse that the EC may rely on this principle in a "post-implementation" scenario. The United States even wants to go as far as to say that the principle of good faith is not part of the DSU. Obviously, this view is contrary to what the Appellate Body has constantly ruled but also irreconcilable with general principles of public international law. Moreover, when we asked Canada about the basis in the DSU of its assumption that an implementing Member faced with retaliation is not entitled to this presumption, it could not provide any answer. Indeed, this is so because there is no basis for Canada's theory.

4.153 Third, during the proceeding we have heard a lot about the risks of an "endless loop of litigation" by a "mere declaration of compliance". Yet, as everybody agrees that the EC has adopted its compliance measure in good faith, it is clear that this "endless loop of litigation" does not arise in this dispute. Indeed, such an endless loop scenario presupposes a sort of scam measures notified by a WTO Member in bad faith. This is not the case before us. Indeed, even the EC would not consider that a "mere declaration of compliance" is sufficient but what matters is that a Member complies with its obligations. This is what the EC had actually done in this case after a most thorough review of its measure involving a comprehensive review and assessment of the available scientific evidence.

4.154 There is a paradox about the approach of the defendants to the principle of good faith. They do not contest that the EC has acted in good faith but they argue that WTO Members in general cannot be expected to act in good faith. They argue, Members with a duty to implement will adopt sham or scam measures to escape retaliation, it is argued that implementing Members must have the burden of proving their compliance. The EC does not believe that WTO Members act in bad faith. No Member wants to lose WTO disputes – and to do so repeatedly and ignominiously. There would be a high political cost. Also, WTO Members are not excessively litigious and do not gaily engage in endless loops of litigation. This fear is unfounded. But if this argument about bad faith is allowed, it can also be used the other way around – to argue that the United States' and Canada's approach will lead to Members seeking and exploiting retaliation rights for improper purposes. Seeking redress of WTO violations must not be too difficult; and implementation and removal of retaliation must not be made subject to the often impossible task of proving a negative. Retaliation rights should not become a new means of advancing unilateralist agendas.

4.155 Fourth, when it comes to the DSB authorization, the United States and Canada argue that this may be revoked if the EC would launch a proceeding under the DSU, be it Article 21.5, 22.8 or Article 25 etc. However, both defending parties cannot explain how this would even result in revocation of the DSB authorization. Well, Canada argues that the DSB could probably eventually make a recommendation to itself to revoke the DSB authorization but there is absolutely no basis for this in the DSU. And I am not talking about the procedural implications which this could entail. For instance – according to Canada – in an Article 21.5 proceeding brought by the EC against itself the burden of proof would be partly on the EC for the implementation of the original DSB recommendations and ruling. On the other hand, Canada could bring in its "defence" (in which they would complain about the WTO consistency of the measure) new claims for which it would bear the burden of proof. And of course, Canada's theory cannot even address the question on how these new claims could be reconciled with the more limited Panel request.

4.156 Finally, let me once stress again that the EC is not seeking to avoid a proper examination of its compliance measures in the Hormones dispute. We would be delighted if the United States and Canada would initiate an Article 21.5 dispute tomorrow and would do all we can to facilitate and accelerate its conclusion. However the United States and Canada stubbornly refuse to take this logical – indeed appropriate – step. It is they who have sought to avoid having to confront the new EC measures and set out their objections to it in a manner in which the EC can properly respond. They have, it is true, started to set out – for the first time – their objections in their first written submissions. The EC does not understand why they did not want to do this in a proper Article 21.5 proceeding.

4.157 We hope that we have assisted the Panel in its important task and look forward to helping the Panel in any further way that we can in the coming weeks.

F. ORAL STATEMENT OF CANADA DURING THE FIRST SUBSTANTIVE MEETING

1. Introduction

4.158 The EC was found in *EC – Hormones* to be acting inconsistently with its WTO obligations. It was given fifteen months to comply, but failed to do so. As a result, the DSB authorized Canada to suspend concessions to the EC, on the basis of which Canada adopted in 1999 the *European Union Surtax Order*. The consistency of Canada's measure was not challenged for many years, as it was understood to be adopted on the authorization of the DSB that remained in effect and as a part of a dispute that remained under the surveillance of the DSB. The EC is now, however, challenging the consistency of that measure.

4.159 What has changed? Canada's measure does not suspend concessions at a level higher than originally authorized; there has been no mutually satisfactory solution; the DSB has not revoked its authorization; and there have been no findings of EC compliance. Rather, the EC claims that what has changed is that it has adopted Directive 2003/74/EC, amending the EC measure originally found WTO-inconsistent. The EC notified to the DSB that with these amendments it "considers itself" to have fully implemented the recommendations and rulings of the DSB in *EC – Hormones* dispute and therefore Canada's measure is no longer justified. The EC did not ask whether the DSB "considers" the EC to be in compliance, nor did it ask whether Canada and the United States "consider" the EC to be in compliance. It simply asserted that it "considers itself" to be in compliance. While the EC alleges Canadian "unilateralism", it is the EC that has engaged in unilateralism: it is the EC that has unilaterally determined that it now complies and that the DSB authorization no longer applies. On the basis of these unilateral determinations, the EC alleges that Canada's measure is WTO-inconsistent.

4.160 While the EC seeks to prevent the Panel from considering the issues in the context of *EC – Hormones*, for it to prevail on any of its allegations, the Panel initially will have to make findings that relate in some way to the issue of the EC's "compliance". In fact, all parties agree that this dispute turns on the current status of the EC measure under WTO law. For the EC, the issue is whether the EC is *presumed* to have complied; for others, the issue is whether the EC has *actually* complied.

4.161 Since the EC does not benefit from a presumption of compliance, Canada cannot be found to have acted inconsistently with its WTO obligations without considerably more evidence and argument from the EC on how it has actually complied. The EC acknowledges itself in its alternative argument that if the Panel finds that the EC does not benefit from a presumption of compliance, the only way for it to prevail on its allegations would be for it to demonstrate its actual compliance. However, the EC falls far short of meeting even the lowest threshold of evidence and argument required to discharge this burden. Despite the fact that it is not Canada's burden to do so, Canada will highlight some of the reasons why the EC has not complied with the recommendations and rulings in *EC – Hormones*.

2. Since the EC is not presumed to have complied, Canada has not acted inconsistently with its obligations under the DSU

4.162 The EC's claim that it should be presumed to have complied with the recommendations and rulings in *EC – Hormones* is unsustainable. Rather, the EC bears the burden of having the DSB authorization terminated by seeking multilateral confirmation of its actual compliance.

(a) The EC's measure does not benefit from a presumption of compliance

4.163 The EC's claims rely on the general principle that States are presumed to act in conformity with their international obligations. While not disagreeing with this principle, Canada does disagree that it applies in these circumstances. The presumption of compliance applies to WTO Members prior to them being engaged in a WTO dispute. It even applies to WTO Members found to be in breach, as long as they comply within the prescribed period, and prior to authorization to suspend concessions. If the EC measure had been adopted outside the context of a WTO dispute, or if it had been adopted within the period granted to the EC to comply once it was found non-compliant, it would have benefited from a presumption of compliance. But in this case, the EC has abused its privilege of being granted a period of time to comply. The resulting DSB authorization gave the original dispute an entirely different legal character, altering the "fundamental logic" that underpins the presumption of compliance. Since the WTO compliance of Canada's measure cannot co-exist with the presumed compliance of the EC's measure, the latter must yield to the former. The explicit authorization granted under the terms of the DSU must prevail over a presumption of compliance. Therefore, the EC cannot claim the benefits of such a presumption.

(b) The EC bears the burden of demonstrating that its has complied

4.164 According to the EC, the presumption that its measure complies simply "overtakes" the DSB authorization, automatically rendering Canada's measure non-compliant. However, it cannot be correct that a unilateral assertion of compliance is sufficient to terminate a multilateral authorization. The EC's unilateralist approach to terminating the authorization runs directly counter to the object and purpose of the dispute settlement system that disputes be decided multilaterally and in a manner that ensures the security and predictability of the trading system. Since the DSB authorization is based on findings that the EC was non-compliant, it is up to the DSB to revoke that authorization should it subsequently find that the EC has complied. The onus is now on the EC to take appropriate steps within the multilateral system to confirm its compliance if it wishes to have the DSB authorization terminated. No provision of the DSU prohibits the EC from either initiating proceedings under Article 21.5 of the DSU or initiating proceedings *de novo*.

(c) Canada has not acted inconsistently with Articles 22.8 and 3.7 of the DSU

4.165 The EC alleges that Canada has failed to terminate its suspension of concessions despite the EC's notification that it has "removed" the measure found to be inconsistent in *EC – Hormones*. Canada agrees that the issue is whether the EC has complied and Canada also agrees that its suspension of concessions may only be temporary, but this is where agreement ends. The EC justifies its claim that its measure has been "removed" on the basis that it is presumed to comply – a presumption that Canada has demonstrated does not apply in these circumstances – but the EC has neither sought nor received multilateral confirmation of this. In the absence of a presumption of compliance or multilateral confirmation of compliance, the EC has not satisfied the pre-conditions of Article 22.8 of the DSU, and Canada cannot therefore be held to have contravened that provision. Without a finding that Canada has contravened Article 22.8 of the DSU, Canada also cannot be found to have acted inconsistently with Article 3.7 of the DSU.

(d) Canada has not acted inconsistently with Articles 23.1, 23.2(a) and 21.5

4.166 The EC's claims that Canada is seeking the redress of a perceived WTO violation (Article 23.1 of the DSU), that Canada has made a unilateral determination regarding the consistency of the EC measure (Article 23.2(a) of the DSU) and that Canada's failure to initiate compliance proceedings constitutes prohibited unilateral conduct (Article 21.5 of the DSU) are also unsustainable. Contrary to the EC's mischaracterization of the legal basis for Canada's actions, Canada is not seeking the redress of a perceived WTO violation; Canada has already sought and obtained redress, after which it was authorized by the DSB to suspend concessions to the EC. Since it is this authorization – which remains in effect in the absence of confirmation of EC compliance – that continues to form the basis of Canada's suspension of concessions, Canada's assessment of the inconsistency of the EC's recent amendments is unrelated to, and irrelevant to, Canada's measure. Any interpretation of the DSU that would compel Canada to initiate proceedings to challenge the EC's measure runs counter to the principle that WTO Members cannot be compelled to launch proceedings.

3. The actual compliance of the EC's measure with the recommendations and rulings of the DSB

4.167 In the absence of a presumption of compliance, the EC must establish that it has actually complied with the recommendations and rulings in *EC – Hormones*. While the EC chose not to have an Article 21.5 panel confirm its compliance, if the EC wishes to see the DSB authorization cease to apply, it must have this Panel confirm its actual compliance, although it appears unenthusiastic to do so and has submitted insufficient evidence on this point. Despite the fact that the EC has failed to demonstrate that it has complied, Canada will demonstrate why it has not.

(a) The EC has not presented a prima facie case that its measure complies

4.168 While the EC implicitly acknowledges in its alternative argument that it might bear the burden of demonstrating that it actually complies, the evidence it has put before the Panel falls far short of what is required to make a prima facie case. A prima facie case must be based on "evidence and legal argument" in relation to each of the elements of the claim. While the EC claims that it has complied, it has put forward mere assertions of compliance. It does not attempt to substantiate these assertions in relation to the recommendations and rulings in *EC – Hormones*. For example, it has not provided any evidence, nor advanced any arguments, that the documents it claims to be that risk assessment relating to oestradiol-17β actually constitute a "risk assessment". Nor does it explain how it has met the requirements justifying its ban on the five other hormones as a provisional measure. The Panel should also reject the EC's alternative claims that its measure actually complies.

(b) The EC's measure does not comply

4.169 Canada will nonetheless demonstrate that, were the EC to make a more substantial attempt to establish the actual compliance of its continued hormones ban, it would be unable to do so.

(i) The permanent ban on oestradiol-17β

4.170 The EC fails to satisfy the two conditions required to demonstrate that its permanent ban on oestradiol-17β is based on a risk assessment: that the SCVPH opinions constitute a "risk assessment", and that the EC measure is "based on" that risk assessment. The SCVPH opinions do not identify adverse effects arising from oestradiol-17β when used specifically as a growth promotant, nor do they evaluate the potential that these effects will occur. Much of what has been presented is speculation – based on incomplete and unconfirmed science – about potential adverse effects of oestradiol-17β consumed via meat from treated animals.

4.171 The more conclusive the evidence is about potential adverse effects associated with oestradiol-17β in specific circumstances, the less applicable that evidence is in identifying and evaluating any adverse effects associated with oestradiol-17β consumed through meat from treated animals. The SCVPH concludes – without evidence – that concern about the adverse effects of oestradiol-17β in specific circumstances is relevant to the use of oestradiol-17β as a growth promotant. Since the quantity of oestradiol-17β absorbed by the human body from residues in meat is a fraction of that absorbed from other sources, the identification of adverse effects that may occur as a result of the latter does not automatically suggest that adverse effects may occur from the former. The SCVPH acknowledges that it has no evidence that the potential adverse effects it identifies arise from the consumption of meat from treated animals.

4.172 The SCVPH places considerable emphasis on oestradiol-17β as a possible genotoxin, presenting a profoundly problematic hypothesis about how reactive oestrogen metabolites can damage DNA and initiate tumours. This hypothesis has emerged from a limited set of studies done at exceedingly high doses either on laboratory animals or *in vitro*. The SCVPH has disregarded or downplayed – because it refutes its hypothesis – established scientific evidence that defence mechanisms exist to control the formation of potentially genotoxic metabolites. The SCVPH's incomplete model of genotoxicity has attracted little support from the international scientific and regulatory communities.

4.173 While reasonable and responsible governments may act on the basis of minority scientific opinions, these minority opinions must be based on credible evidence of actual adverse effects and not on hypotheses and speculation based on models that disregard established scientific principles. The SCVPH fails to address the issue of the dose required to create an adverse effect, but concludes anyway that no dose threshold level can be established. In other words, the SCVPH presents no evidence that an adverse effect that may theoretically occur at high levels of oestrogen metabolites actually does occur at normal levels of oestradiol-17β, nor does it present evidence that the residues in meat from treated animals are capable of reaching this theoretical level. Therefore, the three SCVPH opinions do not individually, or collectively, constitute a risk assessment.

4.174 With respect to the second condition – that the EC measure must be based on a risk assessment – since the opinions on which the EC relies do not amount to a risk assessment for the purposes of the *SPS Agreement*, the measure cannot be said to be "based on" a risk assessment.

(ii) The "provisional" ban on the other five hormones

4.175 As for the EC's "provisional" ban on the other five hormones, the EC appears to be availing itself of the qualified exemption provided for in Article 5.7 of the *SPS Agreement*. The EC bears the burden of proving that its "provisional" measure meets the four cumulative requirements. The EC must first demonstrate that its provisional ban was adopted in a situation where the "relevant scientific evidence is insufficient" to allow it to perform a risk assessment. Second, the EC must demonstrate that its provisional ban was adopted on the basis of "available pertinent information". Third, in order to maintain its provisional ban, the EC must seek to obtain the additional information necessary for a more objective assessment of risk. Fourth, it must review its ban accordingly within a reasonable period of time.

4.176 The EC has made no attempt to demonstrate the "insufficiency" of the scientific evidence relating to the five provisionally banned hormones. The body of scientific data relating to these five hormones is such that the EC cannot plausibly argue that there is "insufficient" scientific evidence to conduct an adequate risk assessment. Since the five hormones have been the subject of multiple scientific assessments by reputable national regulatory agencies and international expert committees such as the JECFA, the EC's contention that there is insufficient scientific evidence to do so is simply not credible.

4.177 The EC has also not established that there is a rational connection between its provisional ban and the "available pertinent information" on these five hormones, including information from relevant international bodies such as JECFA and Codex. In fact, the EC's hormones ban is inconsistent with JECFA's conclusions and with the standards adopted by Codex regarding residues of these hormones in meat.

4.178 Finally, the EC has presented no evidence that, while maintaining its hormones ban, it is fulfilling the third and fourth substantive requirements of Article 5.7 of the *SPS Agreement*. It has been nearly two years since the adoption of the EC's so-called provisional ban on these five hormones. Yet there is no indication that the EC has reviewed its measure in the light of the scientific data available in the intervening period leading to these proceedings.

4. Conclusion

4.179 In order to resolve this dispute, the first finding of the Panel in this case will have to relate to the current status of the EC measure under WTO law. The EC claims that it should be presumed to have complied with the recommendations and rulings of the DSB in *EC – Hormones*, and as a result Canada has acted inconsistently with several of its DSU obligations. However, without the benefit of a presumption of compliance, the EC cannot succeed on the basis of the arguments it has made so far. Canada's DSB authorization remains in effect, and it is the EC that bears the burden of proving that it now complies. If the EC continues to refuse to discharge its burden under the DSU to demonstrate its own compliance, the outcome of this case is decided. On the other hand, if the EC accepts that burden, Canada has provided some of its own views on whether the EC has actually complied. Seven years after the DSB issued its recommendations and rulings in *EC – Hormones*, the total ban re-issued by the EC remains unwarranted by the evidence adduced.

5. Concluding statement of Canada

4.180 As is typically the case at this stage of dispute settlement proceedings many points have been made by the participating parties on many subjects. You may not find all of the points raised to be necessary for the purpose of reaching a proper resolution. With this in mind Canada would like to reinforce some of the basic issues at stake that have been raised before you.

4.181 In 1998, the EC was found by the DSB in the *EC – Hormones* dispute to be acting inconsistently with its obligations under the *SPS Agreement*. In 1999, in an attempt to induce the EC to comply with its recommendations and rulings, the DSB authorized Canada to suspend concessions to the EC. Neither of these facts is contested. Pursuant to that authorization, Canada enacted the *European Union Surtax Order*, the measure now challenged by the EC. This is also not contested.

4.182 The EC adopted a Directive in 2003 that it considers to have implemented the recommendations and rulings of the DSB. The EC now claims that the moment that it notified the DSB that it had adopted this implementing measure, Canada was required either to remove its measure or to challenge the EC's measure. The EC claims that this is the case regardless of whether the DSB has confirmed its compliance.

4.183 How does it happen that Canada's measure enacted as a consequence of a multilateral authorization cannot be applied subsequent to the EC considering itself that it has brought itself into compliance and notifying the DSB to this effect?

4.184 Apparently the answer is that the EC is presumed to have complied such that its implementing measure prevails over Canada's duly-authorized measure. Moreover, not all measures of all Member States benefit from the same presumption. According to the EC, only those that satisfy some arbitrary criteria that have no textual basis in the terms of the DSU benefit from this presumption.

4.185 Despite the EC's efforts to make this dispute a case about presumptions, the key to resolving the dispute lies first in determining how, and at the initiation of which party, the actual compliance of the EC is to be confirmed multilaterally. In fact, all of Canada's actions at issue in this dispute can be explained – not in terms of Canada having made any determination about the compliance of the EC's amendments – but in terms of Canada requiring, in the absence of mutual agreement, multilateral confirmation that the EC has complied. The EC asserts that it has. Canada disagrees.

4.186 But the fact of the matter is that due to the existence of Canada's authorized suspension of concessions, neither the EC nor Canada on its own can make such a determination. The only determination of EC compliance that matters at this point is one that must be made by the DSB. And until that happens, Canada is under no obligation to remove its measure. The issue remains, however, as to how to have the DSB arrive at such a determination.

4.187 The EC would like to make this dispute about good faith. Canada does not question whether the EC is acting in good faith. For Canada, the issue is simply one of compliance, and more importantly, which party bears the burden of demonstrating the compliance of the measure taken by the EC to implement the recommendations and rulings of the DSB.

4.188 In our view, and as the EC itself readily admits, it is the party alleging the affirmative of a claim that bears the burden of proof. In this case, since it is the EC that is alleging that one of the three elements of Article 22.8 has been met, it bears the burden of proving it. The EC's claims notwithstanding, Article 22.8 is not "self-executing". To suggest that the EC needs simply to notify its "removal" in order for Canada to be required to remove its measure, is just another way for the EC to say that its unilateral declaration of compliance can terminate a multilateral authorization. Further, in this case it is the EC that is alleging that Canada's presumptively valid DSB authorized retaliation measure ceases to apply. The EC can only effect this by demonstrating the validity of its own measure.

4.189 With respect to DSU Article 23, this provision only applies where, subsequent to a WTO Member making a unilateral determination that another Member has violated a WTO obligation, the Member making the determination then seeks to redress that perceived violation by methods other than DSU dispute settlement. The question of unilateral determination in this case is a moot point. All WTO Members make their own assessments of the consistency of other Member's measures on a regular basis. What is relevant is whether a Member has acted on that assessment to seek redress outside of the dispute settlement process.

4.190 While the EC asserts that its violation that permitted the DSB to authorize Canada's measure no longer exists, it insists Canada must forego the exercise of that measure even where the EC declines to put the matter before a panel. Also, if we understand the EC correctly, even if Canada were to submit the matter to a panel, because of the presumed compliance of the EC's measure, Canada cannot apply its DSB authorized measure while that review takes place.

4.191 Is there a disagreement between Canada and the EC? The EC thinks its measure complies. As stated earlier, Canada disagrees. However, it doesn't follow that Canada is now obliged to initiate a panel under Article 21.5. In the past week the Panel has heard agreement that the DSU provisions we are dealing with contain many interpretative difficulties. Clearly the rules are not a model of clarity.

4.192 However, one thing is clear. Article 21.5 does not create an *obligation*. It creates a *right* that WTO Members can use in dispute settlement proceedings. Somehow, the EC reconstructs it as an obligation in conjunction with Article 23.

4.193 Canada is not advocating a formalistic approach to the termination of the DSB authorization. What we are saying is that Canada is entitled to rely on this DSB authorization until such time as the EC demonstrates to a WTO panel that the basis on which the DSB authorization was granted no longer exists. It is insufficient, as the EC has done in this case, to simply assert that the basis of the authorization no longer exists as a matter of fact. The EC must prove that this is so by demonstrating to this Panel that it has complied with the recommendations and rulings of the DSB. Until such time as the EC has met this burden, Canada's suspension of concessions remains authorized by the DSB.

G. SECOND WRITTEN SUBMISSION OF THE EUROPEAN COMMUNITIES

1. Introduction

4.194 The European Communities' case is straightforward. WTO Members that apply sanctions against another WTO Member cannot adopt a lean-back-and-wait-attitude over years and continue to suspend concessions in the presence of a subsequent compliance measure. Just as WTO Members who have been found to be in violation of the covered agreements have a positive obligation to implement, so have retaliating Members a positive obligation under Article 22.8 not to apply sanctions any more and/or, if they disagree with the compliance measure, to initiate WTO proceedings under Article 21.5 of the DSU. This has always been the practice in WTO proceedings. If a retaliating WTO Member fails to respect these rules and procedures under the DSU, it will be in violation of Articles 23.1 and 23.2(a) of the DSU.

2. PART 1: Violation of Articles 23.1, 23.2(a), 21.5 and 22.8 of the DSU (systemic issues)

(a) Canada is in violation of Article 23.1 and 23.2(a) read together with Article 21.5 of the DSU

4.195 The existence of a DSB authorization does not exclude that a WTO Member is still seeking to redress a violation within the meaning of Article 23.1 and making a determination under Article 23.2(a). The very fact of applying sanctions implies that a Member is seeking to redress a violation. And this in turn implies that this WTO Member has made a "determination" about the WTO-inconsistency of the measure. The application of these sanctions may be justified if a measure by a WTO-Member has been properly found to be WTO-inconsistent and, if on that basis, the DSB authorizes the suspension of concessions. However, the situation is different regarding the *continuation* of sanctions in the presence of a compliance measure which the DSB has not found to be WTO-inconsistent. A DSB authorization which has been granted in view of an original WTO-inconsistent measure can not justify the continued application of sanctions against a different measure which has never been found multilaterally to constitute a WTO-violation. Rather, since the application of sanctions requires a causal relationship to a WTO-inconsistent measure, any *present* application of sanctions must be linked to a *present* measure. Conversely, the *present* application of sanctions to a *past* and no longer existent measure is not justified as it would be unjustified to link the *present* application of sanctions to a *future*, not yet existing measure.

4.196 Canada's counter-argument would lead to the absurd result that Canada could continue to apply sanctions irrespective of any events occurring after the DSB authorization and thus ignoring the object and purpose of sanctions, i.e. to induce compliance and to rebalance rights and obligations in case of a WTO violation. If Canada applies sanctions merely because of the existence of a DSB authorization and irrespective of a subsequent compliance measure, it is neither inducing nor rebalancing anything.

4.197 The true motives for Canada's continued application of sanctions are revealed by Canada's reply to EC Question No.13. Canada makes a link of its current measure to the original purpose of the DSB authorization. Yet, as the original purpose of the DSB authorization was to induce compliance and to rebalance rights and obligations, Canada obviously determines that the EC compliance measure

has not achieved either and that, therefore, the original purpose still exists. By doing so, Canada acts in an illegal way because the continued application suspension of concessions is thus based solely on a unilateral determination of non-compliance. Canada's action also fits precisely into the definition of "seeking of redress" as developed by the relevant case law.

4.198 In this context, Canada has also met the threshold of a unilateral "determination" in violation of Article 23.2(a). The term "determination" is defined, *inter alia*, as an "authoritative opinion"; "a conclusion reached"; "the action of coming to a decision"; "the result of this"; "a fixed intention". This term has been further elaborated by the Panel in *US – Section 301 Trade Act*. Thus, even an implicit determination by the appropriate behaviour, such as the continuation of sanctions, would be covered by a "broad reading" of this requirement, in particular, if the continuation occurs deliberately and is accompanied by respective statements.

4.199 Moreover, the interpretation of the word "determination" should be guided by the context of Article 23.2(a), i.e. Article 23.1, and the object and purpose of this provision. This provision as a whole aims at preventing that a Member takes "the law in its hands" and seeks the redress of a violation on the basis of a unilateral determination. The importance of this general principle is confirmed by the title of this provision. The crucial importance of Article 23 has also been acknowledged by the Panel in *US – Section 301 Trade Act*. It is therefore necessary to look at a Member's behaviour as a whole when confronted with a respective situation. If a WTO Member repeatedly and consistently states that a violation by another Member exists and if, in this context, this Member applies concrete measures against the other Member, it can be concluded that this Member is seeking a redress against a violation on the basis of a unilateral determination. Applying these principles to the present case, there can be no doubt that Canada has made a unilateral "determination" of non-compliance of the EC measure. This is already demonstrated by Canada's comments in the SPS Committee in respect of the EC draft proposal as early as in 2000 as well as its comments in the DSB meeting of 1 December 2003.[18] Considering Canada's whole conduct there can equally be no doubt that Canada has made a "determination" since it deliberately *continues* to apply sanctions against the European Communities.

4.200 By refusing to initiate a compliance proceeding in this situation, the European Communities considers that Canada is also in breach of Article 21.5. Canada's counter-argument that such an obligation would "vitiate" the existence of the DSB authorization is fallacious as Canada is essentially saying that it cannot be obliged to invalidate its DSB authorization by initiating and losing an Article 21.5 proceeding. The European Communities does not believe that this is the correct reading of the DSU. Apart from policy reflections Canada has not offered any legal arguments on why the continued application of sanctions is not violating Article 21.5 in conjunction with Articles 23.1 and 23.2(a). Canada fails to understand that in this case the obligation to initiate a compliance review under Article 21.5 is linked to its continued application of sanctions against the EC compliance measure. Because of this continued application of sanctions against the European Communities, Canada is under a positive obligation to bring a compliance proceeding against the EC measure. Thus, in this specific situation, Canada's discretion regarding whether or not it is appropriate to initiate WTO proceedings is limited as the failure to do so automatically encroaches on the EC rights, i.e. its right not to be exposed to sanctions for a measure which another WTO Member unilaterally determines as WTO-inconsistent.

4.201 Canada's argument that an obligation to initiate a compliance proceeding in this specific situation would "seriously undermine" the WTO dispute settlement system is for these reasons equally not credible. The purpose of the WTO dispute settlement system is not the application of sanctions but to resolve disputes in a prompt manner. Canada's protracted application of sanctions and its refusal to initiate a compliance proceeding against the EC measure runs diametrically against this very basic

[18] WT/DSB/M/159.

objective of the WTO. The WTO dispute settlement system has to balance the interests of complaining and defending parties, it is not an exclusive tool for a retaliating Member. Consequently, a Member in violation of its WTO obligations is under an active obligation to comply. Conversely, the retaliating Member is under an active obligation to initiate a compliance review under Article 21.5 and failure to do so will result in a violation of Article 23.1, 23.2(a), 21.5 of the DSU.

4.202 Finally, the European Communities would take issue with Canada's theory regarding a self-initiated Article 21.5. As repeatedly stated in its Written and Oral Statement, it is not possible or meaningful to initiate a compliance review against its own implementing measure. The DSU is based on a contradictory proceeding whereby a complaining party alleges a WTO-violation against another party. Conversely, the DSU does not provide for a situation where a "complaining party" alleges the WTO-consistency of its own measure, in particular to prove the negative that its measure is *not* WTO-inconsistent. Contrary to what Canada asserts this is also clearly spelt out in Article 6. The terms "complaining party" and "complaint" cannot be read in the "broad sense" as Canada suggests. The *New Shorter Oxford Dictionary* defines the term "complaint" as a "formal accusation or charge, a subject or ground of dissatisfaction". Obviously a case initiated under Article 21.5 would not fulfil any of these definitions as the European Communities would not bring a "charge" against its measure or express any dissatisfaction about its compliance measure. By way of context, Articles 3.8 and 1.1 also demonstrate the proper distribution of the parties' roles under the DSU.

(b) Canada's continued suspension of concessions and related obligations is in violation of Article 23.1, read together with Articles 22.8 and 3.7 of the DSU

4.203 The European Communities disagrees with Canada's assertion that the continued application of the sanctions is unrelated to the EC compliance measure. Since the original EC measure has been removed, Canada's argument would mean that Canada is currently applying sanctions against a non-existent measure. Such a conclusion would not only be illogical but also in plain contradiction with the very purpose of sanctions, namely to rebalance rights and obligations and to induce compliance in the light of a *current* WTO violation. Instead, as explained several times, it is obvious that Canada continues to apply sanctions because it considers the EC compliance measure as WTO-inconsistent. However, the continued application of an "old" DSB authorization cannot be justified against a "new" measure on which the DSB authorization is not based and if this measure has never properly been found WTO-inconsistent.

4.204 Contrary to what Canada believes the prohibition to continue the application of sanctions under Article 22.8 of the DSU does not depend on whether the DSB authorization has formally been removed. Article 22.8 of the DSU is unequivocal in the sense that the suspension of concessions and related obligations may only be "applied" until the inconsistency of the measure has been removed. Canada constantly fails to acknowledge the difference between the "existence" of a DSB authorization and the "application" of sanctions. Under Article 22.8 it is quite noteworthy that the scope of application of sanctions is limited to a "measure found to be inconsistent with a covered agreement". Yet, the only way to "find" a measure to be WTO-inconsistent under the DSU is through the multilateral procedure. Consequently, it is not possible to apply sanctions under Articles 22.8, 23.1 solely on the basis of a "unilateral finding" of inconsistency. In the same vein, the continuation of sanctions cannot be based on a unilateral finding of inconsistency of the compliance measure. In this context, the self-executing nature of Article 22.8 also needs to be taken into account. The termination of the application of sanctions under this provision does not depend on a specific finding of the DSB or a withdrawal of the DSB authorization. Rather, once the conditions under Article 22.8 of the DSU are met – including in the presence of an unchallenged compliance measure – the application of suspension "shall" stop.

4.205 The European Communities also takes issue with Canada's assertion about the reversed burden of proof in this "post-suspension scenario". Apart from the fact that Canada's theory is rooted

in the misconception that otherwise the DSB authorization would be terminated merely on the basis of a presumption of good faith compliance it has also no basis whatsoever either under WTO law or under public international law. The WTO jurisprudence is crystal clear that the party bearing the burden of proof is the one that asserts the *affirmative* of a claim or defence. Furthermore, the burden of proof is one concrete example of the general good faith principle, i.e. the presumption of compliance. This principle applies to an implementing measure as such but not to a specific timing when the measure had been adopted. The absurdity of Canada's theory is best exemplified in the present case where the European Communities had to study in detail the difficult scientific questions. Because of its carefulness the European Communities was not in a position to respect the reasonable period of time (RPT). Yet, according to Canada, if the European Communities had hastily adopted a compliance measure within the RPT this measure would benefit from a presumption of compliance whereas a measure which has been prepared with much more carefulness does not.

4.206 Even though there might be a question about the relationship between this principle and the "application" of a DSB authorization, the DSU also provides for a solution to this question which is the compliance proceeding under Article 21.5. Thus, if a retaliating Member contests the WTO consistency of an implementing measure it must initiate a compliance proceeding. In this context, Canada's argument to the security and predictability of the trading system is also off the point. In Canada's view the only secure and predictable way of the trading system is obviously the application of sanctions. However, the application of sanctions under the DSU is not an objective in itself. The application of sanctions is designed to achieve full compliance with the WTO obligations by another Member. Thus, if a violating Member has adopted compliance measures in good faith, it is indeed a matter of security and predictability of the trading system that the application of sanctions ceases to apply, if these measures are never properly challenged.

4.207 Finally, the European Communities disagrees with Canada's theory regarding the way a DSB authorization may be terminated which is not supported by the text of the DSU. As explained in detail in the EC second written submission, Canada's theory contains a number of inconsistencies such as that it is the DSB that recommends to itself the termination of the authorization or perhaps the panel that recommends to the DSB to do so (contrary to Article 19) or in respect of an implicit revocation of the authorization through the adoption of reports. Yet, one wonders how such a recommendation could be made given that under Canada's theory, the DSB authorization makes the continued sanctions *by definition* legal. Also, this raises the question how the suggested implicit authority can be squared with Article 2.1 which explicitly lists the tasks of the DSB. An implicit revocation of a DSB authorization is not included in this list. In the same vein, Article 2.4 refers to the decision-making powers of the DSB "where the rules and procedures of this Understanding provide". Yet, Canada cannot explain where the DSU provides for such an implicit revocation of a DSB authorization. Furthermore, under Canada's theory new "claims" would suddenly become "defences" even in case of a self-initiated Article 21.5 proceeding. This means in other words that Canada assumes a right to redraft the Panel's terms of reference on the basis that a new claim (e.g. a violation of Article III) is a "defence" against an old claim (e.g. Article I). However, Canada cannot explain how an alleged violation of Article I could be "defended" by a new violation under Article III. Moreover, Canada appears to arguing the absurd theory that the subject-matter of an Article 21.5 is not only the compliance measure but also the application of the sanctions which is however, in plain contradiction to the terms of Article 21.5.

3. PART 2: The WTO-consistency of the EC compliance measure

4.208 The European Communities, in its Oral Statement at the first substantive hearing as well as in a number of replies to the Panel's questions, has explained the various steps undertaken to carry out the comprehensive risk assessment which led to the adoption of its implementation measure, i.e. the revised Hormones Directive 2003/74/EC. As the Appellate Body found that the studies and other evidence presented by the European Communities was relevant but not sufficiently specific, the

objective of the compliance effort undertaken was to re-assess all existing and most recent data from any relevant source for the six hormones and to complement these data in particular in three respects, namely: (a) on certain issues regarding specific health risks from residues in meat treated with hormones for growth promotion purposes, (b) on risks arising from possible abusive use and difficulties of control, and (c) on an appropriate risk assessment for melengestrol acetate (MGA), which had not been carried out so far. To this effect the European Communities launched 17 specific studies and tried to collect information from all relevant sources, including from third countries, international scientific bodies (such as JECFA) and industry. All these steps were undertaken in full transparency and after consulting the relevant scientific committees and bodies that are responsible under Community law to conduct this kind of assessment.

4.209 In November 1998, the European Communities mandated its Scientific Committee on Veterinary measures relating to Public Health (SCVPH), to address the potential risks to human health from hormone residues in bovine meat and meat products treated with the six hormones for growth promotion. The SCVPH adopted its opinion unanimously taking into account all pertinent scientific information available at the time, including JECFA's revised assessment of the three natural hormones oestradiol-17β, testosterone and progesterone that had been issued in February 1999. The 1999 Opinion concluded that a risk to the consumer had been identified with different levels of conclusive evidence for the six hormones evaluated. Subsequently, the SCVPH was twice requested to review its opinion in light of new assessments carried out by other bodies or institutions and new evidence. The SCVPH did so in 2000 and 2002. The SCVPH concluded both times that the new evidence did not provide convincing data and arguments demanding revision of its previous conclusions. On the basis of the above scientific risk assessments provided by the SCVPH, the competent European regulatory authorities carried out an analysis of risk management options in light of the appropriate level of protection it had chosen. This lead to the adoption of the EC' compliance measure 2003/74/EC.

4.210 As explained in detail in the second written submission, JECFA's assessment proved insufficient in various respects and where the SCVPH conducted a more thorough analysis. These areas concern *carcinogenicity* of the three natural hormones and the outdated *residues data* as well as for data concerning the dose-response relationship. In respect of the latter, JECFA also neglected the endogenous production in the case of *pre-pubertal children.* Furthermore, the 1999 JECFA report has been seriously undermined by recent developments concerning the *bioavailability* of residues of these hormones. JECFA also failed to address the possibilities for *misuse or abuse* when the administration of these hormones is freely authorized "over the counter", as is the situation in the United States.

4.211 Turning to the legal arguments, the European Communities disagrees with Canada's arguments regarding the burden of proof. The European Communities, at the oral hearing and in reply to the Panel's questions, has demonstrated a violation of Articles I:1 and II of the GATT 1994 by Canada and that the measure found to be inconsistent has been "removed" in the context of a direct claim under Article 22.8. In particular, the European Communities has pointed out that it cannot be required to prove a negative, namely that there is no violation of WTO obligations. In line with the established case law of the Appellate Body, it is for Canada, in this case, to set out a prima facie case of violation, and not for the European Communities to set out a case of non-violation.

(i) The ban on oestradiol-17β is in conformity with Article 5.1

4.212 The European Communities conducted a proper risk assessment within the meaning of Article 5.1 and Annex A Point 4 of the *SPS Agreement*. The European Communities has pointed out in its reply to Question 24 of the Panel, that there is a difference between a scientific risk assessment in the narrow sense clearly referred to here by Canada and the risk assessment within the meaning of Article 5.1 and Annex A Point 4 of the *SPS Agreement*. The latter, as has been stated by the Appellate Body, also comprises a risk management stage which is the responsibility of the regulator to carry out and not the scientific bodies. Canada concentrates its arguments on the alleged flaws in

the scientific risk assessment of the SCVPH and the European Communities will reply to these arguments.

4.213 Canada submits a series of factually and legally incorrect arguments in respect of the identification of the adverse effects. In particular, as the European Communities' written and oral submissions have shown, Canada's arguments are based on outdated data of its own or of JECFA and misinterpret the findings of the latest scientific evidence, including that generated by the 17 EC studies. Indeed, all the references in Canada's submissions are confined essentially to the findings of JECFA of 1988 and 1999 for the three natural hormones and of 2000 for melengestrol acetate. However, these findings by JECFA did not take into account the more recent evidence on which the 1999-2002 evaluations by the SCVPH are based. To overcome this obvious difficulty, Canada argues that the findings of the SCVPH are not specific to residues in meat. This argument of Canada is flawed, because the 1999 and 2002 Opinions of the SCVPH have a specific chapter for each of the six hormones about the dose-response question and the potential risks from residues in meat from animals treated with these hormones for growth promotion. Canada ignores the fact that even JECFA has declared oestradiol-17β for the first time in 1999 to have "genotoxic potential", which means that there is normally no safe threshold for any amount of residues in meat from this hormone. So the issue of specificity for this hormone becomes irrelevant. Canada's claims are also contradicted by the most recent evidence (the US for the first time in 2002 recognised in its National list of carcinogen oestradiol to be a proven carcinogen), which indicates that there is no safe threshold for this hormone. The SCVPH finding is also confirmed by more recent literature as well as more recent data of endogenous production by pre-pubertal children.

4.214 Canada's statement that the SCVPH Opinions did not clearly identify the presence of adverse effects is also incorrect as demonstrated by pages 41 to 43 and 72 of the 1999 Opinion. It is also incorrect, as demonstrated by the JECFA report, to allege that the SCVPH opinion based its conclusions on the genotoxic effects of oestradiol-17β on a hypothesis that is not recognized elsewhere. The UK Sub-Group Report also acknowledges the risk of genotoxic effects of oestradiol-17β. Finally, it is true that some foods that are part of a balanced human diet naturally contain oestradiol-17β. However endocrine hormones regulate a variety of physiological functions and their balance is a very delicate matter; in particular pre-pubertal children are the group of greatest concern in this respect. It is therefore necessary to reduce the amount of additional hormones the population is exposed to to a level that is as low as reasonably achievable by avoiding excess intake due to the use of hormones as growth promoters. It is necessary that substances used in animals provide reasonable certainty of no harm in particular if their use does not provide any benefit for the animals treated that would justify the tolerance of such harm. Therefore, if oestradiol-17β increases, e.g. the incidence of breast cancer as more recent studies seem to indicate, any avoidable increase, however small, is not desirable.

4.215 Contrary to what Canada asserts the risk assessment did also evaluate the potential occurrence of the adverse effects it purports to identify. This issue is referred to in the SCVPH Opinions in several points as specified in the EC second written submission. Furthermore, in arguing that the ban on oestradiol-17β is not based on a risk assessment, Canada essentially repeats the argument on the lack of specificity of the risk assessment which is, as explained, not of any value.

(ii) The provisional bans on five of the hormonal substances do not violate Article 5.7

4.216 Contrary to what Canada argues the provisional bans on the five hormonal substances progesterone, testosterone, trenbolone, zeranol and MGA are in conformity with Article 5.7 of the *SPS Agreement* because the current evidence is insufficient. The European Communities recalls that: (1) what the European Communities had considered to be sufficient evidence had been found to be insufficient by the Appellate Body and proved indeed to be insufficient also in the light of risk assessment standards that were developed in the years after the *EC – Hormones* decision; and (2) the

body of evidence, in the meantime, has developed and, while still not providing enough knowledge to carry out a complete and definitive risk assessment, supports the conclusion that precautionary measures are required in order to achieve its chosen level of protection.

4.217 As further detailed in its Written and Oral Submissions, the European Communities considers, on the basis of the 1999 – 2002 SCVPH opinions, that the current evidence is full of gaps in pertinent information and important contradictions that render the conclusions reached by JECFA in 1988, 1999 and 2000 no longer valid. Thus, it does not allow in qualitative or quantitative 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*. Furthermore, since the latest risk assessment by the SCVPH in 2002, there appeared internationally a number of further scientific developments all of which converge toward, and provide further support to, the conclusions reached by the relevant scientific committee of the European Communities, such as a study supported by the Ohio State University, the US National Cancer Institute and the US Department of Defence Breast Cancer Research program concerning zeranol (and oestradiol-17β) or a large scale epidemiological study in Europe suggesting that high red meat intake is associated with (statistically significant) increased colorectal cancer risk, confirming results from previous smaller studies. Additionally, in 2002, the women's health Initiative Randomised Controlled Trial published findings indicating that the risks outweigh the benefits from the use of oestrogen plus progestin in healthy postmenopausal women, thus reinforcing the previous findings made by the IARC in this respect. All this evidence and most recent scientific developments have now clearly tipped the balance against the previously held assumption (by Canada and Codex/JECFA) that residues of these hormones in meat from animals treated for growth promotion pose no risk to human health.

4.218 Consequently, the evidence which served as the basis in the 1988 and 1999-2000 JECFA evaluations of these hormones is not sufficient to perform a definitive risk assessment, in particular by the WTO Members applying a high level of health protection of no risk from exposure to unnecessary additional residues in meat of animals treated with hormones for growth promotion. To deny the existence of this new scientific reality would deprive the European Communities and other WTO Members of their autonomous right to choose their appropriate level of protection, because it would in effect impose on them a requirement to demonstrate positively the existence of clear harm, which they may not always be able to fulfil in case of cancer because of the long latency period and the numerous confounding factor that play a role. This will render the application of Article 5.7 impossible in a situation where the body of the pertinent scientific evidence is in the process of moving from a state of presumed "sufficiency" into a state of pertinent "insufficiency". The text and preparatory history of the *SPS Agreement* do not support such a (restrictive) construction of Article 5.7, which would moreover be against the principle of effective treaty interpretation.

4.219 Finally, Canada has not put forward any specific arguments as to why the available pertinent information on the five hormonal substances in question would not be insufficient, but instead sufficient. It has therefore failed to meet the burden of setting out any prima facie claim.

4.220 In any case, in its second written submission the European Communities has set out in detail the state of insufficient evidence as determined by the SCVPH for each of the hormones which have been provisionally (progesterone, testosterone, trenbolone, zeranol, MGA) prohibited by the Directive 2003/74/EC. In particular, as regards zeranol, Canada does not put forward any specific argument as to why the evidence assessed by the SCVHP would not be insufficient. The only assessment on zeranol publicly available is that of JECFA which dates back to 1988. The SCVPH took into account this assessment but disagreed with a number of its basic findings on the bases of more recent scientific evidence, some of which was generated by the 17 EC studies. Moreover, the most recent study on zeranol and the risks associated with its administration to meat producing animals is done by independent US scientists mentioned above and it clearly invalidates the findings of the 1988 JECFA opinion.

4.221 Furthermore, as regards MGA, there is currently no international standard or recommendation on MGA, as Codex has not adopted one. JECFA assessed MGA for the first time in 2000 (and in 2004 as regards the calculation of the MRL only), but this has not yet led to the adoption of a standard. If one examines the evidence that served as the basis of the 2000 JECFA report it can be seen that nearly all the studies referred to therein date from the 1960s and 1970s. These very old studies constitute in fact the evidence which the defending parties have refused to provide to the European Communities, despite its repeated requests on the grounds that they are confidential. In the absence of a Codex standard, the opinion of JECFA becomes irrelevant, for the additional reason that it failed to take into account the more recent data generated by the 17 EC studies and the 2002 SCVPH assessment. Canada does not put forward any specific argument as to why the evidence assessed by the SCVPH would not be insufficient. It does not even refer, in this context, to the fact that MGA, in the meantime (2000), has been assessed (for the first time) by the JECFA and which subsequently has been taken into account by the SCVPH in its 2002 Opinion.

4.222 The European Communities adopted the provisional prohibitions on the basis of the available pertinent information. The only argument that Canada raises in this regard is that the European Communities' measure is not based on JECFA's assessment. However, as the European Communities explained, JECFA's assessment was considered to be insufficient, because, *inter alia*, it was found to be outdated.

4.223 The European Communities has also not violated its obligation to seek to obtain the additional information necessary for a more objective assessment of risk or to review the measure in question. Canada does not put forward any convincing argument as to why the European Communities would have failed to fulfil its obligation to seek additional information. Indeed, the European Communities has specifically laid down that obligation in Directive 2003/74/EC. As a matter of fact, it has already undertaken initiatives to seek additional information. In particular, it has issued a new call for scientific data and research from 2002 onwards, on substances with hormonal activity which may be used for growth promotion purposes in bovine meat.

4.224 In the view of the European Communities, and as explained in reply to the Panel's Question 71, a requirement to review a measure "within a reasonable period of time" can only apply as of the coming into effect of the provisional measure in question. The Directive has come into effect on 14 October 2003. Thus, it can hardly be argued that a reasonable period of time has actually already elapsed.

4.225 The European Communities has moreover pointed out that Directive 2003/74/EC contains an obligation to "keep the measures applied under regular review with a view to timely presentation … of any necessary proposals." Regular review certainly implies reacting, as appropriate, to new evidence or information that may appear. As a matter of fact, the only new information that has come to the knowledge of the European Communities is the recent draft assessment of the UK Group. That draft report has already been forwarded to European Food Safety Authority for review. Equally, should the recent call for new scientific information (see above) yield any new evidence, such evidence would also be assessed by EFSA without any undue delay.

4.226 In conclusion, Canada has not put forward any convincing arguments to support its claim that the European Communities has violated Article 5.7 of the *SPS Agreement* in adopting a provisional ban on the five hormonal substances progesterone, testosterone, zeranol, trenbolone and MGA.

H. SECOND WRITTEN SUBMISSION OF CANADA

1. Introduction

4.227 Canada will demonstrate again that the EC's allegations under the DSU are without merit. The EC has recognized that the real object of these proceedings is to review the compliance of the EC measure with the recommendations and rulings of the DSB in *EC – Hormones*. Canada will elaborate further on that issue in this rebuttal submission.

2. The EC's claim under the DSU

(a) Canada has not acted inconsistently with Article 23.1 of the DSU

4.228 The EC claims that DSU Article 23.1 read "in conjunction with" Articles 23.2(a) and 21.5 imposes a new obligation on Canada that finds no textual basis, in that DSU Article 21.5 does not contain an obligation for any WTO Member to initiate compliance proceedings. The EC also claims that Article 23.1 "in conjunction with" DSU Articles 22.8 and 3.7 removes Canada's right to act in accordance with the DSB authorization to suspend concessions without multilateral intervention by the DSB (contrary to DSU Articles 3.2 and 19.2). This interpretation of DSU Article 22.8 would render WTO inconsistent, without multilateral confirmation of the EC's compliance, a Canadian measure enacted pursuant to a multilateral authorization.

4.229 Canada's continued application of an authorized measure suspending concessions cannot be a conduct inconsistent with Article 23 of the DSU simply because the EC claims it has complied. The EC's adoption and subsequent notification to the DSB of its purported implementing measure does not change the legal basis for Canada's measure. Given that the EC is responsible for obtaining multilateral confirmation that it has complied, Canada's conduct is not "seeking redress". The term 'redress' implies a reaction by a Member against another Member, because of a perceived WTO violation, with a view to remedying the situation. Canada's conduct is not aimed at remedying any perceived violations by the EC, but is based on the DSB authorization.

(b) Canada has not acted inconsistently with Article 23.2(a) of the DSU

4.230 Given that Canada is not "seeking redress", Canada cannot have made a "determination" within the meaning of Article 23.2(a) of the DSU. That provision applies only where a Member is seeking redress of a WTO violation. The panel in *US – Section 301 Trade Act* is the authority for this.

(c) Canada has not acted inconsistently with Article 22.8 of the DSU

4.231 Where concessions have been suspended on the basis of an authorization by the DSB (and absent a mutually satisfactory solution), the onus is on the Member originally found to be non-compliant to take steps to confirm multilaterally that it has satisfied at least one of the conditions of Article 22.8. Without such multilateral confirmation, the DSB authorization remains in effect and continues to authorize the suspension of concessions by the original complaining Member. The EC objects to this interpretation of its obligations on several unsustainable grounds.

(i) The EC must confirm its compliance in EC – Hormones

4.232 The result of the EC's failure to comply within the reasonable period of time is that it bears the burden of demonstrating that it has now complied with the recommendations and rulings of the DSB in *EC – Hormones* if it wishes to have the suspension of concessions no longer applied. Given that the 2003 Directive simply amends the 1996 Directive, a review of the compliance of this measure is not an abstract exercise about a review of the EC's compliance in this context. The DSB

authorization does not provide "absolute justification" for any behaviour. Rather, until the EC receives multilateral confirmation that it has brought itself into compliance, Canada is entitled to continue to rely upon the authorization. The immediate threshold issue is therefore which party bears the burden of confirming the compliance. The requirement that the EC bear this burden if it wishes to have the suspension of concessions ended is simply the logical consequence of the position in which the EC has placed itself in the *EC – Hormones* dispute.

(ii) Article 22.8 of the DSU is not "self-executing"

4.233 DSU Article 22.8 cannot be "self-executing" in the light of the overall DSU regime of surveillance in circumstances of non-compliance. In the light of the object and purpose of the DSU, and in the context of the other provisions relating to non-compliance, Article 22.8 requires multilateral confirmation that the conditions precedent have been satisfied before the suspension of concessions can no longer be applied. The authorization to suspend concessions as a result of a failure to comply is granted solely by the DSB. A subsequent, unconfirmed claim that Article 22.8 has been met is insufficient on its own to displace the multilaterally-agreed surveillance regime, regardless of how much effort is put into the measure underlying the claim.

4.234 The EC confuses several distinct issues related to "good faith" and "bad faith". The suggestion by the EC that denying the presumption of compliance would be tantamount to a finding of bad faith should be rejected. The issue of a presumption against bad faith is an entirely separate matter from that of compliance. A finding that a Member does not comply with its WTO obligations amounts to neither an accusation nor a finding of bad faith. According to the EC, the alleged self-executing nature of Article 22.8 is based on the degree to which its efforts to comply are serious and in good faith. Presumably, those who do not satisfy the criteria put forward by the EC bear the burden of demonstrating compliance, whereas those who do satisfy these criteria do not. However, the EC is silent on the mechanisms to determine whether a Member satisfies these criteria. It is to avoid this kind of subjective application of "criteria" that multilateral confirmation is required to give effect to Article 22.8.

4.235 The adoption of a measure in one Member cannot be allowed automatically to render WTO inconsistent a measure of another Member, without some intervening international act. In the light of the overall regime of compliance, the dispute settlement system requires actual findings of compliance or non-compliance before Article 22.8 can be given effect. That the EC bears this burden is the consequence of the status of non-compliance in which it has placed itself.

(iii) The DSB authorization need not be formally terminated

4.236 The obligation to remove the suspension of concessions does not only arise with the formal revocation of the authorization by the DSB. The more important substantive act (between the EC's claim of compliance and the acquisition by Canada of an obligation to remove the suspension of concessions) is "multilateral confirmation" that the EC measure found to be inconsistent in *EC – Hormones* is no longer inconsistent. While no specific provision in the DSU requires the formal revocation of the authorization, this does not mean that there cannot be an act by the DSB that is equivalent to revoking the authorization, whether that is implicit or explicit. The "multilateral confirmation" of compliance would generally come in the form of adoption by the DSB of panel findings of compliance. Thus "confirmation" of compliance and the "revocation" of the authorization are essentially the same act of the DSB.

(iv) The EC has several mechanisms to confirm compliance

4.237 The EC could have obtained multilateral confirmation of its compliance through DSU Article 21.5 proceedings. Nothing prevents the EC from initiating such proceedings. Nor, where

compliance is found, are there any limitations on the jurisdiction of such a panel preventing it from making recommendations to the effect that the DSB authorization should no longer apply.

4.238 The EC may also choose to confirm its compliance in proceedings *de novo*, such as in these proceedings, in order to have the DSB authorization terminated. The main objective of these proceedings should be a review of the compliance of the EC with the recommendations and rulings in *EC – Hormones*. The EC bears the initial burden of proof to demonstrate compliance.

3. The EC's compliance in *EC – Hormones*

4.239 In *EC – Hormones,* the EC measure was found inconsistent with the requirements of Articles 3.3 and 5.1 of the *SPS Agreement*. The EC now asserts that it has complied, on the basis that its permanent ban on oestradiol-17β is supported by a risk assessment within the meaning of Article 5.1 and that its provisional ban on the other five hormone growth promotants is justified under Article 5.7. It has failed to demonstrate this.

(a) The relevant international standards and the EC's level of protection

4.240 Pursuant to Article 3.3 of the *SPS Agreement*, the EC must demonstrate that there is "scientific justification" for its determination that international standards are "not capable of achieving [its] chosen high level of protection" of "zero additional risk". Whereas Codex established MRLs for TBA and zeranol, and decided that none was necessary for oestradiol-17β, testosterone and progesterone, the EC has determined that no threshold exposure levels can be established for any of the six hormones when administered for growth-promotion purposes. Since the SCVPH opinions fail to identify any "additional risks" from ingestion of residues of the six hormones at levels that comply with international standards, they fail to demonstrate that existing international standards are not capable of achieving the EC's appropriate level of protection. The EC measure is therefore also inconsistent with Article 3.3.

(b) "Risk management" under the *SPS Agreement*

4.241 The EC asserts that the risk assessment required by the *SPS Agreement* is "wider in scope" than risk assessment techniques developed by international organizations, that the latter is simply a scientific process, and that the former takes other factors into account at the "risk management" phase. The EC then submits that the three SCVPH opinions constitute a risk assessment only in the narrow sense, and argues that the "wider" risk assessment includes the process of weighing policy alternatives and selecting appropriate control options. This distinction between "risk management" and "risk assessment" is problematic for several reasons.

4.242 First, it finds no support in the *SPS Agreement* or WTO jurisprudence. The EC suggests that the Appellate Body findings in *EC – Hormones* mean that any element of what could be called "risk management" is part of a "wider" risk assessment. However, the findings cited only mean that certain factors cannot be excluded *a priori*. Based on its misreading of the findings, the EC makes the same error as the panel in *EC – Hormones*. Whereas the panel in that case erred in excluding certain factors from the risk assessment on the basis of its distinction, the EC now asks this Panel to include all factors in the risk assessment. This is an erroneous interpretation.

4.243 Second, the EC does not identify the "regulatory authority" responsible for "risk management", which policy alternatives it weighed and whether there is any documentation in support of this evaluation. It simply asserts that its authorities decided that hormones create an "avoidable risk". The EC has therefore not complied with the Panel's request for documentation and supporting information, suggesting instead that the mandate of the Panel is limited to reviewing the narrower,

scientific risk assessment. However, all components of the wider risk assessment should be subject to review.

4.244 Third, the EC inappropriately assimilates the appropriate level of protection, and the adoption of the SPS measure, directly into the risk assessment process. It includes "risk management" in the "wider" risk assessment and then includes in "risk management" the right to set the appropriate level of protection and implement appropriate control options. However, risk management cannot be both part of the risk assessment and part of the process of setting the appropriate level of protection and implementing control options. The EC's interpretation essentially renders meaningless the obligation that SPS measures be based on a risk assessment. The factors that can be considered in a risk assessment are clear, such as those listed in Article 5.2 and including non-scientific and non-quantitative analysis as well as evidence related to misuse. Those factors should be assessed here and not some undefined notion of risk management that finds no support in the *SPS Agreement*.

(c) The risk assessment and the EC's permanent ban on oestradiol-17β

4.245 The EC has failed to demonstrate sufficiently its claim that it has complied with *EC – Hormones* by basing its permanent ban on oestradiol-17β on a risk assessment.

(i) The SCVPH opinions do not amount to a risk assessment

4.246 The SCVPH opinions do not sufficiently complete the two-part analysis identified by the Appellate Body as the requirements of a risk assessment. Furthermore, they do not satisfy the requirement of Article 5.1 to take into account techniques developed by the relevant international organizations, which provide context and guidance to the Appellate Body's two-part test.

4.247 The EC qualifies this failure by arguing that risk assessments are "deterministic" and address poorly "non-linear" situations (presumably referring to genotoxicity). However, the fact that genotoxicity findings may change the approach taken in a risk assessment does not grant the EC licence to avoid completely its requirement, especially when those findings are speculative. Nor can it justify the deficiencies of the risk assessment with respect to other "linear" adverse effects. The EC argues that an exposure assessment is unnecessary when the data are unavailable, but its own scientific studies generated exposure data, finding that exposure to oestradiol-17β from meat from treated animals amounted at most to 16.6 percent of the ADI. In any event, other reputable scientific bodies have conducted complete risk assessments without encountering the limitations expressed by the EC.

4.248 The EC then claims the "table of contents" of the 1999 SCVPH opinion demonstrates that it is a risk assessment. Without any clear explanation by the EC, the table of contents is an unhelpful guide to understanding whether the SCVPH conducted a hazard characterization or a risk characterization. The EC points only to two excerpts that are summaries of the SCVPH's genotoxicity hypothesis and its speculation about the consequences. Neither excerpt amounts to a qualitative or quantitative evaluation of the nature of the adverse effects.

4.249 The SCVPH fails to conduct a dose-response assessment due to its conclusion that no threshold level can be established for genotoxic metabolites or for substances which might have other adverse effects. It provides no justification for its *a priori* rejection *of* the widely-accepted view that adverse effects arising from hormonal activity are dose-dependent. The EC defends the SCVPH on the basis that international risk assessment techniques only recommend such an assessment, but its obligation is to base its measure on a risk assessment that complies with the *SPS Agreement*. The EC refers to a reference in *EC – Hormones* to "qualitative assessment" to suggest that quantitative analysis is not required at any stage of its risk assessment. However, the Appellate Body found that a risk assessment need not identify a minimum, quantifiable magnitude of risk; it did not suggest that a

risk assessment could be conducted without any empirical evidence related to dose-response. An evaluation of the potential occurrence of adverse effects would seem nearly impossible without some idea of the dose of a substance required to provoke an adverse effect. A qualitative assessment is not simply a licence to substitute speculation and hypotheses for objective scientific analysis.

4.250 The SCVPH also failed to conduct an exposure assessment, yet the lack of data on residues in meat does not prevent it from drawing definitive conclusions about the risks arising from exposure to hormone residues from treated meat. The EC argues instead that its risk assessment was not required to conduct an exposure assessment in the light of the EC's decision to allow "zero additional risk". Since the EC has identified that hormones in general have adverse effects, and since consuming meat from treated animals presumably leads to higher intakes of hormone residues, consuming meat from treated animals must generate "additive risks", which according to the EC is all that is required. The EC does not demonstrate that hormone residues from meat from treated animals on their own create risks, nor does it identify the risks to which these hormones are said to be "additive".

(ii) The genotoxicity findings of the risk assessment

4.251 On the basis of the SCVPH's conclusion that oestradiol-17β is genotoxic, the EC rejects other international scientific bodies' findings, ignores current international standards, discounts traditional risk assessment techniques, characterizes hazards without assessing dose-response data, dismisses traditional scientific understanding about the bioavailability of oestradiol-17β, refuses to establish a dose-threshold level, and declares irrelevant the fact that growth promotants are used in low doses in animals. However, the SCVPH conclusion on the genotoxicity of oestradiol-17β is not supported by the evidence.

4.252 First, the SCVPH acknowledges that its conclusion that one single reactive metabolite of oestradiol-17β can damage DNA and lead to tumour initiation is simply a hypothesis. Its conclusion disregards established evidence that bodily mechanisms exist to control the formation of potentially genotoxic metabolites *in vivo* and to eliminate DNA adducts. Considering the SCVPH's acknowledgement that it has no "data on the genotoxic effects of exogenous low-dose oestrogens", its genotoxicity conclusion amounts to merely the identification of theoretical risk.

4.253 Second, other scientific and regulatory authorities have all indicated that the SCVPH's genotoxicity conclusion is more theory than reality. While acknowledging the "genotoxic potential" of oestradiol-17β, JECFA found this would not occur in vivo at physiological concentrations. The CVMP and the Veterinary Products Committee both concluded that there is no evidence that oestradiol-17β is genotoxic. In 2005, The Veterinary Products Committee agreed that oestradiol-17β may have genotoxic potential in theory, but found that there was a "threshold for carcinogenicity". The Australian Department of Health and Ageing found that even though oestradiol-17β may have genotoxic potential there is "no evidence that these occur *in vivo* at levels that would outstrip normal DNA repair mechanisms."

4.254 Third, the EC does not appear to believe that oestradiol-17β is genotoxic. Despite the EC's decision not to allow exposure to even one molecule of oestradiol-17β from meat from treated animals, it is strikingly silent on potential risks arising from all other sources of oestradiol-17β. The EC defence of zootechnical and therapeutic uses of oestradiol-17β is a response one would expect to dose-dependent adverse effects. The one single molecule from meat derived from treated animals that the EC considers so dangerous is suddenly not at all dangerous when consumed from meat from animals treated for other purposes. The risk of adverse effects from the genotoxicity of oestradiol-17β residues in meat from treated animals is more "theoretical uncertainty" than real-world risk. Theoretical uncertainty is not the kind of risk to be evaluated in a risk assessment, and the EC's genotoxicity conclusions cannot be used to warrant its measure.

(iii) The risk assessment is not "sufficiently specific"

4.255 The SCVPH opinions do not assess the specific risks associated with hormone residues in meat derived from treated animals, claiming that general evidence of hormone metabolites' genotoxicity renders specific evidence of residue genotoxicity unnecessary. Not only is there no convincing evidence of genotoxicity, but the specificity requirements in *EC – Hormones* cannot be so summarily disregarded. Even if the SCVPH's hypothesis is accepted, the SCVPH must confirm that a single reactive metabolite will actually result from low doses received from meat from treated animals. Instead, the EC's studies fail to find evidence of such metabolites.

4.256 The EC defends the SCVPH's failure to evaluate the dose of residues from meat from treated animals by stating that low dose is not relevant, and by asserting that the SCVPH did "take into account" the dose. However, it provides only the SCVPH's estimates of how much residue of oestradiol-17β will be consumed through animal tissues, without assessment of whether these residues create any specific risks. The SCVPH's assessment of hormone exposure from treated animals is therefore mere speculation about what these specific risks might be.

4.257 The EC further argues that it is necessary only "in principle" to assess the specific risk, that there are "important qualifications" to this obligation, that it cannot assess the specific risk due to the difficulty in estimating intake of residues from meat, and that it cannot estimate intake due to the variability of consumer exposure patterns and the lack of information about good veterinary practices. Not daunted by the absence of this evidence, the EC concludes by speculating that the only rationale that can be inferred from the available scientific data is that the higher the exposure to residues from these hormones, the greater the risk is likely to be.

(iv) Adverse effects from misuse and misplaced hormone implants

4.258 The EC disagrees with international standards, citing concerns about the difficulty in ensuring they are administered according to good veterinary practice. It has not provided a risk assessment evaluating the existence and level of risk arising from the potential for failure to comply with such practice. Instead, it refers to studies which purportedly formed the basis of the SCVPH's conclusions that implants are misused or misplaced "frequently" or "in daily routine", although such studies merely involve "experiments" addressing whether consumers would be exposed to higher doses of residues if hormone implants were misused. They address neither the actual occurrence of misuse, nor whether misuse would increase the potential occurrence of adverse effects. They also indicate that under misuse conditions, intake of hormone residues remains well below established ADIs. The EC only speculates that abuse leads to an increase in the potential occurrence of adverse effects. A risk assessment cannot be based on speculation about theoretical risks, but must address risks in the real world.

(d) The provisional ban is inconsistent with Article 5.7 of the *SPS Agreement*

(i) Article 5.7 is not a "special regime"

4.259 The EC's claim that Article 5.7 is a "special regime in relation to Article 5.1 of the *SPS Agreement* " and that it is for the party alleging a violation of Article 5.7 to make a prima facie case of non-compliance is without merit. The Appellate Body has found that the party that wishes to rely on the exception of Article 5.7 has the burden of showing that it has met its conditions.

4.260 Article 5.1 is a specific application of the basic obligation contained in Article 2.2 of the *SPS Agreement* not to maintain SPS measures without sufficient scientific evidence. A WTO Member adopting an SPS measure that results in a higher level of protection than would be achieved through a measure based on the relevant international standards must satisfy the requirements of

Article 5.1. Where a measure is not based on a risk assessment, a Member may justify its measure under Article 5.7 of the *SPS Agreement* on the basis that insufficient scientific evidence exists to perform an adequate risk assessment.

4.261 The recommendations and rulings of the DSB require that the EC base its measure on a risk assessment in accordance with the requirements of Article 5.1 of the *SPS Agreement*. The EC cannot circumvent this obligation by characterizing its measure with regard to five of the hormones at issue as "provisional" and then claiming that this "provisional" measure is subject, not to Article 5.1, but to the "special regime" of Article 5.7, which is "not covered by the rulings and recommendations of the DSB". Given that the EC has invoked Article 5.7 to justify its non-compliance with Article 5.1, it must bear the burden of demonstrating that the requirements of Article 5.7 have been fulfilled.

(ii) The relevant scientific evidence

4.262 The four requirements of Article 5.7 are cumulative in nature. The first one functions as a threshold requirement because Members may only adopt provisional measures "[i]n cases where relevant scientific evidence is insufficient".

4.263 To date, none of the reasons given by the EC explains in a convincing manner why the relevant scientific evidence is "insufficient" to allow the performance of an adequate assessment of risk. The EC takes issue with the risk assessments conducted by JECFA on the safety of the five hormones when used according to good veterinary practices because it alleges that it could not review the "basic information and raw data" underlying JECFA's conclusions. However, the majority of these data is in the public domain. Although the EC complains that Canada did not provide it with the scientific studies and data underlying its decision to authorize the use of these five hormones, Canada provided the EC with the full names and addresses of each of the firms with proprietary rights to the information the EC had requested. To date, the EC has provided no confirmation that it has contacted these firms.

4.264 The EC also takes issue with JECFA's conclusions as to the safety of the five hormones when used in accordance with good veterinary practice, by asserting that JECFA's recommendations could not achieve the level of health protection considered appropriate by the EC. The EC seems to suggest that it has conditioned its ability to conduct a risk assessment on these five hormones on whether the available scientific data from JECFA and other sources meet its appropriate level of protection. There is no basis for this approach in the text of the *SPS Agreement* or WTO jurisprudence. The EC confuses the notion of the insufficiency of the relevant scientific evidence with a WTO Member's right to establish its own appropriate level of protection.

4.265 The ability to conduct a risk assessment cannot hinge on a Member's appropriate level of protection. Such an approach undermines the basic logic of the *SPS Agreement*. The EC's approach would allow Members arbitrarily to set their level of protection so high that they could effectively exclude from the pool of relevant scientific evidence any evidence that does not meet their chosen level of protection.

4.266 The Appellate Body has confirmed that Article 5.7 is intended to address "situations where little, or no, reliable evidence [is] available on the subject matter at issue". The EC has not demonstrated why it considers that the vast body of relevant scientific evidence on the safety of these five hormones from reputable sources such as JECFA and Codex have yielded unreliable scientific evidence. The EC also suggests that the simple passage of time is sufficient to invalidate previously-held scientific opinions but it does not provide any reasons why the JECFA studies or the Codex Standards should now be considered to be unreliable.

4.267 The EC has misconstrued its obligations under the *SPS Agreement* and has failed to establish that there is insufficient scientific evidence to conduct a risk assessment on the five hormones concerned.

(iii) Available pertinent information

4.268 Under the second requirement of Article 5.7 of the *SPS Agreement*, Members may only provisionally adopt SPS measures "on the basis of available pertinent information, including that from relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members".

4.269 The EC has acknowledged that the risk assessments conducted by JECFA concerning the safety of these five hormones constitute "available pertinent information" that must be taken into account by the EC. The EC recognizes that there must be an "objective relationship" between the SPS measure at issue and the available pertinent information. However, the EC fails adequately to explain why it is imposing a "provisional" ban in the face of the safety assessments by JECFA and international standards adopted by Codex that attest to the safety of these substances.

4.270 The EC asserts erroneously that a Member may disregard the results of the risk assessments performed by the relevant international organizations because the Member concerned requires more information in order to meet a higher level of protection. This assertion stems from the EC's propensity to use its chosen level of protection to avoid its obligations under Article 5.7 of the *SPS Agreement*. This Article applies in cases where no risk assessment can be performed due to the lack of relevant scientific evidence. Therefore, the EC cannot claim that this provision entitles it to disregard scientific evidence from relevant international organizations on the basis that the EC requires "more information" in order to meet a higher level of protection.

4.271 Thus, the EC has failed to demonstrate that there is a rational relationship between its ban on the five hormones in question and the available pertinent information from JECFA, Codex and other sources.

(iv) Additional information and review

4.272 Pursuant to the third and fourth requirements of Article 5.7, a Member may not maintain a provisional measure unless it: (1) seeks to obtain the additional information necessary for a more objective assessment of risk and (2) reviews its measure based on this new information within a reasonable period of time. Thus, Article 5.7 imposes a burden on Members to make active efforts to gather the additional information necessary for the performance of a full risk assessment and then review the appropriateness of their measure within a reasonable period of time.

4.273 While the length of the reasonable period of time to review a provisional SPS measures may vary from case to case depending on the difficulty in obtaining additional information and the characteristics of the SPS measure at issue, Canada disagrees with the EC's suggestion that a Member's domestic legislative procedures may have an impact on the determination of the reasonable period of time.

4.274 It is a well-established rule of customary international law that internal law may not be invoked as justification for the failure to perform a treaty obligation. Accordingly, the length of the EC's domestic legislative process should not be a factor considered in the establishment of the reasonable period of time to review a provisional SPS measure. In cases where a Member imposes a total import ban, the reasonable period of time to review the measure should be such as to minimize the extent of the trade impact of this measure.

4.275 The EC has provided no explanation as to if and how it is seeking any additional information concerning the safety of these hormones and how it has reviewed its measure accordingly in the two years since the adoption of its new directive.

4. Conclusion

4.276 For the reasons stated in Canada's rebuttal submission and those contained in Canada's earlier submissions, Canada respectfully requests that the Panel reject the EC's claims.

I. ORAL STATEMENT OF THE EUROPEAN COMMUNITIES ON EXPERTS OPINIONS DURING THE SECOND SUBSTANTIVE MEETING

4.277 There are certain "procedural" aspects to this expert meeting which the European Communities would like to comment on before turning to the substantive results of this meeting. As you are well aware, the European Communities, during the selection process last year, had objected to the selection of Drs. Boobis and Boisseau as experts to this Panel. This mainly, because both have been involved in drafting and adopting the very same risk assessments which the European Communities has not accepted as valid basis for its measures regarding hormone treated beef, that is JECFA's risk assessments. The European Communities' concern was that Drs. Boobis and Boisseau would lack the objectivity required to give the Panel the advice needed to make an objective assessment of the facts in this dispute. Last week's meeting has confirmed that this concern was more than justified. It is unavoidable what Drs. Boobis and Boisseau have done, namely to defend the conclusions of the risk assessment they were involved in against any alternative conclusions which the EC's risk assessment has come to. We do not blame them for doing so. However, we do believe that their obvious partiality was not only unacceptable for the purpose of the role of experts in this dispute, it also made it necessary, at times, to enter into technical scientific discussions that we would probably all have rather avoided.

4.278 The European Communities does not wish to discredit in general the work which is done by JECFA and Codex, nor does it believe that these latter would wish to put into question in any way the EC's sovereign choices on the desired level of health protection. This is not a case "EC against JECFA". This is a case between Members of the WTO and it currently turns on the question whether a WTO Member has legitimately relied on its right under the *SPS Agreement* to base its measures on its own assessment of scientific evidence and available pertinent information, assessment which may deviate from that performed (but not necessarily adopted) by an international standard setting body. Objective expert advice of the kind that came from Drs. Guttenplan, Cogliano, Sippell and De Brabander, can explain what the scientific positions on either side are. It is not helpful, therefore, to have had (not only one but even two) scientific experts at this meeting who considered themselves to be representatives of JECFA.

4.279 It is not helpful either to have had JECFA representatives at this meeting who considered themselves to be scientific experts. Both Dr. Tritscher's and Dr. Wennberg 's role would have been to provide, in their capacity as secretaries to JECFA, factual information on how JECFA works, the way Dr. Miyagishima did for Codex. Instead, both have repeatedly overstepped their role and ventured into statements on the substance of the scientific issues. Although we are, for example, quite grateful for Dr. Tritscher's indiscretion on the origin of JECFA's reference to "potential genotoxicity" (she stated that it was because JECFA felt there was scientific uncertainty), we do not think that it was appropriate for her to provide information on the substance of the science or to assume the role of defending the substance of JECFA's work. And we certainly feel that Dr. Wennberg would have done better not to intervene on the issue of residue data used in the 1999 evaluation (on which she was obviously not informed) or to keep her opinion, for example on Radio Immuno Assays, to herself.

4.280 Let me end my comments on the procedural aspects of this expert meeting here by inviting the Panel to take them into account when it assesses all the different advice it has been given at this meeting.

4.281 I will now turn to the substantive results of this meeting and place them in the legal context. For the sake of this discussion, the European Communities accepts for a moment the assumption that your task in this dispute is indeed to assess whether measures taken to comply with DSB rulings and recommendations are consistent or not with Articles 5.1 and 5.7 of the *SPS Agreement*. However, we will come back to this at a later stage.

4.282 The United States and Canada claim that the European Communities has violated Article 5.1 of the *SPS Agreement* in re-adopting its ban on oestradiol-17β for growth promotion purposes. (I'll open a parenthesis here: this is not quite the way they put it as they believe the burden of proof is on the EC to demonstrate compliance. However, the EC strongly rejects this point, and I will also come back to that later. Fact is that they have raised a number of arguments as to why the EC allegedly violated Articles 5.1 and also 5.7 and therefore is not in compliance).

4.283 They argue essentially on two levels. First, that there is no risk assessment, supposedly because the EC Opinions of 1999, 2000 and 2002 failed to perform the second and third of the four steps usually done in a risk assessment on substances of this kind by the members of Codex Alimentarius Commission. Second, that the evidence put forward by the EC allegedly does not support the ban.

4.284 Last week's expert meeting has yielded a wealth of information which is crucial to dealing with these two levels of argument. Rather than repeating all the legal arguments as set out in our submissions, I will concentrate on where the scientific advice you got helps to clarify the issues.

4.285 On the first level of argument, we learned from the rather *unisono* statements of the experts. We have learned that while everyone (including the European Communities) accepts that in a risk assessment you may proceed in the four steps of hazard identification, hazard characterization, exposure assessment and risk characterization, you only do that to the extent possible and necessary. In other words, how you proceed exactly is a function of the data you have available and of how your risk assessment is framed, namely by the mandate you have received from the risk manager. Thus, we learned from Drs. Boobis and Cogliano that data are never complete, but are or are not sufficient for the purpose of completing a risk assessment. We learned that this is a matter of judgment involving considerations on what sort of possible gap/uncertainty/insufficiency we are dealing with and whether that can be dealt with through interpretation or bridging tools such as safety factors and assumptions, or not. Most importantly, however, we learned that this judgment is informed – indeed, is framed – by the risk *manager*. It is the risk manager, as Dr. Miyagishima pointed out, who decides whether or not to carry out an evaluation and who factors into that decision the question of whether there are sufficient data. I draw your attention in this context to paragraph 19 of the Codex draft Risk Analysis Principles for the CCRVDF, which are about to be adopted. Paragraph 19 specifies that it is for the CCRVDF to provide "a qualitative preliminary risk profile as well as specific guidance [to JECFA] on the CCRVDF risk assessment request."

4.286 Finally, it is the risk manager, as several experts repeatedly confirmed, who decides on the acceptable level of risk, in other words on the level of protection. This informs for example concepts such as that of "appreciable risk", as Dr. Guttenplan explained in reply to your question. Let us not go into the whole concept of risk communication, but it is important for you to understand that risk assessors and risk managers – as two different instances of a risk analysis process – do not make decisions in isolation from each other. This has already been confirmed by the Appellate Body in the 1998 *Hormones* report.

4.287 This brings us back to the famous four steps of the risk assessment. If there is a risk management decision that the intended acceptable level of risk is "additional risk to the extent such a risk is judged 'insignificant' or 'non appreciable,'" here is what you do as a risk assessor: once you have identified that there is the possibility of an adverse effect, you go on and calculate whether and at what threshold the risk becomes "non appreciable" using safety factors and whatever other tools you have available to bridge possible gaps of knowledge. This is what JECFA has done.

4.288 If, on the other hand, there is a risk management decision that the intended acceptable level of risk is "no additional risk," the situation is different: as a risk assessor, once you have identified the possibility of an adverse effect and the possibility of its occurrence in real life, there is no point in going on and calculating a threshold, as no additional risk, however minimal, would be accepted. As a risk assessor you have done enough for the purposes of the risk assessment that the risk manager has asked from you. Essentially (I am saying essentially because the European Communities, as even Dr. Boobis had to confirm, has actually quantified exposure to the extent possible) this is what the EC risk assessors have done. Your experts have confirmed this, not least Dr. Boobis, who first advised you that the European Communities had not carried out a proper risk assessment and then qualified his reply by stating that it was based on the assumption that a threshold would apply. Where this is not the case, so he explained last week and in his written replies to Questions 11, 19 and 37, the remaining steps after hazard identification look quite different. In particular, a dose response assessment is unnecessary (see in particular reply to Question 37). However, as to what exactly the remaining steps are supposed to look like in a non-threshold scenario, neither Dr. Boobis nor the other experts gave you clear advice on that question. You heard statements that the European Communities failed to present new residue data or failed to refer to the problem of endocrine effects in its risk assessment or failed to present evidence on *in vivo* genotoxicity, all of which the European Communities proved to be wrong by pointing the Panel to the exact page where this issue was discussed or a study was referred to in the EC Opinions. Frankly, Chairman, one might choose to disagree with the conclusions the EC has come to, but to claim that the EC has not carried out a proper risk assessment is a bit of a joke, obvious to anyone who has actually taken pains to read the EC risk assessments (and, if I may add, to compare them to other relevant risk assessments).

4.289 So let me turn to the second level of argument, which turns on whether the evidence presented by the European Communities supports – or, as the Appellate Body would put it – sufficiently warrants a prohibition on oestradiol-17β. Chairman, I could go back to the details of all the adverse effects that the EC risk assessment has identified and that were at least in part discussed at last week's meeting. I could now launch into discussing everything that was said about old and new residue data, old and new detection methods, good veterinary practice and abuse, hormonal development of children and the value of epidemiological studies. But I think there is probably no better way of putting in a nutshell the controversy at the heart of this debate than the way Dr. Cogliano has done it. He said essentially "at the heart of the scientific disagreement here is the interpretation of data. JECFA's assessment felt that a threshold could be assumed even if there was some evidence on genotoxicity. Therefore they assumed there was a threshold. It seems to me that the EC is unwilling to assume a threshold, because of genotoxicity and because of low dose response and the fact that the shape of the curve cannot be defined with certainty. Those are the scientific arguments on both sides – depending on how you phrase the question, you will get a response of yes or no." On the question, of whether this disagreement is arbitrary or unreasonable, Dr. Cogliano answered by stating that "this is a longstanding area of disagreement for scientists since many years, the reason for the controversy being the assumptions that scientists bring to the risk assessment. It is an area of legitimate disagreement."

4.290 Even Dr. Boobis, who may have wanted to make you believe that JECFA's – that is: his – interpretation of the data is the only reasonable interpretation, had to concede that both genotoxicity and low dose response are issues that are a long way from being resolved. What better way to demonstrate this than the vivid debate between Dr. Guttenplan and Dr. Boobis on proof of *in vivo*

genotoxicity? What better way to say it than Dr. Boobis' reply to the EC expert's intervention on low dose response, when he stated "this is a major issue of scientific controversy. Dr. Vom Saal can point to so many papers which support his argument, but currently this is not resolved in the scientific community."

4.291 I could add to this now an account of the many things that were said last week about pre-pubertal children, where the advice you received from the Panel's experts ranges all the way from warning you not to feed your children broccoli (Dr. De Brabander) to stating that there is no problem whatsoever for hormonal substances despite evidence demonstrating that JECFA's calculations on endogenous production of hormones are actually wrong (Dr. Boobis).

4.292 But the point can already be made: what you should take away from last week's meeting is the following: First, the European Communities bases itself on evidence which well respected scientists, including some of your own experts (Drs. Guttenplan and Cogliano) understand to demonstrate direct genotoxicity of oestradiol-17β. Direct genotoxicity, not only for the EC risk manager but actually for most risk managers in this world (see Dr. Boobis' reply to Question 11) is a reason not to accept any added risk and therefore to decline setting a threshold. Second, the European Communities bases itself on evidence which is read by respected scientists – and, apart from Drs. Cogliano and Sippell this may well include most endocrinologists in the world – to mean that one actually knows precious little about what hormonal substances do at low doses, and in particular, what they do to especially sensitive populations such as pre-pubertal children. For the EC risk manager, and this may well be a position not shared by the risk managers in the US and Canada, this is a reason to decline setting any threshold.

4.293 The European Communities considers that it is not for this Panel to enter into the deep scientific theories and try to resolve the scientific controversies, to which you have become witnesses last week. The scientists have not managed to resolve it and you will not be able to do it with the legal provisions and tools you are supposed to apply here. Indeed, you are not asked to now come down on either side of the debate, apply your own – as Dr. Boobis would put it – "weight of evidence" approach, provide your own interpretation of how the data should be read. It is sufficient for you to ascertain that there is a genuine divergence of scientific opinions here, which may indeed – as the Appellate Body has put it – "indicate a state of scientific uncertainty"[19] and that the European Communities has relied on – and I quote the Appellate Body again – "divergent opinion[s] coming from qualified and respected sources"[20] as your own experts have confirmed. The US and Canada may think that this source may not (yet) represent "mainstream" scientific opinion (although one may well argue that there is at least equal balance between the different opinions) but this, as the Appellate Body teaches us, "does not necessarily indicate 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."[21] There is no other indication that the European Communities may not have acted in good faith (may those who cherish protectionist theories go back to reading what the Appellate Body had to say about that).[22] Therefore, Chairman and Members of the Panel, your conclusion must be that the EC's risk assessment sufficiently warrants – that is to say reasonably supports – its ban on Oestradiol-17β.

4.294 This concludes my comments on the United States' and Canada's claim that there is a violation of Article 5.1 of the *SPS Agreement* as regards the EC's implementation measure on Oestradiol-17β. I should add that this also deals with the rather vague claim made by the United States and Canada that there would also be a violation of Article 3.3 of the *SPS Agreement.* "Vague"

[19] Appellate Body Report on *EC – Hormones*, at para. 194.
[20] Ibid.
[21] Ibid.
[22] Appellate Body Report on *EC – Hormones* at para. 245.

because it is not clear what they would be relying on with regard to oestradiol-17β. The standard adopted by Codex on this substance dates back to 1988 and is outdated, not only in the EC's view but also in the view of Codex' own scientific committee JECFA, which has re-evaluated the substance since. However, JECFA's updated assessment of 1999 has never been adopted as a standard. In any event, as is clear from the above, the European Communities who has a scientific justification not to base itself on the Codex standard, and also (not "or")[23] has a higher level of protection than that implied in the Codex standard, acted consistently with Article 5.1. of the *SPS Agreement.* Therefore, there is no violation of Article 3.3.

4.295 Let me turn to the European Communities provisional ban on the other five substances, progesterone, testosterone, zeranol, trenbolone acetate and melengestrol acetate (MGA). With regard to that measure the United States and Canada claim that there is a violation of Article 5.7 of the *SPS Agreement.* I will not go back to all legal arguments that have been exchanged between the parties on the four conditions that Article 5.7 of the *SPS Agreement* requires, but will instead concentrate on what the expert meeting has yielded in this regard, which mainly relates to the issue of sufficiency.

4.296 Obviously, you as the Panel wonder what to make of the fact that an international body such as Codex and its scientific committee JECFA, with regard at least to four of these substances, has considered that there is sufficient evidence to come to a conclusion on them, while the EC claims that this is not the case.

4.297 This brings us back to the debate touched upon earlier about completeness of data, sufficiency, gaps and scientific uncertainty. For all of those among us lawyers who love to think in clear cut-categories, this is a bit of a disappointment. The world of science clearly does not think in terms of definitive and provisional measures, of sufficiency and insufficiency of evidence. Data are never complete, as we learned; whether you can come to definitive conclusions on a risk assessment is a function of what data you have and how your risk assessment has been framed by the risk manager. Dr. Boobis, who emphasised several times how careful he was about choosing his words, certainly was careful when replying to the question of whether it was possible to complete a risk assessment on the five substances. He agreed with the European Communities that this was a question of risk management and then stated: "I can only speak for JECFA, not for the EC, we considered the data to be sufficient." Indeed, he speaks for a different set of data and against the background of a different decision on acceptable level of risk/intended level of protection! The EC's scientific committee worked on the basis of the most up to date research on these substances and against the background of the risk manager's decision not to accept any additional risk from residues in hormone treated-meat. Under these circumstances, the EC scientific committee, in the face of evidence indicating that there may be risks with regard to genotoxicity and in light of the scientific uncertainty regarding the low-dose response problem, was careful to conclude only provisionally on the existence of a risk, and to recommend further research. Who would have preferred a bold conclusion based on all sorts of gap-bridging assumptions, that these substances present a risk, and on the basis of that a definitive ban adopted by the EC regulator?

4.298 This concludes my remarks on the Article 5.7 claim, which has been shown to be unfounded. Let me add a brief remark, once again on the Article 3.3 claim made by the United States and Canada. The United States and Canada are relying on standards for zeranol and trenbolone acetate adopted in 1988, which are as outdated as the standards for progesterone and testosterone also dating back to 1988. Again, as is clear from the above, the European Communities who has a scientific justification not to base itself on the Codex standard, and also a higher level of protection than that implied in the Codex standard, acted consistently with Article 5.7 of the *SPS Agreement*. Therefore, there is no violation of Article 3.3.

[23] As the Appellate Body has put it so delicately, "Article 3.3. is evidently not a model of clarity in drafting and communication", see Appellate Body Report on *EC – Hormones*, para. 175.

4.299 These remarks of the European Communities attempted to help you place the results of last week's experts' meeting in the context of your analysis on the relevant provisions of the *SPS Agreement*. Before turning to my reservation on that exercise, which I stated in the beginning, let me make one final remark. It seems fashionable, in the debate on the *SPS Agreement*, to raise the spectre of regulators who close off their markets by putting never ending demands for more evidence on scientists on the basis of a declared need to prove safety. There is a danger for abuse of the *SPS Agreement* in this respect, no doubt. But there is another spectre out there, which is equally haunting: that the *SPS Agreement* would be abused by those who value market profit over safety. That those who do not bother to look into possible health concerns, referring, at best, to industry data that no member of the public has ever seen, would benefit from some sort of presumption of being right under the *SPS Agreement*.

4.300 With this, I have ended my opening remarks on the outcome of the expert hearing. Now, with regard to my earlier reservation: Chairman, we want to raise the question with you, why it is we are going through this exercise of looking into a violation of the *SPS Agreement*. As suggested in your e-mail we will come back to this issue in the second part of our opening statement when we discuss legal issues.

J. ORAL STATEMENT OF CANADA ON EXPERTS OPINIONS DURING THE SECOND SUBSTANTIVE MEETING

1. Introduction

4.301 Canada considers that the conclusions to be drawn from the expert meeting are that the ban on oestradiol-17β is not based on a risk assessment and the evidence is sufficient to conduct a risk assessment for the other five hormones. Canada understands that, in discussing the experts' advice, the parties may not introduce new evidence into the record and further that any statements made by the disputing parties' own experts should be viewed and assessed as an argument of the party concerned, rather than as evidence contained in free-standing scientific testimony.

4.302 The experts' advice is particularly pertinent where it addresses the scientific questions that are within the legal framework of this dispute, namely, whether the EC's ban on meat from animals treated with oestradiol-17β is based on a risk assessment appropriate to the circumstances, and whether there is sufficient scientific evidence to conduct a risk assessment for the other five hormones. The advice from the Experts on these claims was that the EC's risk assessment was not appropriate to the circumstances and that there is sufficient evidence to conduct a risk assessment for the other five hormones.

4.303 In light of the sensitivities surrounding public health and safety aspects of this case, the Experts' role was more significant than the legal questions imply. It is not the role of the Panel or even the Experts to pass judgment on the safety of the hormones, but this case also does not consist entirely of technical legal questions. These hormones have been studied extensively, and the studies demonstrate that they do not pose any real-world risk to human health and safety. Also, science evolves, methodologies and techniques improve, conceptions change, appreciation of hazards and risks in our environment alters, but no credible evidence has brought into question the safety of these hormones. Further, in the face of scientific uncertainty, inquiry does not end and public health is not managed on the basis of anecdotal observations, speculation and fear. Finally, risk assessors have developed rigorous, reliable and recognized ways to handle uncertainties responsibly.

4.304 The importance, therefore, of the contribution of the Experts is that they have collectively underlined and stressed these simple facts and have firmly deflected the EC's assault on the integrity of scientific methodologies and techniques that underlie all scientific inquiry and of organizations such as JECFA and Codex. The EC's claims to the contrary notwithstanding, even in the absence of

data that cannot be acquired, "with an understanding of biology, you can responsibly conduct a risk assessment."

2. The EC's risk assessments

4.305 The Experts' advice on the two legal issues was unambiguous. The EC risk assessment is not a complete risk assessment; it focused on hazard identification, some hazard characterization and no independent exposure assessment. And the evidence is sufficient for the performance of a risk assessment for the other five hormones. These answers should be sufficient to complete the assessment of the legal issues. Any remaining controversies have to do with matters more foundational and ancillary to these basic legal questions. These relate to the nature of the risk assessment exercise in general and specific issues of the genotoxicity and potential adverse effects on sensitive populations.

3. The nature of assessing risk

4.306 The Experts raised several issues that are relevant to evaluation of the EC's assessment, including the nature of risk assessment techniques and the appropriateness of these techniques in these circumstances.

(a) Hazard versus risk

4.307 Understanding the difference between "hazard" and "risk" leads to a better understanding of approaches to risk assessment and the steps within the kind of risk assessment appropriate in these circumstances. This understanding also illuminates the central deficiency of the EC's approach to these growth-promoting hormones.

4.308 Calling a substance a hazard reveals something about its intrinsic properties, its capacity to cause adverse effects. For example, some substances have the intrinsic capacity to cause cancer because of the way they interact with human cells. The role of IARC, the US Report on Carcinogens (RoC) and the first step of the four-step risk assessment technique is to identify and classify such substances. However, calling a substance a hazard says nothing about whether adverse effects will occur in any given scenario involving that substance. IARC and the RoC stop after identifying the hazard and provide no information on the likelihood that any particular exposure to the substance will lead to cancer. It is the role of other agencies to complete the analysis of risk.

4.309 Risk is not only about whether a substance is capable of causing adverse effects, but is also about identifying the likelihood that a given exposure to a substance will cause adverse effects. Whereas the identification of a hazard is a qualitative assessment about the intrinsic capacities of a substance, the evaluation of risk often involves a quantitative evaluation. It is, therefore, not sufficient for the EC simply to identify these substances as posing a hazard. The EC's risk assessment must say something about the risks from the specific uses of the hormones as growth promoters.

(b) Risk versus thresholds / dose-response assessments

4.310 There are many substances for which not all exposure scenarios lead to the quantification of risk, because there are exposures, known as a threshold, below which there is no risk of adverse effects. In these cases, identifying a substance as carcinogenic precludes neither further evaluation of it nor the identification of safe exposure levels. The issue is not the quantum of risk, but whether a given exposure may have adverse effects, which is the role of dose-response assessments. A dose-response assessment allows one to "characterize a hazard" by revealing the dose required for adverse effects to occur.

4.311 For substances known to be carcinogenic through a direct genotoxic mode of action it is assumed that there is no threshold below which no adverse effects will occur, making a dose-response assessment unnecessary. Even in these rare cases, however, risk assessors may conduct a dose-response assessment because the effects of most mutations are not deleterious. A risk assessor is not justified in skipping a dose-response assessment for substances known to have a threshold. The Experts believed that in this case a dose-response assessment should have been conducted.

(c) Integrity of the international risk assessment system

4.312 The scientists, regulators and administrators who work in the international standard setting system for veterinary drugs act with professionalism and integrity. The four-step risk assessment process – hazard identification, hazard characterization, exposure assessment and risk characterization – is time-tested and universally adopted at the international and national levels. To question these methodologies with respect to the evaluation of one substance calls into question the work of risk assessors everywhere.

4.313 Advanced techniques, such as conservative assumptions, ensure that standards based on them address global regulatory needs. The basic principle of every risk assessment is to be protective of the most sensitive sub-populations. This is accomplished through the use of the most sensitive adverse effects in identifying the threshold for adverse effects, the use of safety factors, and overestimation of the intake of residues in determining exposure.

4.314 Since science evolves and our understanding of science evolves, the risk assessment process remains flexible. The fact that new questions can be raised at any time does not stand in the way of decision-making, but decisions remain subject to review. Members of Codex and JECFA are invited to submit new data and call for a review of existing standards if they believe that they are no longer sufficient. Since the Members share responsibility for ensuring that standards are continually updated to reflect emerging data, the failure of one Member to provide new data and seek review of an existing standard can not be ascribed to the failure of the standard-setting system itself. The EC has chosen not to avail itself of the review process for these international standards.

(d) Scientific uncertainty, appreciable risk and zero risk

4.315 Because science cannot guarantee with 100% certainty that a substance will never cause adverse effects, risk assessments are not expressed in terms of absolute certainty. This is not to acknowledge that there are risks, but to acknowledge that we can never definitively say that there <u>are</u> no risks, or that the risk is zero. This uncertainty is reflected in the term "no appreciable risk", which is not the subjective value judgment of the risk assessor, but simply that unknowable and unquantifiable residual risk inherent in living. Several Experts expressed this uncertainty in quantitative terms, not to quantify real risks from veterinary drugs, but to illustrate just how small these risks, if any, really are.

4.316 Risk managers who require guarantees of "zero risk" are imposing unreasonable and unachievable demands. The methodologies do not exist to provide those kinds of assurances, particularly for substances that are endogenously produced in the human body and available from other dietary sources. Although uncertainty will be present in any scientific inquiry, risk assessors take that uncertainty into account and, when possible, eliminate it. The result is risk guarantees that leave room for theoretical risk, but not more.

4. Specific scientific issues

4.317 The two most significant scientific conclusions made by the SCVPH were that oestradiol-17β is carcinogenic through a genotoxic mode of action and that there are potential adverse hormonal effects for sensitive populations.

(a) Evidence of carcinogenicity through genotoxic mode of action of oestradiol-17β

4.318 The SCVPH declined to conduct a dose-response assessment in any of its three opinions as a result of its conclusion that oestradiol-17β was genotoxic *in vivo*. That conclusion is not justified by the available data. It is necessary to understand the mechanism – or mode of action – through which a compound can cause cancer in order to assess the risks. Since compounds capable of causing cancer through a hormonal mode of action exhibit a threshold below which cancer will not occur, the risk of cancer is dependent on exposure at doses higher than the threshold. It is not in dispute that oestradiol-17β is carcinogenic through a hormonal mode of action, for which there is a threshold. It is disputed that oestradiol-17β is also carcinogenic through a genotoxic mode of action.

4.319 While there is evidence from *in vitro* studies that oestradiol-17β has "genotoxic potential", to conclude that it is carcinogenic through a genotoxic mode of action requires confirmed *in vivo* evidence of genotoxicity. This has not been confirmed due to the existence of defence mechanisms such as metabolite inactivation, excretion and anti-oxidant systems, DNA repair mechanisms and natural (homeostatic) controls. These mechanisms are redundant and effective because cell damage occurs quite regularly and naturally in the human body. The "genotoxic potential" of oestradiol-17β can be observed *in vitro* because these mechanisms are unavailable, suppressed or overwhelmed. It is not observed *in vivo* due to the existence and correct functioning of these mechanisms. Studies relied upon by the EC to demonstrate genotoxicity *in vivo* simply confirm that, if thresholds for adverse effects are overwhelmed, there can be dramatic results.

4.320 The Experts confirmed that oestradiol-17β is not genotoxic *in vivo*, let alone carcinogenic through a genotoxic mode of action, and the EC provided no evidence whatsoever that oestradiol-17β can cause mutations leading to cancer. It is also not just an issue of judging one scientist's opinion over another, but that the EC's studies are simply not credible enough to support any other interpretation on the weight of all the evidence. The carcinogenicity of oestradiol-17β is therefore considered to be subject to a threshold. Since the SCVPH made an erroneous interpretation of the evidence related to thresholds for oestradiol-17β, it was wrong not to conduct a dose-response assessment.

(b) Potential adverse hormonal effects for sensitive populations

4.321 The Experts also advised on the potential for adverse hormonal effects, particularly in prepubertal children. They pointed to homeostatic control mechanisms that adjust endogenous production of hormones in response to exogenous exposure and advised that exogenous hormones are indistinguishable from endogenous hormones. While these controls may not be 100% effective, the assessment of risk must take them into account. The Experts also advised that the bioavailability of a substance is important and that it can be substantially less than what is orally ingested. While there was speculation that hormones may be more bioavailable in children than in adults, there is no evidence for this.

4.322 Some Experts considered that there is no direct evidence of adverse effects on prepubertal children from exposure to hormones from treated meat. Others did not contest this conclusion but claimed it had not been properly investigated. The "indirect evidence" cited, such as epidemiological studies related to puberty, simply does not implicate hormone growth promoter residues due to the problems of "confounding" factors. The EC had no explanation as to why, if minute increases in

hormones have such significant effects, prepubertal children do not suffer adverse effects from consuming eggs, meat and milk. The explanation provided by others is that metabolic and homeostatic control systems are functioning as they were designed and no adverse effects occur.

4.323 There are also questions about claims that exposure to low doses of oestradiol-17β *in utero* carries a risk of breast cancer in adult life. In light of the high amount of oestradiol-17β produced daily by pregnant women and the low amount consumed from treated meat, the dose of oestradiol-17β to which the fetus is exposed is hardly low, and any incremental exposure from growth promoter residues is about as negligible as one can get.

4.324 The SCVPH also did not evaluate the potential for endocrine disruption in prepubertal children, but limited itself to an exposure assessment. It relied on data derived from an analytical method that has not been validated, one that has resulted in inconsistent estimates. It made dubious assumptions about bioavailability in children. In the end, it failed to evaluate potential adverse effects by not performing a dose-response assessment. Instead, it presumed adverse effects from exposure to hormones and speculated about the ratio of daily production in prepubertal children to exposure from treated meat. However, one cannot adequately assess risks without assessing exposure from normal food consumption. At least one Expert indicated that based on consensus levels of hormones in children JECFA's ADI would still be protective of sensitive populations.

5. Issues related to good veterinary practice

4.325 There was little discussion at the Experts meeting of issues relating to compliance with good veterinary practice, but a few points can be highlighted. First, the Experts clarified that mechanisms exist for testing meat and meat products to determine compliance with established MRLs. Second, since analytical methods for detecting residues need only be sufficient to identify whether residues exceed established MRLs, the availability of new and more sophisticated analytical methods for detecting residues is largely irrelevant when there is an established MRL with a validated detection method. Third, there are no new residue data, no reason to believe the residue data relied upon by JECFA are insufficient, and no reason for existing residue data to be recalculated simply because new methods have been developed. Finally, Dr. de Brabander's written statement that no control measure short of a complete ban can adequately protect against misuse and abuse is of questionable applicability to Canada in light of his admission that he has no knowledge of control measures in Canada.

6. Conclusion

4.326 The results of the meeting with the Experts are clear and consistent on the key issues. The Experts unanimously advised that the EC did not perform a risk assessment consistent with appropriate methodologies and that scientific evidence was sufficient to allow the performance of a risk assessment for the other five hormones.

K. ORAL STATEMENT OF THE EUROPEAN COMMUNITIES ON LEGAL ISSUES DURING THE SECOND SUBSTANTIVE MEETING

1. Introduction

4.327 The European Communities made a reservation in its statement yesterday when it questioned the point of going through this exercise of looking at the possible violation of provisions under the *SPS Agreement*. I am afraid that we have to postpone our discussion of that issue once again, to the end of this meeting, as it seems more important at this stage to respond to the Panel's request to clarify a few issues about the *SPS Agreement* and its application to the facts of this case. This is without

prejudice to our position on the provisions of the *SPS Agreement* which, if any, might be invoked against our measures.

2. Article 5.1 of the *SPS Agreement*

4.328 Let us start with the main violation found by the Appellate Body in the original *EC – Hormones* case, Article 5.1 of the *SPS Agreement*. The first point to make is that the situation today is very different from that which confronted the Appellate Body in 1998.

4.329 The Appellate Body had found that the old risk assessment performed by the European Communities was not specific enough to address residues in meat treated with hormonal growth promoters.

4.330 The optimal way to remedy that would be to establish a quantitative dose response relationship. However, the scientists last week have agreed (even though we did not need them to tell us) that this is not possible to perform because the necessary studies would entail, as the 2002 US Carcinogenesis Report says, conducting studies of long term human exposure and cancer incidence in very restricted environments which will be able to eliminate with confidence confounding factors in the initiation and promotion of cancer over a long latent period.

4.331 Visualize the study: a perfect place would seem a prison where you have a sufficient number of very long term prisoners living in identical conditions, half of whom would eat non-hormone treated beef and the other would eat hormone treated beef. Even under these circumstances, which can not possibly be more restricted, the results of the study would be rebuttable due to differences in the past exposure history of those in custody. You may visualize another situation where you have a sufficient number of newly born children with whom you perform a similar experiment for about 30 years. Do I need to go on?

4.332 In the absence of such studies we had to follow an alternative approach which is also acceptable under the *SPS Agreement*. Let's review what we have done and some important knowledge that we have acquired:

4.333 First, we now have sufficient scientific evidence that oestradiol-17β is genotoxic. This is not a theoretical risk, it is not negligible and definitely not "zero", it is a real risk however minimal.

4.334 Second, we have sufficient evidence that endogenous production of natural hormones by pre-pubertal children is by many times less than what was originally thought to be the case.

4.335 Third, most of the scientists have agreed that the dose-response curve cannot be defined with certainty for low exposure to these substances.

4.336 Fourth, there is sufficient evidence, which is consistent with the observation that already exposure from background endogenous production can lead to cancer;

4.337 Fifth, we know today that the old data used by the defending parties and JECFA and the method by which they have been collected, are questionable or no longer valid (*e.g.* depletion data produced with method of analysis not apt to detect metabolites);

4.338 Sixth, there is a sufficient body of evidence indicating increased rates of cancer in the US and Canada which is consistent with the argument that residues of meat treated with these hormones can contribute to these higher rates.

4.339 Seventh, we know that under realistic conditions of use, good veterinary practice cannot be respected in the administration of hormones in the US and Canada and this invalidates the ADIs and MRLs (as Dr. Boisseau confirmed last week).

4.340 These things we did not know back then in the 1990s, but do know them now. Last week we have heard that there is a difference of scientific views and of interpretation of data about some of these issues, but that this difference is not arbitrary and indeed reflects genuine scientific uncertainty. In light of this, it is not indispensable that the third step of the risk assessment, the exposure assessment, is performed in a quantitative manner.

4.341 With these data the European Communities has conducted a qualitative dose-response assessment and has come to the conclusion that residues of hormone-treated meat will constitute an added risk to human health. As the Appellate Body has explained in 1998, risk is not measured in the laboratories but in the real world where people live and work and die.

4.342 In conclusion on this point, we believe that the European Communities performed a risk assessment as appropriate to the circumstances and the very nature of these substances, and therefore the ban on oestradiol-17β is based thereon – that is: sufficiently warranted by that risk assessment.

4.343 Before turning to some comments on other SPS provisions, I would like to stress the important point that we have made. A proper risk assessment can come to the legitimate conclusion that there are gaps in knowledge. This is expressly recognized in point 11 of the General Working Principles for Risk Analysis of Codex Alimentarius Commission. JECFA's risk assessment bridges all knowledge gaps and scientific uncertainty by assumptions in favor of allowing the use of hormones in growth promoters.

4.344 It seems that the US and Canada do not accept that a proper risk assessment can conclude that there are gaps and scientific uncertainty. For example, the US relies on a contention, at para 56 of its statement of yesterday, that a risk assessment must fully address the four "mandatory" steps (and it claims that the European Communities has not done so).

4.345 There is no basis for this. Article 5.1 of the *SPS Agreement* states that a risk assessment must be "appropriate to the circumstances" and *take into account* techniques developed by international organizations. As the European Communities has so often explained, and the experts have confirmed, the four steps of the Codex guidelines only need to be taken where possible and necessary. A qualitative assessment of the exposure of the kind performed by the EC must be acceptable. Our exposure assessment is not worse than that performed by the defending parties and JECFA, because both are based on assumptions and extrapolations from data on animal experiments to human beings.

4.346 It seems that the US and Canada would like to make it almost impossible for the European Communities to conduct a risk assessment they would ever accept. If they were to succeed with this tactic, however, the result would not be more authorizations but more provisional measures under Article 5.7 SPS.

3. Article 3.3 of the *SPS Agreement*

4.347 There has also been mention of Article 3.3 of the *SPS Agreement*. The argument is not clear but the European Communities would like to make a couple of important points. First, WTO Members have a sovereign right to set a higher level of protection than reflected in international standards. Article 3.3 only requires Members to have a scientific justification for their measures reflecting this higher level of protection, not for the higher level of protection itself.

4.348 Another point that needs to be made is that Article 3 of the *SPS Agreement* applies to standards and measures, and does not require Members to accept risk assessments by organizations such as JECFA. Accordingly, the fact that JECFA may have made a different risk assessment, which is outdated by today's standards and reflects a lower level of protection is not a basis for holding the EC risk assessment to be inadequate. In any event, the European Communities has shown that its measure has the necessary scientific justification and aims to achieve a higher level of protection. For this reason we fail to see the relevance of Article 3 SPS as a basis for the claims of US and Canada in this case.

4. Article 5.7 of the *SPS Agreement*

4.349 Similarly, the fact that JECFA could carry out risk assessments on the five other hormones, is not a reason for holding that the European Communities cannot adopt provisional measures based on Article 5.7 of the *SPS Agreement*. For JECFA, the information is apparently sufficient to conduct risk assessments; for the European Communities it is not. Even Dr Boobis agreed (and the US misrepresents his position at para 35 of its statement yesterday morning).

4.350 The US is also wrong to say (in para 6 of its statement) that the European Communities has failed to review the provisional bans within a reasonable time. The European Communities is in fact now conducting such a review once again.

5. Article 5.5 of the *SPS Agreement*

4.351 There have also been suggestions that the EC ban on oestradiol-17β (and the provisional prohibition of the other five hormones) are unreasonable or arbitrary in view of the large amounts of hormones that human beings are already exposed to from many different sources. Here again, we are not sure what the argument is. We cannot see how compatibility with Article 5.5 SPS is relevant to this case since no violation of this provision has been invoked by the Defendants. But even if it were, we would remind you of the interpretation of the Appellate Body of this provision. You cannot compare natural presence of these substances in a great many products with added risk from hormone-treated meat.[24]

6. Conclusion on the *SPS Agreement*

4.352 Chairman, Members of the Panel, our review of the possible relevance of the *SPS Agreement* has been somewhat cursory. Our problem is that we do not know what we are accused of. The US and Canada have not set out their claims in a Panel Request and their arguments criticizing our measures are varied and wide-ranging. We would be happy to discuss these issues in more detail if only we would be told exactly what it is we are doing wrong, because it is scientifically unsound and arbitrary.

7. Concluding statement of the European Communities

(a) Introduction

4.353 The European Communities would first of all thank you again for the professionalism and objectivity with which you have conducted these proceedings. Let me just recall that it was more than a year ago that we met for the first time to discuss the main claims of the European Communities against the US's s and Canada's illegal unilateral determination of the alleged inconsistency of the EC's implementing measure and, based thereupon, their illegal continuation of the sanctions against the European Communities.

[24] See para.221 of the Appellate Body Report on *EC – Hormones*.

4.354 The European Communities has explained in detail why in order to resolve these disputes it is not necessary for you to address the scientific issues related to the use of hormones as animal growth promoters. Chairman, Members of the Panel, you have nevertheless decided to look at these scientific issues. And we are the first to acknowledge that the scientific debate has not facilitated your life. As we have learned, the questions related to the use of these hormones are subject to a longstanding legitimate scientific debate amongst scientists with respected and reasonable arguments on both side.

4.355 However, one bottom line with which probably everybody will agree is that these hormones do not improve your health. These hormones are animal growth promoters but not health promoters. Instead we discuss scientific issues such as genotoxocity, mutagenicity, carcinogenesis, DNA repair mechanism, the risks of early puberty to our children, obesity, cancer as well as abuse and misuse of these hormones. Whatever one may think about this, it does certainly not increase our appetite for meat.

4.356 Another bottom line, which can be safely drawn, is that these hormones present a hazard and potentially a risk. Now, I agree that this is where the controversy starts. But whatever one may think about it as lawyers or consumers, neither of the scientists nor of the Defendants can reasonably argue that there is no potential risk related to the use of these hormones as growth promoters in cattle. Instead, we have heard a lot of talk about "thresholds", "appreciable risk" or "acceptable risk". But whether a risk is appreciable or not, whether a risk is acceptable or not, it still remains a risk. And contrary to what the defending parties have argued yesterday this is not a theoretical risk. No, the risk is real, however minimal it may be.

4.357 Why should we accept such a risk? Why should we expose our public to an additional risk to human health? Indeed, Chairman, Members of the Panel, we have heard repeatedly that we should not care about the addition of the natural hormones since they are also present in natural food, such as broccoli, milk, eggs or butter or produced endogenously. But the question persists why we should add on top of this an additional burden on the consumer without any health benefit in return. It is true that we all take risks in life whether we drive with a car, or when we take the plane or if we drink a glass of milk. However, we take these risks because we also see the benefit. Driving a car is comfortable, taking the plane is fast and milk contains a lot of vitamins. Yet, the story is different with hormones used as growth promoters in cattle. Here the risk is on the consumer. He has to face an additional health risk by being exposed to higher hormone levels. But he has no additional health benefit. Thus, from the perspective of a public health regulator, the risk/benefit calculation does not speak in favour of the use of these hormones either.

4.358 If at all, one may argue that the issue of not allowing hormones as growth promoters in cattle while we allow our children to drink milk is a matter of consistency. However, that would also be a very superficial view of the issues at stake. As we have explained yesterday and as the Appellate Body has already decided, one cannot compare these two things. On the one hand, we talk about natural food products that are part of our daily life over centuries and where there is a concrete risk/benefit for the consumer. On the other hand, the use of hormones in beef is an unavoidable risk which does not bring any advantages to public health.

4.359 How can this be better exemplified than by looking at our children. Children are the most sensitive part of the population and we must protect them wherever we can. There is a lot of uncertainty about how the mechanism of hormones in these children work but one can be sure that doubling the oestradiol doses – as would be the case by allowing hormones in beef – will have an effect. One of your experts, Dr. Sippell, has confirmed this pointing to the examples of early puberty or obesity. We should take his judgment very seriously when he drew the conclusion of the scientific hearing that he is "very concerned". Whatever toxicologists or veterinarian may have to say we should take this testimony of a paediatrician very, very seriously.

4.360 This brings me to one last point in this introduction which is about misuse and abuse of hormones as growth promoters. It is already striking that we always refer to "Good Veterinary Practices" even though no veterinarian or other trained health professionals is involved in the use of these hormones in the United States and Canada. As they are sold freely over the counter to farmers you will admit that controlling the correct use of these substances is difficult under these circumstances. It should strike us all that one implant contains the amount of hormones contained to up to 10,000 carcasses of animals. The European Communities has assessed what happens if these implants are misused and, indeed, there exists concrete evidence on this in the United States and Canada.

(b) The scientific debate

4.361 Let me now turn briefly to the outcome of the scientific debate regarding the use of these hormones as growth promoters in cattle. The European Communities is still puzzled by the United States' and Canada's attempts to present this debate as if there were only one single monolithic opinion in the scientific world on the safety of these hormones. This serves the US's and Canada's purpose but it is not objective.

4.362 It is true that we are all sometimes tempted to provide easy answers to difficult questions. And, certainly, this natural reflex is made even easier in the face of scientists who are able to "quickly dismiss" scientific evidence that they have not taken into account in the first place.

4.363 What is important for your decision, however, is to look at the differences and to see whether these differences are scientifically legitimate. The European Communities has never claimed that its scientific findings are the only valid ones, unlike what the United States and Canada have done. However, what the European Communities has repeatedly insisted upon is that its scientific views and its risk assessment are appropriate to the circumstances and that they come from respected and legitimate sources. One may not like the EC' conclusions but one cannot ignore or discredit them either.

4.364 It also appears sometimes ironic to present the EC' risk assessment in opposition to the JECFA's assessment. There is no doubt that the JECFA assessments have been based on outdated data since despite its assessment in 1999 this does not mean that the data also come from the 90's. Rather the JECFA representative admitted that they only review data as they receive them and in this particular case they had only received data from the FDA some of which date back to the 1960s. Despite the general acknowledgement that science is constantly moving forward and reveals new evidence this is an astonishing procedure itself which, again, we leave to your discretion on how you take this into account. A second undisputable issue is that JECFA's (and indeed the United States and Canada's) approach to risk is different to the one by the European Communities. JECFA has set thresholds in order to minimize the risk, the European Communities has prohibited the use of these hormones in order to exclude avoidable risks.

4.365 These are two completely different risk management decisions. Both are legitimate and we are, therefore, not criticizing JECFA for what it has done. However, we also cannot be blamed for deviating from JECFA's approach. It is ultimately the responsibility of the regulator or risk manager to decide what level of risk he wants to accept, and as I have indicated earlier, this is a very complex decision to which no easy answer can be given.

4.366 Let me then turn to our puzzlement by the United States and Canada's characterization of the scientific debate. We mentioned already yesterday that they very selectively refer to the scientific evidence in order to make their case. Chairman, Members of the Panel, we trust that you have a better recollection of what was actually said.

4.367 Let me just give a few examples. The United States has stated that "the experts agree that the EC has not presented any scientific evidence that estradiol is genotoxic *in vitro* or *in vivo* at physiological levels". However, may I remind you about the lively debate between Dr. Boobis and Dr. Guttenplan on this particular issue where Dr. Boobis "quickly dismissed" a study that was co-authored by one of his expert colleagues. Isn't it simply disingenuous to present this debate as if "all experts agree" that there is no evidence? And I'm not even talking about the experts that have not expressed an opinion on this issue.

4.368 Another example is the US's statement that "the experts have confirmed that the evidence for each of the five hormones is sufficient to complete a risk assessment". This is again incorrect. First, some of the experts have not even expressed a view on this. And even Dr. Boobis, who the United States often likes to rely on has merely stated that JECFA had enough information for completing a risk assessment whereas he could not say this for the European Communities. Again, as we have just explained, we all know the difference in these perceptions which is based on the fundamentally different approach by JECFA and the European Communities on how to deal with risks and whether or not it is appropriate to set a threshold in light of the possible direct and indirect genotoxcity of these substances.

4.369 A third and last example is Canada's today's statement that "nothing in what the Experts have written, nothing in what we have heard from the Experts (…) or the Experts have said demonstrates that there is any risk to human health, adult or child, old or young, man or woman, boy or girl, arising out of the correct use of these growth-promoting agents in cattle". It suffices to contrast this simplistic summary by Canada with Dr. Sippell's conclusion of last week that he is "very concerned" about the health of children if they were exposed to these hormones in beef. Again, we trust the Panel Members that they take into account what has actually been said by the scientists in their variety and not what the United States or Canada make out of it.

4.370 In this context, let me also refer to the closing statements by some of the experts during last week's hearing and which summarizes adequately the level of differences in the scientific world. Dr. Guttenplan stated that as regards young girls and boys we have to worry about the developmental effects of estradiol on them and that hormones sensitive cancer might be increased by raising the level of oestradiol. Dr. Sippell stated that we do not know enough about children and that the data are insufficient to be confident that the additional exposure from hormones treated beef poses no risk. Dr. Cogliano himself referred to the messiness of science and to the split within the scientific community. He also stated that these issues are not likely to be resolved any time soon. Finally, Dr. De Brabander even referred to other aspects related to the use of hormones as growth promoters such as animal welfare or environmental concern.

4.371 The European Communities considers that there is a bottom line that one cannot ignore. The scientific issues on which the European Communities and the United States and Canada disagree are not arbitrary but they are the result of a legitimate and genuine disagreement amongst scientists. This was the main result of the Panel' experts hearing. We do not believe that this Panel is in a position, or required, to resolve these long-standing scientific issues. Instead. we would urge you to acknowledge the legitimate scientific controversy and to draw the respective conclusions from it in resolving these two disputes.

(c) The context of the scientific debate

4.372 With these remarks, let me come back to where we ended last year after our discussion on the systemic issues under the DSU.

4.373 The European Communities would recall that these two disputes are still not about the *SPS Agreement* despite the extensive scientific debate that has taken place on the public health risk

related to hormones in animal treated beef. Chairman, Members of the Panel, the panel requests by the European Communities which provide the legal basis for these two disputes do not refer to any single provision under the *SPS Agreement*. Rather, as we discussed extensively last year, the European Communities has based its case against the illegal continuation of sanctions by the United States and Canada on systemic violations of the DSU, in particular Article 23, paragraphs1 and 2(a), Article 21.5 and Article 22.8.

4.374 As repeatedly stated, in order to resolve these disputes it is not necessary for you to make a substantive finding on the scientific issues. We have already set out that in our view the proper forum and the right procedural way to deal with these would be a compliance Panel under Article 21.5 of the DSU initiated by the United States or Canada.

4.375 This said, it is true that the European Communities has also made an alternative claim which requires you to address the substantive scientific aspects in order to determine that the original inconsistent measure has been removed and that the European Communities has addressed all the rulings and recommendations of the DSB.

4.376 However, this alternative claim has been only made "if, and only if" the Panel were to disagree with the European Communities on its systemic arguments under the DSU. Up until now, the Panel has not decided that this is the case. Therefore, the main claims and arguments as set out by the European Communities in its submissions are still valid and you are still called upon to take a decision.

4.377 Our discussion of the scientific issues may nevertheless be useful in respect of the main systemic claims made by the European Communities. I would just like to recall that one of the claims is that the US's and Canada's continued suspension of obligations is in violation of Article 23.1 and Article 22.8 of the DSU. This is so because by continuing to apply sanctions against the European Communities, the United States and Canada are unilaterally seeking to redress an alleged WTO inconsistency through the EC compliance measure. Furthermore, as you recall, in view of the requirements of Article 22.8 of the DSU, the European Communities has explained in great detail that its implementing measure must be presumed to be WTO-consistent since there is no multilateral finding to the contrary. This presumption is derived from the general principle of good faith whereby WTO Members are presumed to act in conformity with their obligations.

4.378 In this particular context, the European Communities considers that the scientific debate fully supports its proposition of a presumed compliance of its implementing measure. Indeed, since the scientific evidence demonstrates that the EC compliance measure is in actual compliance, it follows a *fortiori* that the lower standard of presumed compliance is also fulfilled.

4.379 Let me explain this aspect in more detail.

4.380 From the beginning of these two proceedings, the United States and Canada have tried to discredit the European Communities' compliance measure and its scientific foundations. Arguably, by this criticism the defendants have tried to undermine the European Communities' reliance on the principle of good faith (or in this case the presumption of compliance) under Article 22.8 of the DSU. And one has to admit that this litigation tactic by the United States and Canada was not completely unsuccessful because you felt the need to address the scientific issues related to the use of these six hormones as growth promoters in cattle notwithstanding the applicability of the general principle of good faith.

4.381 However, following the extensive discussion of the scientific issues, it is clear that this approach by the United States and Canada is not any longer sustainable. As we have seen last week, there can be no doubt that there exists a real and actual risk to public health related to the use of the

six hormones as growth promoters. The European Communities was therefore fully entitled to ban the use of these hormones in beef. And in legal terms, the European Communities was therefore also right in invoking the principle of presumed compliance within the context of its systemic claim under Article 23.1, 22.8 of the DSU.

4.382 The logic of this argument may also be further elucidated when the invocation of good faith is linked to the issue of burden of proof. The United States and Canada have attempted to make a prima facie case against the EC compliance measure. Yet, following the scientific debate the European Communities has refuted this prima facie case. The burden of proof is therefore still on the United States and Canada for questioning the European Communities' conclusion that the use of these six hormones for animal growth promotion is a risk to public health. The United States and Canada have failed to meet this burden of proof and they could not support their conclusions that the EC's ban on hormones treated beef was scientifically unsound.

4.383 We would like to recall that the European Communities also made violation claims under Articles 23 and 21.5 of the DSU that do not depend on the WTO-consistency of the EC's compliance measure. Rather these claims are directly linked to the US's and Canada's unilateral determination of the alleged inconsistency of the EC' compliance measure.

4.384 Finally, we have heard again this morning that the United States maintains that it could not have possibly made a "determination" that the EC's new ban is in fact WTO-consistent by the time the EC initiated these proceedings because the European Communities failed to provide all the necessary materials relevant to its measure.

4.385 This is a rather disingenuous characterization of the real facts and I will, at this stage not recall all our arguments that we have submitted to you. Let me just first point out that the United States erroneously keeps referring to a determination of WTO-consistency which it claims it could not make. The DSU neither requires nor forbids such "consistency determination". What the DSU prohibits, however, is the unilateral determination of a WTO violation by another Member.

4.386 Let me also recall, that while the United States in its view struggled to come up with a "determination" as early as from November 2003 they dismissed the EC compliance measure and explicitly stated in its Trade Policy Review of 2005 that "they failed to see how the revised measure could be considered to implement the recommendations and rulings of the DSB" . And in addition to that, since then the United States simply continued to apply its sanctions against the European Communities. There is no other way than to qualify this behaviour as an illegal determination of non-compliance. And, finally, it is also simply not true that the United States had been confronted with the evidence for the first time in 2003. All the underlying studies have been peer-reviewed and been published in journals and the European Communities undertook even an effort to discuss with the United States in Washington the scientific evidence. All this is on the record. The European Communities, therefore, cannot express again its puzzlement by the way the United States represents the facts in this dispute.

(d) Conclusion

4.387 For all these reasons, the European Communities would ask the Panel to find:

(a) First, that the United States' and Canada's continued suspension of concessions against the European Communities was inconsistent with the provisions referred to under Part I of the EC's first written submission.

(b) In the alternative, the United States' and Canada's continued suspension of concessions against the European Communities is inconsistent with the provisions set out under Part II of the EC's first written submission.

L. ORAL STATEMENT OF CANADA ON LEGAL ISSUES DURING THE SECOND SUBSTANTIVE MEETING

1. Introduction

4.388 Almost ten years ago, the DSB ruled that the EC ban on Canadian beef treated with growth-promoting hormones was inconsistent with the *SPS Agreement* because it was not based on a risk assessment. After the EC refused to bring itself into compliance, the DSB authorized Canada to impose retaliatory measures. The EC reaffirmed its ban in 2003, claiming that it was now based on a risk assessment in respect of one of the hormones and that there was insufficient scientific evidence to conduct a risk assessment for the other five. The EC launched this dispute, claiming: first, that the DSB authorization was no longer valid and that Canada had an obligation to suspend its authorized retaliatory measures; and, second, that if Canada does not, it has an obligation to bring a compliance case against the EC. The EC's DSU claims are wrong on the question of process and its alleged "compliance" with the *SPS Agreement* is unsupported by evidence and flatly rejected by the experts.

4.389 The EC's argument that Article 21.5 of the DSU provides that a complaining party has a legal obligation to launch compliance proceedings every time there is a "disagreement" as to compliance should be rejected for its systemic absurdity. The EC argues that, on the sole basis of an assertion of compliance by the EC, Canada should forego its rights under the WTO and launch dispute settlement proceedings. If the EC were to be found again in violation it could make another unilateral assertion of compliance and, if its procedural arguments prevail, force the parties into another dispute. Few things can be better calibrated to undermine confidence in WTO dispute settlement than the endless litigation loop that would result from this.

4.390 The EC's allegation of a breach of Article 22.8 on the basis that its unilateral assertion overrides the multilateral authorization of the DSB is also plainly wrong. Canada, having acted consistently with a DSB authorization, may not be found to be in violation of Article 22.8 on the sole basis that the EC has asserted that it has complied. To end the retaliatory measures in light of the disagreement as to its compliance, the EC must establish its compliance multilaterally. It is the EC's burden, since it seeks to overturn an existing DSB authorization. This case is therefore not about procedural lacunae in the DSU, but about the compliance of the EC measure.

4.391 The rest of Canada's submission addresses the legal requirements of the *SPS Agreement*. Canada makes the following preliminary observations. First, Canada's reference to exposure to hormones from other sources does not relate to the regulatory aspects of the "consistency" required by Article 5.5, but to the "appropriate circumstances" in relation to which the EC's risk assessment is conducted, pursuant to Article 5.1. The EC's position on the risks from these hormones is either irresponsible or disingenuous: if the hormones are as hazardous as it has claimed, the EC must conduct an assessment to determine in what doses there are health risks, regardless of how natural the products are; where it refuses to do so and insists that natural sources can be consumed every day but residues from treated meat cause adverse effects, scepticism about the EC's reasoning is warranted. Second, the EC seems to be saying that even if it loses, its ban will remain in place, justified not by Article 5.1 but by Article 5.7, because it will claim there are insufficient data to conduct a risk assessment. This makes it all the more important for the Panel to make findings about what constitutes "sufficient evidence", which is different from scientific uncertainty, minority opinion or speculations based on clinical observations.

2. The EC has not demonstrated that the relevant international standards are insufficient to meet its appropriate level of protection

4.392 The EC's measure is not justified under Article 3.3 because existing international standards are capable of achieving the EC's higher level of protection. While the EC alleges that these standards are insufficient and wrong, it has provided only unconfirmed evidence, considered within an artificially constructed level of protection of "zero additional risk".

4.393 Existing international standards have been developed using methodologies so widely accepted that to call them into question for these hormones calls them into question for other compounds as well. The EC misrepresents the level of protection inherent in these standards. For example, in light of other sources of exposure to the three natural hormones, standards for these hormones are such that it is not necessary to determine maximum allowable levels of hormone residue in meat, reflecting the conclusion that the ADI could never be exceeded simply by consuming treated meat. The EC considers the concept of "no appreciable risk" to be subjective and qualitative. However, that concept reflects scientific reluctance to guarantee zero risk in the case of very small, unquantifiable risk. Since the risk inherent in this concept is the risk from exposure to hormones at the level of the ADI, which includes exposure from all other sources, the risk from exposure to oestradiol-17β from treated meat is only 4% of the risk inherent in that concept. The level of protection achieved by international standards is therefore as close to zero as possible and reflects theoretical risk.

4.394 The EC claims that its ban is necessary because international standards cannot achieve its level of protection, which it has set at "zero additional risk" to get around the fact that risk management methodologies cannot provide for "zero risk". The EC therefore believes that it need do no more than establish that exposure to treated meat increases overall exposure to hormones, and then assume this automatically increases risk. This is based on incorrect assumptions that adverse effects will occur at anything close to normal levels of exposure to hormones and that levels of exposure to treated meat alter the level of hormones in the body sufficiently to alter the level of risk. However, since the EC provides no evidence that exposure to hormones from treated animals alters the risk that might already exist from exposure to other sources of hormones, it has not demonstrated that there are additional risks.

3. The EC has not demonstrated that its permanent ban on oestradiol-17β is based on a risk assessment appropriate to the circumstances

4.395 The EC claims that its reaffirmed ban on oestradiol-17β is now based on a risk assessment, but that assessment is not appropriate to the circumstances, does not identify and evaluate the potential for adverse effects from exposure from treated meat, does not demonstrate that exposure from this source causes cancer and does not demonstrate that sensitive populations are at risk from exposure from this source.

(a) The EC has not demonstrated that existing international risk assessment techniques are inappropriate to the circumstances

4.396 While the EC does not dispute that the four-step risk assessment process is appropriate to these circumstances, it does make two incorrect claims about the application of these steps in these circumstances. First, its claim that the *SPS Agreement* envisages a risk assessment that is "wider in scope" than the four-step process does not find support in the *SPS Agreement*. Article 5 addresses risk assessment techniques and not the separate and defined process of risk management. The EC reliance on sections of the Appellate Body ruling in *EC – Hormones* is also unjustified. There is a parallel between the four-step process and legal requirements to "identify adverse effects and evaluate the potential for their occurrence from exposure to hormones from meat from treated animals".

4.397 Second, the real reason the EC seeks to confuse the parameters of an appropriate risk assessment relates to its claim that the scientific risk assessment was justified in short-circuiting the process because of instructions from the risk managers related to "zero additional risk". A risk manager is not justified in instructing a risk assessor to skip certain steps of the assessment to serve risk management objectives. The risk assessment process is a scientific exercise that should arrive at the same scientific results regardless of the risk management framework within which it is conducted. The issue is therefore whether the EC's purported risk assessment unjustifiably departed from the four-step process.

(b) The EC has not demonstrated that the risk assessment on which its measure is based is appropriate to the circumstances

4.398 The EC measure is based on the three SCVPH opinions. While the EC has also submitted additional material, it has not attempted to demonstrate how this material constitutes a risk assessment. It is therefore the SCVPH opinions that must satisfy the four-step process. The Experts confirmed that it suffers from two critical flaws. First, the Experts confirmed that a dose-response assessment is a necessary component of a risk assessment, without which it is impossible to know the dose at which adverse effects will occur. In their own reviews, JECFA and others conducted dose-response assessments. Operating under the instructions to avoid "additional risk", the SCVPH declined to conduct such an assessment, concluding that the adverse effects from oestradiol-17β did not exhibit a threshold for adverse effects, and as such all exposure would lead to "additional risk". This conclusion is not justified by the scientific evidence.

4.399 Second, the failure to conduct a dose-response assessment led to the failure to complete a risk characterization, which corresponds to the requirement to evaluate the potential for the occurrence of adverse effects. The Experts disagreed with the EC that the SCVPH conducted a risk characterization. Assessment of risk from a substance in general was simply conflated with assessment of risk from a single source of that substance. After identifying oestradiol-17β as a hazard, the SCVPH concluded that exposure to it from treated meat poses additional risk. The finding that the original EC ban was not based on a "sufficiently specific" risk assessment applies equally this time, and the artificial construct of "zero additional risk" does not save it. The failure to complete these steps stemmed from mistaken interpretations of the scientific evidence, which the next section reviews.

(c) There is no evidence that oestradiol-17β is genotoxic *in vivo*

4.400 The SCVPH concluded that there is no threshold for adverse effects from oestradiol-17β on the basis of erroneous and scientifically unjustified interpretations of genotoxicity test results. While there is no dispute that oestradiol-17β is carcinogenic through a dose-dependent hormonal mode of action, and that there is evidence of "genotoxic potential", the SCVPH was wrong to conclude that oestradiol-17β is carcinogenic through a genotoxic mode of action. It ignored the fact that *in vitro* test conditions neutralize effective and redundant defence and repair mechanisms, meaning that *in vitro* genotoxicity must be confirmed by positive *in vivo* results. The "weight of evidence" is against oestradiol-17β being carcinogenic through a genotoxic mode of action. Other national and international regulatory bodies, as well as the Experts, have indicated this and the SCVPH has no credible evidence that all these experts are wrong.

4.401 While the EC raises the spectre of "scientific uncertainty" and "minority scientific opinion", the conclusion that oestradiol-17β is genotoxic *in vivo* is not supported by any reasonable interpretation of the available scientific evidence. For a contrary interpretation of the data to constitute a credible minority opinion, or for it to reflect "scientific uncertainty", there would need to be at least some evidence that could not be explained by the existing understanding of the issues.

According to the Experts, this is not the case. Any evidence there is that oestradiol-17β may be genotoxic can be explained according to common understandings of biological mechanisms.

(d) There is no evidence of adverse effects on the endocrine system

4.402 While the EC cites various revised estimates of blood concentrations of oestradiol-17β in prepubertal children, the issue is whether these estimates tell us anything about the implications of incremental increases in exposure from one particular source for the risk profile of prepubertal children. The JECFA analysis focuses on determining the level at which no adverse hormonal effects would occur in the most sensitive sub-groups of the population. The SCVPH did not evaluate the occurrence of potential adverse hormonal effects. It compared intake of oestradiol-17β from treated meat with this "new" daily production rate, concluded that the excess intake would exceed the daily production in prepubertal boys and then implied an increase in risk to prepubertal boys.

4.403 Apart from questions about the validity of the data and the justifiability of the assumptions, this approach suffers from basic methodological flaws. Since natural hormones are part of a normal diet, a risk assessment must take into consideration background dietary exposure. There is no evidence that there is no safe threshold for daily consumption of oestradiol-17β in part because of homeostatic control mechanisms. The SCVPH failed to consider the question of a threshold for safe daily intake because it did not conduct a dose-response assessment. The fact that background levels are lower than previously thought says nothing about the potential occurrence of adverse effects. Thus, as a result of a failure to conduct a dose-response assessment, the SCVPH has failed to evaluate the potential occurrence of adverse hormonal effects from exposure to hormones.

4. The EC has not, and cannot, demonstrate that there is insufficient evidence to conduct a risk assessment on the five other hormones

4.404 There are three legal issues concerning the interpretation and application of Article 5.7 in this dispute. First, the mere existence of scientific uncertainty does not imply that the scientific evidence is insufficient to allow the performance of a risk assessment. Techniques have been developed to address scientific uncertainty in the risk assessment process and these techniques can be seen in practical application here.

4.405 Second, the Appellate Body has clarified that "insufficiency" implies a relationship between scientific evidence and the ability to perform an "adequate" risk assessment. The EC suggestion that a WTO Member can determine what constitutes "sufficiency" of scientific evidence through the selection of its level of protection was already rejected by the panel in *EC – Biotech*. The advice sought by this Panel confirmed that the relevant scientific evidence is sufficient for the performance of a risk assessment. The "new" evidence provided by the EC does not call into question the JECFA risk assessments and the conclusion that these hormones are safe when good veterinary practice is followed.

4.406 Finally, Codex has a procedure whereby any Member can request a re-evaluation of a substance that has been previously reviewed by JECFA or for which a Codex standard exists. The EC has deliberately avoided using this procedure, despite its insistence that new information casts doubt on the validity of the Codex standards and JECFA risk assessments. One would expect the EC to invoke this procedure not only to protect its own citizens but also to protect the citizens of other countries that rely on Codex standards. Since the EC cannot demonstrate that the relevant scientific evidence is insufficient to perform a risk assessment on the other five hormones, it has not fulfilled the first condition of Article 5.7.

5. The EC has not demonstrated that the failure to follow good veterinary practice results in increased risk of adverse effects

4.407 The EC's purported assessment of the failure to respect good veterinary practice involves exaggerated and unrealistic overdosing scenarios and suffers from other flaws. First, despite the EC's assumption to the contrary, there is no evidence to suggest that there is an economic incentive to misuse growth-promoting hormones where their use is approved and controlled. The EC's experience with the abuse of banned hormones is not relevant to Canada where their use is permitted. There are in fact significant economic disincentives to overdose an animal as implants have been calibrated to provide an optimal dose. Second, even if some misuse occurs, the evidence presented by the EC does not support the conclusion that the misuse scenarios will lead to residue levels that create potential for adverse effects to occur.

4.408 Third, the EC has not evaluated whether unrealistic misuse scenarios occur in real life. It has ignored data from Canada's National Chemical Residue Monitoring Program, and has provided no evidence that Canadian meat contains hormones at levels exceeding the JECFA ADI. It depicts successful detection of non-compliance as a failure of controls, and misrepresents non-compliance as the norm. By ignoring the way in which hormones are actually used and the results of Canada's official residue monitoring program, the EC has failed to take into account "relevant processes and production methods" and "relevant inspection, sampling and testing methods" in the conduct of its so-called risk assessment on misuse and abuse, as required by Article 5.2 of the *SPS Agreement*. The EC's risk assessment does not meet the requirements for a risk assessment under the *SPS Agreement*.

6. Conclusion

4.409 The key legal questions at issue in this dispute have clear answers. For these reasons and those contained in Canada's earlier submissions, and the arguments and evidence submitted by the United States, Canada respectfully requests that the Panel reject the EC's claim that it has complied with the recommendations and rulings in *EC – Hormones*.

7. Concluding statement of Canada

4.410 It is natural, given the subject matter, that the parties on occasion may have shed more heat than light on the discussions. I hope that none of that has reflected poorly on us or on you.

4.411 The questions at issue are indeed emotive. I note for example that there was an entire section in the EC statement this afternoon about the protection of children. Certainly, there is nothing more important than protecting the health of our children. This is a concern to us as parents, brothers and sisters, public officials and, indeed, private citizens.

4.412 But it is essential to make a distinction between real concerns and the speculative references that have also been at play. There is no need to go into them in detail at this stage, but there have been a lot of them. That will surely present a difficult challenge as you proceed with this matter in your decision making.

4.413 Canada takes it as given that the parties, as democratic, law-abiding countries and entities, and also as public officials, all have as a principal objective the protection of public health and children's health. The question is not whether we protect the children – that's a given. We do so rigorously and without reservation. The question is how to approach doing so, and in doing so whether we are abiding by the law.

4.414 We have set out the law in detail, both on procedural issues and on substantive SPS issues, and will not repeat those points now. But the one point I wished to stress in closing is this: on

whichever side of the law you land, your decision will not harm the children. It would be a disservice to us all to cast the dispute in any other terms.

V. ARGUMENTS OF THE THIRD PARTIES

A. AUSTRALIA

1. Introduction

5.1 According to Australia, this dispute is about one fundamental question; whether the DSU provides that a Member's announcement of its compliance with DSB recommendations and rulings triggers an obligation on a retaliating Member to either (i) cease retaliation or (ii) initiate a new process for a multilateral determination of compliance.[25]

2. Opening Panel meetings for observation by the public

5.2 Australia contends that when parties agree not to follow the Working Procedures in Appendix 3, or parts thereof, it would be difficult for the Panel to justify a decision that goes against the wishes of the parties. In Australia's view, to do so would undermine a basic principle of dispute settlement whereby parties consult with each other and with the Panel and seek mutual agreement on the conduct of disputes, according to Article 12.1 of the DSU.[26]

5.3 Australia submits that the decision to open the meetings with the parties to the public would not pose a problem, in principle, to Australia. Australia was however concerned about the modalities of organising the meetings, equity of access and logistic issues. Australia was of the view that the opening of the Panel's meetings to the public should be subject to the provisions that allow for protection of confidential information.[27]

3. Whether the DSB authorization remains in effect

5.4 Australia argues that a Member's announcement of its compliance with DSB recommendations and rulings triggers an obligation on a retaliating Member to either cease retaliation or initiate a new process for a multilateral determination of compliance. Australia claims that as seen in Articles 22.1 and 22.8 of the DSU, the right to suspend concessions authorized by the DSB is temporary and conditional upon the respondent continuing to be in non compliance or upon a solution not being reached. According to Australia, by continuing retaliation in the face of a respondent's notification of compliance, a complainant is effectively challenging the measure(s) taken to comply. According to Australia therefore, in such a case it is for the complainant to invoke a compliance panel pursuant to Article 21.5 of the DSU.[28]

5.5 Australia contends that the suspension of concessions or other obligations is the "last resort" for Members invoking the dispute settlement procedures, as stated in Article 3.7 of the DSU.[29]

4. Article 21.5 of the DSU

5.6 Australia acknowledges that Article 21.5 of the DSU does not explicitly place the obligation to invoke a compliance panel on a complaining party. The text simply provides that in cases of disagreement over compliance such dispute shall be decided through recourse to the dispute

[25] Third party submission of Australia, para. 4.
[26] Replies by Australia to Panel questions concerning open hearings, question 1.
[27] Replies by Australia to Panel questions concerning open hearings, question 2.
[28] Third party submission of Australia, para. 5.
[29] Replies by Australia to Panel questions, question 5.

settlement procedure. Australia however argues that requiring a respondent to invoke a compliance panel against its own measure(s) constitutes an implicit unilateral determination of inconsistency by the complainant and undermines the presumption that Members act in good faith in taking action to comply with DSB recommendations and rulings.[30]

5.7 Australia further submits that this position is consistent with Appellate Body findings on the presumption of good faith in *Chile – Alcoholic Beverages*,[31] where the Appellate Body stated that Members of the WTO should not be assumed, in any way, to have *continued* previous protection or discrimination through the adoption of a new measure, as this would come close to a presumption of bad faith.[32] Australia also noted observations on good faith made by the Appellate Body in *US – Hot-Rolled Steel*[33]and *US – Line Pipe*.[34]

5.8 Australia thus points out that the fact that a complainant may have been granted temporary authorization to retaliate against a Member found to be in non-compliance does not change the fundamental application of the presumption of good faith. Australia stresses that disregarding the presumption in the specific circumstances of a Member announcing that it has taken action which it considers brings it into compliance would go against the design and underlying logic of the DSU.[35]

5.9 Australia posits that the DSU is explicit on the following points, which provide context for the interpretation of Article 21.5:[36]

- Members must not take unilateral action to seek redress for alleged violations of obligations or other nullification or impairment of benefits (Article 23).

- Instead, Members must have recourse to the DSU and abide with its rules and procedures (Article 23).

- DSU procedures, including those provided for in Article 21, must be used to resolve disagreements over compliance (Article 23.1).

- The suspension of concessions or other obligations is a "last resort" by Members and is temporary. That is, it is only authorized until compliance is achieved (Articles 3.7 and 22).

5.10 Australia contends that by refusing to invoke a "compliance panel", a complainant who disagrees with the respondent's announcement of its compliance allows the dispute to continue unresolved.[37] Australia argues that the longer the time period in which the United States did not take action under Article 21.5, the greater the firmness or immutability the United States made of its determination. Australia emphasizes that this is because a determination within the meaning of Article 23.2(a) of the DSU may be inferred once a certain amount of time has passed after communication by a responding party that it has complied and in which a complaining party continues to retaliate. According to Australia therefore, the longer the period of time that a complaining party

[30] Third party submission of Australia, para. 6.
[31] *Chile – Taxes on Alcoholic Beverages*, (WT/DS87/AB/R and WT/DS110/AB/R), paragraph 74, (emphasis in original, footnote omitted).
[32] Third party submission of Australia, para. 7.
[33] *US – Anti-Dumping Measures on Certain Hot-Rolled Steel Products from Japan* (WT/DS184/AB/R), para. 101.
[34] *US – Definitive Safeguard Measures on Import of Circular Welded Carbon Quality Line Pipe from Korea* (WT/DS202/AB/R), para. 110.
[35] Third party submission of Australia, para. 8.
[36] Third party submission of Australia, para. 9.
[37] Third party submission of Australia, para. 10.

continues its retaliation in the face of this communication, the greater degree of certainty there is for the inference that the retaliating party has determined 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.[38]

5.11 Australia argues that there is no procedure that a Member claiming compliance can invoke in order to obtain a multilateral determination of actual compliance. According to Australia, the possibility of a new dispute whereby the original respondent complains against the continued retaliating measures on the basis of actual compliance assumes that there is no obligation upon the retaliating Member to either initiate an Article 21.5 panel or cease retaliation after communication of compliance by a respondent, which is an incorrect interpretation of the DSU.[39]

B. BRAZIL

1. Introduction

5.12 Brazil claims that it files the present submission in light of its interests in the interpretation to be developed by the parties and the Panel in these proceedings. Brazil states that it will address what it considers to be the fundamental objective of the European Communities in the current dispute, namely to obtain multilateral recognition that it has fully implemented the recommendations of the DSB without having to bear the burden of proving how it would have effectively implemented those rulings.[40]

2. Opening Panel meetings for observation by the public

5.13 Brazil questioned the specific grounds and the DSU provisions on which the Panel based its decision to accept the parties' request to open the panel meetings for observation by the public. According to Brazil, transparency is one of the key issues in the DSU review process and constitutes an important element in the debate carried out by Members in the DSB meetings. As such, Brazil notes that the debate on transparency will largely benefit from any further clarification by the Panel as to the legal reasons which motivated its decision to open the meetings to the public.[41]

5.14 Brazil argues that a decision on whether or not to open panels' proceedings to the public relies solely on the WTO membership, in particular the DSU review process which is the appropriate *locus* to deal with issues regarding the Dispute Settlement Mechanism. According to Brazil, if panels were to decide on this issue, they would go beyond their mandate, playing a role that is exclusive to the WTO membership.[42]

5.15 Brazil further submits that the right to be present at or to watch a panel meeting should be granted first to WTO Members subject to the rules for third party participation set forth in Article 10 of the DSU. Brazil also contends that opening the meetings to the public would represent a reinterpretation of Article 14 of the DSU, signaling that there are cases to which confidentiality is not applied, such as Panel and Appellate Body meetings.[43]

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[38] Third party submission of Australia, para. 10.
[39] Replies by Australia to Panel questions, question 4.
[40] Third party submission of Brazil, paras. 1 and 2.
[41] Oral statement of Brazil, para. 2.
[42] Replies by Brazil to Panel questions concerning open hearings, question 1.
[43] Replies by Brazil to Panel questions concerning open hearings, question 1.

3. Whether the DSB authorization remains in effect

5.16 In Brazil's point of view, the European Communities must prove that the new measure is in full compliance with the DSB recommendations. Brazil stresses that the European Communities' claim is based only on a unilateral sole assertion of compliance. However, a mere assertion is insufficient to prove compliance. Brazil submits that the European Communities may modify its legislation over and over and notify changes to the WTO without actually bringing the measures into conformity with WTO rules.[44]

5.17 Brazil considersthat if the European Communities argument were accepted, it would give the implementing Member the power to unilaterally dispel a previous multilateral determination authorizing suspension of concessions. Brazil contends that such Member would therefore be allowed to act as arbitrator, making use of a procedural artifice that could go on *ad infinitum*. Brazil notes that it would be absurd to have that practice accepted as the common practice in the implementation of WTO disputes. It would mean that a mere assertion that a Member has changed a measure found to be inconsistent automatically revokes a DSB authorization to suspend concessions, while exempting the Member from proving why and how the new measure complies with the DSB recommendations and rulings.[45]

5.18 Brazil submits that only in case of multilateral determination confirming that the European Communities has fully complied could there be grounds for consideration of whether the United States and Canada are in breach of Articles 23, 21.5, 3.7 and 22.8 of the DSU and Articles I:1 and II of the GATT'94, as claimed.[46]

5.19 Brazil argues that just as the initial imposition of suspension of concessions must be preceded by a DSB determination of non-compliance, the authorization for a Member to discontinue the suspension of those concessions can only be made by a DSB determination of compliance, be it for the initial suspension of concessions, or at a later stage for the lifting of the authorized suspension of concessions.[47]

5.20 Brazil posits that the right to suspend concessions is temporary and conditional because it can only be applied based on a multilateral authorization (Article 23.2 (c) of the DSU) and until the party in violation complies with the recommendations of the DSB or a mutually satisfied solution is agreed between the parties in the dispute (Article 22.1 and 22.8 of the DSU).[48]

4. Article 21.5 of the DSU

5.21 Brazil contends that the present situation is different from the one resulting from the relationship between Articles 21.5 and 22.6 of the DSU and it does not consider examples refered to by the European Communities regarding the *US – Subsidies on Upland Cotton* dispute,[49] and *Softwood Lumber*[50] disputes, to be applicable to the present proceedings. Brazil argues that the proceedings under Article 21.5 in those disputes had been already established at the time the implementing party requested the arbitration to determine the level of the suspension of concessions.

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[44] Third party submission of Brazil, paras. 5 and 6
[45] Third party submission of Brazil, para. 8.
[46] Third party submission of Brazil, para. 9.
[47] Third party submission of Brazil, para. 20.
[48] Replies by Brazil to questions from the European Communities, question 3.
[49] *US – Upland Cotton*, WT/DS267/22.
[50] *US – Softwood Lumber VI*, WT/DS277/11.

Brazil stresses that in the current dispute, Article 21.5 proceedings and Article 22.6 arbitration are not "simultaneously ongoing", since no request for a compliance panel has been presented.[51]

5.22 Brazil submits that in the post retaliation phase, one should bear in mind that there is a multilateral authorization in effect. According to Brazil, a presumption of good faith in carrying out the implementing measure cannot by itself override a DSB authorization. That authorization should be revoked by a multilateral determination of compliance not by a unilateral declaration of implementation or a presumption of compliance.[52]

5. Burden of proof

5.23 Brazil posits that the party who makes a particular claim bears the burden of proof. Brazil further contends that by merely asserting that it has removed the inconsistency found by the DSB, the European Communities is not supporting its claim.[53]

5.24 Brazil also argues that the European Communities professes that no Member shall be 'judged' except through multilateral judicial proceedings.[54] However, Brazil notes that this notwithstanding, the European Communities serves itself with a "blank authorization" to determine unilaterally its compliance with WTO obligations and the inconsistency of the continued suspension of concessions granted by the DSB to the United States. Brazil states that had the European Communities wanted to follow multilateral rules, it should have requested an Article 21.5 compliance panel, as it did in *EC – Bananas III (Article 21.5 – EC)*.[55]

5.25 Brazil argues that Article 21.5 of the DSU does not specify which Member is to initiate Article 21.5 proceeding. Therefore, in Brazil's point of view, when disagreement exists as to the consistency of the measures taken to comply with the DSB recommendations, any party to a dispute may have recourse to the Article 21.5 proceedings. Brazil asserts that nothing in the DSU precludes an implementing Member from resorting to an Article 21.5 panel review. Brazil further argues that Article 6 of the DSU provides a rule for the development of special terms of reference, which could be applied in those cases where the implementing Member requests a panel to analyse its own measure.[56]

C. CHINA

1. Introduction

5.26 China submits that the disputes raised in this case are derived from loopholes embedded in the DSU. China states that this brings to attention the importance of amending those loopholes in the new round of negotiation. According to China, in absence of any revision of the DSU, it is a challenge for this Panel to find suitable dispute settlement solution according to the current DSU.[57]

2. Opening Panel meetings for observation by the public

5.27 China did not provide a reply on the potential legal constraint that would exclude the Panel from opening the Panel meeting for observation by the public. China however preferred the Panel to

[51] Third party submission of Brazil, paras. 22-24.
[52] Replies by Brazil to Panel questions, question 3.
[53] Third party submission of Brazil, paras. 10 and 11.
[54] See EC's first written submission, para. 1
[55] Third party submission of Brazil, paras. 13 and 14.
[56] Replies by Brazil to Panel questions, question 2 and 5.
[57] Third party submission of China, paras. 1 and 2.

meet the third parties in closed session. It argues that based on Article 18.2 of the DSU, panels do not have the right to unilaterally disclose the third party submissions and oral presentations.[58]

3. The current status of the DSB authorized suspension of concessions

5.28 China submits that under Article 22.8, a DSB authorized suspension of concessions shall not be applied, if one of three of the following conditions has been met:[59]

(a) The measure found to be inconsistent with a covered agreement has been removed;

(b) The Member that must implement the recommendations or rulings provides a solution to the nullification or impairment of benefits;

(c) A mutually satisfactory solution is reached.

5.29 China contends that if a mutually satisfactory solution is reached by the parties on (a) or (b) above, it will fall into condition (c) and then a DSB authorized suspension of concessions shall not be applied. China posits that if there is no mutually satisfactory solution reached by the parties on whether condition (a) and/or (b) above has been met, the parties have to invoke the dispute settlement procedures to let the Panel make such determination. China posits that in case the responding party declares any of the above conditions has been satisfied, there are only two options for the complaining party: (a) to admit the compliance of new measures; or (b) to deny it.[60]

5.30 In China's view, in case the original complaining party denies the compliance of new measures, that is, if no agreement is reached between the parties as to whether the conditions under Article 22.8 of the DSU have been met, under Article 23 of the DSU, the parties shall have recourse to the DSB's determination to avoid unilateral determination.[61]

5.31 China thus considers that there are only two ways to terminate a DSB authorized suspension of concessions: (i) to reach a mutually satisfactory solution; (ii) to get a final determination from the DSB. According to China, this is the case, even when the original complaining party needs a reasonable period of time to evaluate the WTO consistency of the implementation measure.[62]

5.32 China argues that the European Communities' allegation that it has removed the measure at issue in itself could not give the European Communities ground to terminate the authorization of suspension of concessions. China asserts that Article 23 of the DSU lays down the fundamental principle that the dispute settlement system of the WTO is the exclusive means to redress any violation of any provision of the WTO Agreement. It argues that since there is no mutually satisfactory solution between the European Communities and Canada, the DSB authorized suspension of concessions shall be applied until the DSB makes a new determination on the authorization of suspension of concessions. China notes that the suspension of concessions pursuant to a DSB authorization is temporary and conditional, with the condition being that the original responding party fully implements the rulings and recommendations of the DSB. China emphasizes that no party can make a unilateral determination on whether condition (i) and/or (ii) has been met.[63]

5.33 China emphasizes that if this Panel allows the original responding party to terminate a DSB authorized suspension of concessions by introducing an implementing measure, there is a risk that it

[58] Replies by China to Panel questions concerning open hearings, questions 1 and 2.
[59] Third party submission of China, para. 6.
[60] Third party submission of China, paras. 7 and 8.
[61] Replies by China to Panel questions, question 7.
[62] Third party submission of China, para. 9.
[63] Third party submission of China, para. 10 and oral statement of China, paras. 3-4.

could be abused by an original responding party who, instead of bringing its measures into full conformity with the recommendations and rulings of the DSB, may implement legislation which does not cure all the defects in its earlier inconsistent legislation. China argues that if this Panel finds a DSB authorized suspension of concessions to remain in effect after the original responding party introduced an implementing measure, it can help enforcing WTO rules by inducing actual compliance.[64]

5.34 China is of the view that the suspension of concessions has at least two functions: (i) to rebalance the interests among parties; (ii) to force the responding party to bring its measure into compliance with the covered agreement. China posits that if this Panel allows the original responding party to introduce an implementing measure to override the DSB-authorized suspension of concessions, it invalidates the second function of suspension of concessions.[65]

4. Article 21.5 of the DSU and burden of proof

5.35 China states that Article 21.5 of the DSU does not preclude the original responding party from having recourse to the dispute settlement procedures in the event that there is disagreement as to the existence or consistency with a covered agreement of measures taken to comply with the recommendations and rulings. China advances the following reasons for this argument.[66]

5.36 First, according to China, it would be natural and logical only for the original complaining party to initiate an Article 21.5 proceeding. China quotes *Chile – Alcoholic Beverages*[67] and *Canada – Aircraft (Article 21.5 – Brazil)*[68]and argues that the original responding party when adopting measures to implement recommendations and rulings of the DSB shall be presumed to have fulfilled its WTO obligations, and therefore, shall not bear the burden to demonstrate compliance. China notes that this is further justified because the European Communities' implementation measure requires conducting extensive scientific studies and performing a comprehensive risk assessment in a transparent and objective manner. According to China therefore, after the European Communities notifies the DSB of its measure to implement the recommendation and rulings of the DSB, it has fulfilled the procedure obligation under the DSU, and should not be required to bear the burden of proof.[69]

5.37 Secondly, China refers to the practice of treaty interpretation as elucidated in Article 31.3 of the *Vienna Convention on the Law of Treaties* and *Japan – Alcoholic Beverages II*[70], and points out that the statistics of panel proceedings on compliance under Article 21.5 of the DSU show that in most cases, it is the original complaining party that initiates the dispute settlement procedure under Article 21.5 of the DSU. China stresses that the only precedent for an original responding party to initiate the dispute settlement procedure under Article 21.5 of the DSU is in the *EC – Bananas*[71] dispute where the European Communities as an original responding party sought the establishment of a compliance panel under Article 21.5 of the DSU with the hope of preventing the United States from having recourse to Article 22.6 of the DSU directly. China asserts that this subsequent practice in the

[64] Third party submission of China, paras. 11 and 12.
[65] Replies by China to Panel questions, question 3.
[66] Third party submission of China, para. 15.
[67] Third party submission of China, para. 17.
[68] Third party submission of China, para. 18.
[69] Third party submission of China, paras. 19 and 20.
[70] See Appellate Body Report on *Japan – Alcoholic Beverages II* (WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R) p. 13
[71] *European Communities – Regime for the Importation, Sale and Distribution of Bananas – Recourse to Article 21.5 by the European Communities*, Report by the Panel (WT/DS27/RW/EEC), 12 April 1999 – report never adopted.

application of Article 21.5 of the DSU establishes the agreement of the parties regarding their interpretation that the original complaining party should initiate the Article 21.5 proceeding.[72]

5.38 Thirdly, China argues, the balance of hardship to initiate an Article 21.5 proceeding does not favour the original complaining party. China believes that the original complaining party will suffer no cognizable harm if it initiates an Article 21.5 proceeding, because the DSB authorized suspension of concessions is still in effect. China asserts that it is not proper to let the European Communities initiate an Article 21.5 proceeding simply because the original complaining party is reluctant or has no incentive to do so.[73]

5.39 China stresses that it should be presumed that when the original responding party introduces an implementation measure, it has fulfilled its WTO obligation, and it should be the duty of the original complaining party to demonstrate that the implementation measure is still inconsistent with the covered agreement. China believes if this Panel rules that the European Communities, as an original responding party, should initiate an Article 21.5 proceeding, it will unduly shift the heavy burden on the shoulders of the European Communities to establish the compliance, which is against the nature and logic of the Article 21.5 proceeding.[74]

5.40 China contends that it is usually the case that the responding party has more information on its implementation measure, therefore it is better positioned to demonstrate the WTO consistency of the measure. However, according to China, the nature and logic of the Article 21.5 proceedings stands against this approach. China stresses that subsequent practice in the application of Article 21.5 confirms this conclusion. China is therefore of the opinion that the original complaining party should bear the burden to institute the Article 21.5 proceeding.[75]

5.41 China continues that the unique part of this case is that the original complaining party has a DSB authorized suspension of concessions. According to China, in addition to the function of inducing compliance, this authorized suspension of concessions can rebalance the trading relationship between the complaining and the original responding party in order to restore the economic equilibrium embodied in the original WTO deal. China submits that if after the original panel proceeding, an original complaining party finds that the original responding party does not implement the recommendations and rulings of the DSB, it has incentive to initiate an Article 21.5 proceeding, because it still suffers from a WTO inconsistent measure. However, in this case, China submits that due to the rebalance by the authorized suspension of concessions, the original complaining party may not have the same incentive, therefore it may be necessary to set up a time limit for it to initiate an Article 21.5 proceeding.[76]

5.42 China argues that the proceedings under Article 21.5 of the DSU shall be initiated in a reasonable period of time. China points out that it is in line with the good faith requirement established by Article 26 of the *Vienna Convention on the Law of Treaties* and it is also consistent with the requirement of "prompt settlement of situations" in Article 3.3 and the "temporary nature" of the retaliation system of the DSU.[77]

5.43 China stresses that it wants to bring to the Panel's attention that both Article 22.8 and Article 21.5 of the DSU do not preclude this Panel from setting a time limit to initiate the dispute settlement proceedings. If this Panel holds that it should be the original complaining party to invoke

[72] Third party submission of China, paras. 21-24.
[73] Third party submission of China, para. 25.
[74] Third party submission of China, para. 26.
[75] Third party submission of China, paras. 27 and 28.
[76] Third party submission of China, para. 29.
[77] Third party submission of China, para. 31.

Article 21.5 of the DSU, to facilitate the implementation of this recommendation and ruling, it may be necessary to set up a time limit for the original complaining party to initiate an Article 21.5 proceeding.[78]

5. Article 23.2 of the DSU

5.44 China argues that to establish a violation of Article 23.2 (a), the Panel shall first assess whether the act of "determination" is made "in such cases", where a Member seeks the redress of a WTO violation.[79]

5.45 China analyses the different interpretations of the term "seek the redress of violation" in *US – Section 301 Trade Act,*[80] in *US – Certain EC Products*"[81] and in *European Communities – Measures Affecting Trade in Commercial Vessels,*[82] and states that the term "seek the redress of a violation" should be read broadly to cover any act as long as it seeks to obtain unilateral results that can be achieved through means other than recourse to the DSU. China states that in this case, the original complaining party's continued suspension of concessions could be considered as a measure seeking the redress of a WTO violation, if it had a chance to challenge the European Communities' WTO violation but held back, allowing the DSB authorized suspension of concessions to apply continuously.[83]

5.46 China argues that after the European Communities provided notice of the Directive to the DSB in October 2003, the original complaining party cast doubt on the WTO consistency of this European Communities' implementation measure. Since then the complaining party has had a reasonable period of time to review the European Communities measure and to initiate Article 21.5 proceedings. China argues that it is the lack of action under Article 21.5 of the DSU by the original complaining party, rather than the DSB authorized suspension of concessions itself, that may be considered as seeking the redress of a violation.[84]

5.47 With respect to the meaning of the term "determination", China refers to the panel in *US – Section 301 Trade Act*[85] and argues that the term "determination" in Article 23.2(a) of the DSU needs to be read broadly and it does not require that a measure clearly sets out in its text that a WTO violation has occurred. China argues that such a determination may be inferred from actions. According to China, the longer the time period in which the original complaining party took no action under Article 21.5 of the DSU, the greater the firmness or immutability it made such a determination.[86]

5.48 China argues that where there is no official determination, the Panel has to find a way to evaluate the firmness and immutability of the alleged determination. China notes that before the decision becomes final, there could be a gradual change process in which a time lapse can be a parameter. According to China, in the post-retaliation phase, the clock starts ticking when the original responding party introduces a new measure. China argues that the amount of time needed to constitute a final determination by the original complaining party under Article 23 of the DSU depends on several factors, including but not limited to (1) the complexity of the compliance measure;

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[78] Third party submission of China, para. 32.
[79] Third party submission of China, para. 35.
[80] See Panel Report on *US – Section 301 Trade Act*, para. 7.50, footnote 657.
[81] See Panel Report on *US – Certain EC Products,* paras. 6.22 and 6.23.
[82] See Panel Report on *EC – Commercial Vessels,* WT/DS301/R, para. 7.196
[83] Third party submission of China, paras. 36-39.
[84] Third party submission of China, para. 40.
[85] See Panel Report on *US – Section 301 Trade Act*, para. 7.50, footnote 657.
[86] Third party submission of China, paras. 41 and 42.

(2) sufficiency of information related to the compliance measure; and (3) the ability of the original complaining party to evaluate such new measure.[87]

D. INDIA

1. Introduction

5.49 India submits that it takes no position on the respective assertions of the parties in this dispute. India notes however that the treaty text is not clear on the respective rights and obligations of the party taking a compliance measure and the party applying sanctions. India contends that this is evidenced by the fact that this is one of the major issues on which the WTO Membership is currently engaged in negotiation with a view to improve or clarify the legal text. India states that it has views on how the lacunae in the DSU on this issue can be improved or clarified, but that is a matter for the Membership to decide through future negotiations.[88]

2. Opening Panel meetings for observation by the public

5.50 India submits that the issue of external transparency is being discussed in the ongoing negotiations in the Special Session of the Dispute Settlement Body. India states that the negotiations have not yet been completed, and there is no consensus on whether and which form of external transparency is acceptable to the WTO Members. Until that happens, India believes that the Panel proceedings have to be in closed session,[89] and its deliberations have to remain confidential[90] as provided in the DSU.[91]

5.51 India posits that it is not a function of a panel to respond to any requests from the parties that do not assist in resolution of the matter before it, and which are not in the terms of reference of the panel.[92]

5.52 India contends that the possibility of a panel to decide to deviate from the Working Procedures in Appendix 3 has been provided with a view to have panel procedures with sufficient flexibilities so as to ensure high-quality panel reports[93]. In India's view, deviation from the Working Procedures, therefore, should meet this qualitative objective. India quotes Article 12.1 of the DSU and the Panel in *India – Patents (US)*[94] *and argues that although p*anels are given some discretion in establishing their own working procedures, they do not have the discretion to modify the substantive provisions of the DSU. India argues that the confidentiality requirements for panel proceedings are a substantive provision of the DSU, and the Panel cannot use its discretion to modify them in order to cater to a request by the parties on a matter that does not serve to improve the quality of the Panel's Report.[95]

5.53 India argues that Article VII of the Rules of Conduct[96] requires each "covered person" to maintain the confidentiality of dispute settlement deliberations and proceedings at all times. India

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[87] Replies by China to Panel questions, question 1.
[88] Oral statement by India, para. 3.
[89] Paragraph 2 of the Working Procedures in Appendix 3 of the DSU
[90] Paragraph 3 of the Working Procedures in Appendix 3 of the DSU
[91] Replies by India to Panel questions concerning open hearings, question 1.
[92] Oral statement of India, para. 5.
[93] Article 12.2, DSU
[94] *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products – Complaint by the United States*, Panel Report, WT/DS50/R.
[95] Oral statement of India, para. 6.
[96] Rules of conduct for the understanding on rules and procedures governing the settlement of disputes adopted by the DSB on 3 December 1996 (WT/DSB/RC/1).

questions how the Panel is going to ensure that these requirements are met after opening the proceedings to the public for observation.[97]

5.54 India submits that the decision of the Panel to open its proceedings to the public necessarily involves some issues on which consultation and decisions with WTO members, and not just the parties and third parties, would have been necessary. For example, India questions how the Panel, at its own level, addressed issues relating to the implications on the functioning of the WTO Secretariat, budgetary implications and implications relating to the use of the official languages of the WTO, for which rules and practices have been established by other bodies of the WTO. India also questions how the Panel could take a view on the additional costs arising out of the opening up of the proceedings to public without the Budget Committee having considered the matter.[98]

5.55 According to India, the WTO is a Member driven organization and it is solely for the WTO Members to decide whether or not to change the WTO rules and open up panel proceedings to the public; a Panel cannot take upon itself that function, even at the request of parties to the dispute.[99]

5.56 India posits that the meeting of the Panel's session with the third parties should be in closed session as required under paragraph 2 of the Working Procedures contained in Appendix 3 of the DSU.[100]

E. MEXICO

1. Introduction

5.57 Mexico submits that the systemic implications of this dispute are of great importance in terms of the functioning of the DSU and in particular of defining a way of proceeding when there is an authorization to suspend benefits and then further disagreement as to whether or not the DSB's recommendations and rulings have been implemented. In Mexico's view, the most important issue in this case is whether the adoption of implementation measures "require" immediate termination of retaliatory measures and if not, who should require termination and how. According to Mexico, the role of the Panel in this case is to give precise answers to these questions and to ensure that they fulfil not only the letter of the DSU, but also the objectives of security, predictability and prompt settlement of the dispute.[101]

2. Opening Panel meetings for observation by the public

5.58 Mexico disagreed with the opening of the panel meetings to the public on the grounds that panel meetings constitute panel "deliberations" and as such should be confidential, as per Article 14.1 DSU. Mexico also argues that transparency is a sensitive issue that is currently under discussion in the negotiations to amend the DSU thus to force one or another negotiating position by taking such a decision is inappropriate. Mexico argues that the DSU rules require that the meetings be confidential and therefore, bilateral agreement among parties is not suffice to bend the rules. In its view, therefore, the decision of the two parties should only prevail to the extent that it does not affect the right of other DSB Members including third parties. Mexico contends that if the Panel is to depart from the Working Procedures of Appendix 3, the Panel must do so with caution as such deviation is meant to grant flexibility so as to ensure high quality panel reports, as seen in Article 12.2 DSU.[102]

[97] Oral statement of India, para. 7.
[98] Oral statement of India, para. 8.
[99] Oral statement of India, para. 9.
[100] Replies by India to Panel questions concerning open hearings, question 2.
[101] Replies by Mexico to Panel questions concerning open hearings, question 1, paras. 2, 3 and 9.
[102] Oral statement of Mexico, para. 2; Replies by Mexico to Panel questions, paras. 3 and 9.

5.59 Mexico emphasizes that public hearings are a cross-cutting issue that should be addressed in all the discussions conducted in the WTO, and should not be imposed by a panel at the request of three Members. Mexico regrets that the decision will set a precedent that may affect the outcome of the negotiations and which will in all likelihood end up complicating the preparation of working procedures of future panels.[103]

5.60 Mexico notes that if the Panel is to open the meetings to the public observation, as a policy perspective, it poses systemic questions as to the necessity to open negotiation meetings and ordinary sessions of the WTO bodies to the public.[104] Mexico suggests that third party sessions follow the established WTO practice of being closed session.[105]

3. Whether the DSB authorization remains in effect

5.61 According to Mexico, the Panel should reject the argument that a simple unilateral notification is enough to reduce multilateral effort to nothing. Mexico contends that the Panel should bear in mind the lengthy procedure and high political costs to Members of obtaining a multilateral authorization to suspend concessions.[106]

5.62 Mexico stresses that it can not allow a dispute settlement system to deprive all effect of the authority to suspend benefits when a Member has failed to implement the DSB's recommendations and rulings within the reasonable period. In its view, in such a case, if the parties fail to agree, the matter must be resolved by a multilateral decision.[107]

5.63 Mexico argues in its reply to the questions posed by the European Communities that a DSB decision may be affected only by another DSB decision taking away the effect of the first decision.[108]

4. Article 21.5 of the DSU

5.64 Mexico claims that Article 21.5 DSU affords the most suitable procedure for resolving this dispute and it could be initiated by any party. Mexico however submits that the dispute could be dealt with either by an ordinary panel, or through arbitration under Article 25 DSU or indeed by any of the proceedings provided for in Article 5 DSU. Mexico however points out that it takes a constructive approach and good will by the parties to make Article 21.5 DSU function and be able to resolve any disagreements.[109]

F. NEW ZEALAND

1. Introduction

5.65 New Zealand submits that this case raises important issues about the integrity and effectiveness of the WTO dispute settlement system, as it is principally about issues of compliance and the proper interpretation and application of the rules of the DSU as they relate to the post-retaliation phase. In New Zealand's view, the case taken by the European Communities is for all intents and purposes a compliance case and is thus akin to an Article 21.5 case. According to New Zealand, the same determinations are required to resolve the case at hand, as would be required had it

[103] Oral statement of Mexico, para. 3.
[104] Replies by Mexico to Panel questions concerning open hearings, question 1, para. 7.
[105] Replies by Mexico to Panel questions concerning open hearings, question 2.
[106] Oral statement of Mexico, para. 5.
[107] Oral statement of Mexico, para. 4.
[108] Replies by Mexico to questions from the European Communities, question 4.
[109] Oral statement of Mexico, para. 6.

been commenced under Article 21.5. In New Zealand's view, the Panel's terms of reference[110] are sufficiently broad to encompass this question and in doing so, the Panel should focus on actual compliance and not presumed compliance.[111]

2. Opening Panel meetings for observation by the public

5.66 According to New Zealand, there are no legal constraints that would prevent the Panel from opening the Panel hearings to the public. New Zealand quotes Article 12.1 which allows panels to follow Working Procedures unless the panel decides otherwise after consulting the parties. New Zealand argues that while Appendix 3 provides for closed session hearings, the Working Procedure can be amended on the consent of the panel and the parties. New Zealand further stipulates that the reference in Article 14.1 of the DSU to panel deliberations being confidential refers to the internal deliberations of the panel, not the hearings with the parties. New Zealand submits that this is in line with the practice of other international tribunals which have open hearings but whose deliberations are nonetheless confidential. According to New Zealand, Article 18.2 of the DSU allows parties to waive confidentiality. New Zealand did not object to its third party hearings being public.[112]

3. Whether the DSB authorization remains in effect

5.67 New Zealand submits that there is no obligation on the United States to take an Article 21.5 case, and that in the absence of a determination of compliance from the DSB, the DSB's authorization of suspension of concessions remains valid.[113]

5.68 New Zealand argues that underlying the European Communities' arguments is the assumption that it should benefit in these circumstances from a presumption of compliance on the basis of the principle of good faith.[114] New Zealand however does not agree that the said principle applies in the current circumstances, to require the United States to cease the suspension of concessions and commence Article 21.5 proceedings simply because the European Communities has notified that it now considers itself to be in compliance. According to New Zealand, a presumption of good faith cannot override an explicit multilateral authorization from the DSB to impose a retaliatory suspension of concessions.[115]

5.69 In New Zealand's view, the cases cited by the European Communities in support of the application of a presumption of compliance involve measures that were implemented within the reasonable period of time and where there was no authorization to suspend concessions, which is not the situation at present. New Zealand opines that even if it can be said that a presumption of compliance operates in the pre-retaliation period while the reasonable period of time is still pending, in the current circumstances any presumed compliance on the part of the European Communities has

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[110] WT/DS320/6 of 14 January 2005 and WT/DS/320/7. The Request for the Establishment of a Panel by the European Communities states, *inter alia*, that:

The United States has acted inconsistently with Article 22.8 of the DSU by failing to apply the suspension of concessions or other obligations only until such time as the measure found to be inconsistent with a covered agreement has been removed, or the implementing Member has provided a solution to the nullification or impairment of benefits previously caused to the United States. (emphasis added).

[111] Third party submission of New Zealand, paras. 1.06 and 2.19.

[112] Replies by New Zealand to Panel questions concerning open hearings, questions 1 and 2.

[113] Third party submission of New Zealand, para. 2.09.

[114] The European Communities sets out its arguments on the 'presumption of compliance' in paras. 81-94 of its First Written Submission in addressing its argument that the United States is in violation of Article 23.1 read together with Articles 22.8 and 3.7 of the DSU.

[115] Third party submission of New Zealand, paras. 2.10 and 2.11.

given way to the actual compliance of the suspension of concessions which has been duly authorized by the DSB.[116]

4. Articles 21.5, 22.8 and 23 of the DSU

5.70 New Zealand argues that while it would be open to the respondent to initiate compliance review under Article 21.5, the argument that Article 23 read with Articles 21.5, 22.8 and 3.7 imposes a requirement to do so cannot be sustained. New Zealand insists that Article 21.5 merely states that the disagreement shall be dealt with through recourse to the dispute settlement procedures, but does not place any particular onus on any one to commence proceedings.[117]

5.71 New Zealand contends that Article 23 is the framework provision setting up the requirement to have recourse to dispute settlement when seeking redress of a violation of obligations. New Zealand however argues that Article 23 does not address the specific situation in this case, where the United States has had recourse to dispute settlement in accordance with this Article and has taken all the steps there identified. New Zealand submits that Article 23 does not impose an obligation on the United States to cease the application of the suspension of concessions or to take a compliance review case where it does not accept that the measure has been removed. Nor does it do so when "read together" with Articles 3.7 and 22.8. New Zealand argues that it cannot see how these provisions can be read to displace the specific authorization under Article 22.6, which has never been revoked.[118]

5.72 New Zealand posits that if the Panel were to adopt the European Communities' approach, it would give rise to a situation where an implementing Member could continually impose successive rounds of litigation at will, by a mere assertion of compliance. In New Zealand's view this could render useless the mechanism of suspension of concessions. According to New Zealand, this approach is inconsistent with the aims and objectives of the dispute settlement system given the fundamental importance of suspension of concessions as the 'last resort' of the dispute settlement system, as per Article 3.7 DSU.[119]

5.73 New Zealand points out that the suspension of concessions may not be maintained indefinitely in circumstances where the violation has been addressed as stipulated in Article 22.8 of the DSU. According to New Zealand, if the respondent maintains the suspension notwithstanding, then there is a "disagreement as to the existence or consistency ... of measures taken to comply" with the recommendations within the terms of Article 21.5. As a consequence it is open to the party concerned about this to have recourse to the dispute settlement procedures to resolve the disagreement.[120]

5.74 New Zealand notes that this does not mean however, that sanctions may go on forever even in cases where there is full compliance but the new measure has not been challenged. New Zealand considers that if a measure taken to comply does indeed remove the inconsistency with the recommendations and rulings of the DSB, the suspension of concessions should be ceased. In its view, the justification for continuing to suspend concessions would be the combination of the continuing DSB authorization and the absence of any agreement that the original respondent has brought its measures into compliance.[121]

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[116] Third party submission of New Zealand, para. 2.12.
[117] Third party submission of New Zealand, para2.14.
[118] Third party submission of New Zealand, paras. 2.14-2.16.
[119] Third party submission of New Zealand, para. 2.17.
[120] Third party submission of New Zealand, para. 2.18.
[121] Replies by New Zealand to questions from the European Communities, questions 4 and 5.

5.75 In New Zealand's view, it is possible for an implementing Member to initiate an Article 21.5 proceeding in any case "where there is disagreement as to the existence or consistency with a covered agreement of measures taken to comply with the recommendations and rulings" of the DSB.[122]

5.76 New Zealand states that Article 21.5 does not specify the procedures to be applied, beyond stipulating that the matter be referred to the original panel and that there be an accelerated timeframe for circulation of the report. It further contends that the consequence is that it is up to the Panel to establish the Panel procedures in accordance with Article 12 of the DSU.[123]

5.77 New Zealand submits that there is no textual basis in the DSU for concluding that an original complainant that maintains a multilaterally authorized suspension of concessions after notification of a compliance measure by the original respondent and does not initiate Article 21.5 proceedings, is in violation of its obligations under the DSU.[124]

5. Burden of proof

5.78 New Zealand submits that the European Communities bears the burden of proving a prima facie inconsistency with Article 22.8 of the DSU. New Zealand refers to the Appellate Body decision in *US – Wool Shirts and Blouses*[125], and contends that the European Communities must adduce evidence sufficient to raise a presumption that the suspension of concessions continues to apply and that: (a) it has removed the measure found to be inconsistent with the *SPS Agreement*; or (b) it has provided a solution to the nullification or impairment of benefits; or (c) a mutually satisfactory solution has been reached. The European Communities does not argue (b), and (c) is clearly not the case, but it instead relies on (a).[126]

5.79 New Zealand submits that the European Communities has not demonstrated in its first written submission that it has removed the inconsistent measure. According to New Zealand, 'removal' of an inconsistent measure for the purposes of Article 22.8 of the DSU may be interpreted as compliance with the recommendations and rulings of the DSB. 'Removal' of the measure in this case could involve the removal of the import prohibition and/or establishing a justification for the prohibition through a risk assessment consistent with the *SPS Agreement*, taking into account the particular requirements which the Panel and Appellate Body reports identified.[127]

6. Article 5.7 of the *SPS Agreement*

5.80 New Zealand posits that as the Member seeking to have recourse to Article 5.7, the burden of proof rests on the European Communities to demonstrate that the four requirements of that provision have been met.[128] New Zealand is of the view that while not explicitly stated by the European Communities, the provisional import ban on the five hormones other than oestradiol-17β appears to be an attempt to bring those measures within the qualified exemption provided of Article 5.7 of the *SPS Agreement*. According to New Zealand, as seen in *Japan – Agricultural Products II*[129], the European Communities must demonstrate that: (a) its measure was imposed in a situation where

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[122] Replies by New Zealand to questions from the European Communities, question 6.

[123] Replies by New Zealand to Panel questions, question 2.

[124] Replies by New Zealand to Panel questions, question 5.

[125] *United States – Measure Affecting Imports of Woven Wool Shirts and Blouses from India (US – Wool Shirts and Blouses)*, WT/DS33/AB/R, 25 April 1997, p. 14.

[126] Third party submission of New Zealand, paras. 2.21-2.22

[127] Third party submission of New Zealand, para. 2.26.

[128] The Panel in *Japan – Measures Affecting the Importation of Apples* (*Japan – Apples*), WT/DS245/R, 15 July 2003, discussed at para. 8.212 the burden of proof under Article 5.7.

[129] Appellate Body Report on *Japan – Measures Affecting Agricultural Products (Japan – Agricultural Products II)*, WT/DS76/AB/R, 22 February 1999, para. 89.

'relevant scientific evidence is insufficient'; and that (b) its measure was adopted "on the basis of available pertinent information, including that from relevant international organisations as well as from sanitary or phytosanitary measures applied by other Members."[130]

5.81 New Zealand claims that pursuant to the second sentence of Article 5.7, the European Communities may not maintain its measure unless it also: (a) 'seek[s] to obtain the additional information necessary for a more objective assessment of risk'; and (b) 'review[s] the measure accordingly within a reasonable period of time'. New Zealand posits further that the Appellate Body added that "[w]herever *one* of these four requirements is not met, the measure at issue is inconsistent with Article 5.7."[131] New Zealand argues that the European Communities states that its provisional ban on five of the six hormones was adopted "on the basis of the available but still incomplete data".[132] However, according to New Zealand, the European Communities is not required under Article 5.7 to show that the relevant scientific evidence was 'incomplete', but rather that it was 'insufficient'. New Zealand quotes the Appellate Body in the *Japan – Apples* case, which analysed the meaning of this expression that:[133]

> " '[R]elevant 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*."[134]

5.82 New Zealand is of the opinion that the European Communities in its first written submission does not establish a prima facie case that relevant scientific evidence does not allow an adequate risk assessment to be carried out. New Zealand argues that the European Communities fails in its first written submission to explain how the current state of scientific knowledge has prevented it from conducting an adequate risk assessment with respect to the five hormones. According to New Zealand, this is even more difficult to understand when the same measure, an import ban, which the European Communities previously maintained was based on sufficient scientific evidence to be definitive, is now held out as a merely 'provisional' measure.[135]

5.83 New Zealand submits that on the other hand, the respondent in its first written submission shows that a considerable body of relevant scientific evidence exists as to the use of hormones for growth promotion purposes.[136] New Zealand argues that the United States points out that the hormones at issue have been "intensively studied over the last twenty-five years"[137] and that the five particular hormones subject to the provisional ban have been "studied in greater detail in the intervening period (since the original *Hormones* case)".[138] According to New Zealand, the inference to be taken is that the relevant scientific evidence is both quantitatively and qualitatively sufficient to have enabled the European Communities to conduct an adequate risk assessment, and avoid the need for recourse to provisional measures.[139]

5.84 New Zealand further opines that even if the Panel were to accept that there was insufficient scientific evidence for the European Communities to conduct an adequate risk assessment, the European Communities must also show that its new measure was adopted 'on the basis of available

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[130] Third party submission of New Zealand, paras. 2.28 and 2.29.
[131] Appellate Body Report on *Japan – Agricultural Products II*, para. 89. Emphasis original.
[132] EC's first written submission, para. 145.
[133] Third party submission of New Zealand, paras. 2.30-2.32.
[134] Appellate Body Report on *Japan – Apples*, para. 179.
[135] Third party submission of New Zealand, para. 2.34.
[136] See US's first written submission at paras. 55-91.
[137] US's first written submission, para. 122.
[138] US's first written submission, para. 123.
[139] Third party submission of New Zealand, para. 2.35.

pertinent information'. New Zealand stresses that in order to satisfy the burden of proof, the European Communities must present the 'available pertinent information' it evaluated and the factors that led it to conclude that a provisional import ban on the five hormones could reasonably be based on this information. New Zealand states that the European Communities failed in its first written submission to establish any connection between its provisional import ban and: (a) the available pertinent information; (b) information from relevant international organisations; and (c) information from sanitary or phytosanitary measures applied by other Members.[140]

5.85 According to New Zealand, by contrast, the United States claims that a large body of 'available pertinent information'[141] indicates that proper use of the hormones in question poses no risk to consumers.[142]

5.86 New Zealand submits that under the third limb of Article 5.7, in a situation where the relevant scientific evidence is insufficient to conduct an adequate risk assessment, the European Communities is required to 'seek to obtain the additional information necessary for a more objective assessment of risk'. New Zealand contends that the European Communities implies that this requirement is reflected in Directive 2003/74/EC, which obliges the Commission "to seek more complete scientific information from any source which could shed light and clarify gaps in the present state of knowledge on [the hormones]."[143] New Zealand however submits that the European Communities offers no evidence in its first written submission to explain how the Commission is fulfilling this obligation.[144]

5.87 New Zealand further opines that the final element of Article 5.7 requires the European Communities to 'review' its provisional measures 'within a reasonable period of time'. New Zealand notes that while a competent WTO body has yet to analyse what constitutes a 'reasonable period of time,' Directive 2003/74/EC has been in force for nearly two years, but the European Communities makes no suggestion in its first written submission that a review of the provisional import ban is contemplated at all, let alone within a 'reasonable period of time'. New Zealand submits that the European Communities has failed to discharge its burden of proof with respect to the four elements of Article 5.7 in its first written submissions.[145]

7. Article 5.1 of the *SPS Agreement*

5.88 New Zealand alleges that the European Communities has not demonstrated in its first written submission that its new measures meet the requirements of Article 5.1 *SPS Agreement*. New Zealand contends that the Appellate Body in *EC – Hormones* established that the obligation in Article 5.1 contains two elements: (a) an assessment of risks; and (b) that Members ensure that their SPS measures are "based on" such an assessment. New Zealand argues that concerning the first element of Article 5.1, paragraph 4 of Annex A of the *SPS Agreement* sets out the definition of a "risk assessment". New Zealand quotes the Appellate Body[146] that recalled Article 5.2 of the *SPS Agreement*, which provides an indicative list of factors that must be taken into account in a risk assessment.[147]

5.89 New Zealand further argues that the panel in the *Japan – Apples* case summarised its consideration of the elements of Article 5.1 by recalling that a risk assessment would also involve an evaluation of whether the risk assessment was 'as appropriate to the circumstances', and whether it

[140] Third party submission of New Zealand, para. 2.36.
[141] See US's first written submission, paras. 127-128.
[142] Third party submission of New Zealand, para. 2.37.
[143] EC's first written submission, para. 145.
[144] Third party submission of New Zealand, para. 2.38
[145] Third party submission of New Zealand, paras. 2.38 and 2.39.
[146] Appellate Body Report on *EC – Hormones*, para. 187.
[147] Third party submission of New Zealand, paras. 2.42-2.44.

took into account 'risk assessment techniques developed by the relevant international organizations'.[148] New Zealand posits that the panel in that case added that these two factors would "pervade the entire assessment of the risk".[149]

5.90 New Zealand stresses that while the European Communities claims to have conducted "a comprehensive risk assessment" since the Appellate Body decision in 1998[150], it devotes only three paragraphs of its first written submission to attempting to establish what constitutes a valid risk assessment for the purposes of Article 5.1. New Zealand submits that the European Communities notes that it has initiated 17 scientific studies and research projects, but enters into no discussion of the substance, conduct or conclusions of these studies.[151] According to New Zealand, the European Communities observes that it addressed specific requests for scientific data to several countries and published an open call for relevant and recent scientific data and information from any interested party, but makes no comment on the information received.[152]

5.91 New Zealand further opines that in its first written submission, the European Communities simply refers to the SCVPH Opinions and presents a three-paragraph excerpt from Directive 2003/74/EC[153] which provide, on the face of it, a rather limited and constrained justification for the European Communities' import ban. Further, New Zealand posits that the European Communities articulates no clear link between "excess intake of hormone residues" (which is not defined in relation to use as a growth-promoting hormone) and "a risk" that has been identified.[154]

5.92 In New Zealand's view, the European Communities' recital and its bare conclusion fall well short of demonstrating that the European Communities has met the threshold required under the *SPS Agreement* for the existence of a valid risk assessment. New Zealand notes that in particular, the European Communities fails in its first written submission to adduce sufficient evidence that its risk assessment: (a) adequately identifies any adverse effects on human health arising from the presence of the hormones in question when used as growth promoters in meat;[155] (b) evaluates the potential or possibility of occurrence of such adverse effects;[156] (c) is 'as appropriate to the circumstances';[157] (d) takes into account risk assessment techniques developed by the relevant international organisations;[158] and (e) takes into account the available scientific evidence as matters specified in Article 5.2 of the *SPS Agreement*.[159]

5.93 New Zealand argues that none of these criteria is optional in the performance of a risk assessment, and therefore the European Communities is required to demonstrate that all of them have been satisfied in the development of its opinions. New Zealand submits that the European Communities has failed to adduce sufficient evidence to discharge this burden.[160]

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[148] Panel Report on *Japan – Apples*, para. 8.236.
[149] Panel Report on *Japan – Apples*, para. 8.237.
[150] EC's first written submission, para. 142.
[151] EC's first written submission, para. 142.
[152] Third party submission of New Zealand, para. 2.48.
[153] EC's first written submission, para. 144.
[154] Third party submission of New Zealand, para. 2.49.
[155] *SPS Agreement*, Annex A, paragraph 4. Extrapolated from the Panel Report in *EC – Hormones*, para. 8.101, as considered in the Appellate Body Report at paras. 183-184.
[156] *SPS Agreement*, Annex A, paragraph 4. Extrapolated from the Panel Report in *EC – Hormones*, para. 8.101, as considered and modified in the Appellate Body Report at paras. 183-184.
[157] *SPS Agreement*, Article 5.1.
[158] *SPS Agreement*, Article 5.1.
[159] Third party submission of New Zealand, para. 2.51.
[160] Third party submission of New Zealand, para. 2.52.

5.94 New Zealand contends that in contrast, the United States outlines some of the scientific evidence that exists on the use of growth-promoting hormones[161], and evokes long-standing practice on the proper assessment of risks related to veterinary drug residues.[162] According to New Zealand, this casts doubt on both the process and the substance of the European Communities' risk assessment.[163]

5.95 New Zealand states that in the event that the Panel decides that the European Communities' opinions constitute a valid risk assessment for the purposes of Article 5.1, the European Communities is also required to demonstrate that the measures in question are 'based on' a risk assessment. According to New Zealand, the Appellate Body analysed this relationship in *EC – Hormones*[164], and states that the term 'based on' required a certain objective relationship between the risk assessment and the measure in question.[165]

5.96 New Zealand argues that the European Communities does not attempt to explain in what way or to what extent its new measures are considered to be 'in accordance' with the scientific conclusions of the SCVPH. New Zealand further stipulates that the European Communities offers no basis at all for concluding that its risk assessment 'reasonably supports' its new measures. New Zealand argues that in this case, the European Communities bears the burden of establishing that its risk assessment 'sufficiently warrants' the new measures it adopted. In New Zealand's view it was not open to the European Communities to leave the existence of a 'rational relationship' to be inferred from a brief summary of the conclusions of the European Communities' opinions.[166]

G. NORWAY

1. Opening Panel meetings for observation by the public

5.97 Norway considers that Article 12.1 of the DSU gives the Panel the discretion to follow other working procedures than the ones provided in Appendix 3 after consulting the parties. It sees no legal constraints in granting the request to the parties to open the hearings to the public. Norway also agrees to have the third party session of the hearing open to the public.[167]

2. Whether the DSB authorization remains in effect

5.98 Norway considers that the right to apply the suspension of concessions pursuant to a DBS authorization is temporary and conditional. According to Norway, the application of the right rests on two basic conditions. First; that there be an authorization pursuant to Article 22.6 DSU and that the conditions set out in Article 22.6 DSU and 22.7 DSU, are respected and secondly, that the temporal condition of Article 22.8 is met.[168]

5.99 Norway opines that the temporal condition in Article 22.8 has three alternative elements: (a) the measure found to be inconsistent with a covered agreement has been removed; or (b) the Member that must implement recommendations or rulings provides a solution to the nullification or impairment of benefits; or (c) a mutually satisfactory solution is reached.[169]

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[161] See, for example, US's first written submission, paras. 55-91.
[162] US's first written submission, para. 136.
[163] Third party submission of New Zealand, para. 2.53.
[164] Appellate Body Report on *EC – Hormones*, para. 193.
[165] Third party submission of New Zealand, para. 2.55.
[166] Third party submission of New Zealand, para. 2.58.
[167] Replies by Norway to Panel questions concerning open hearings, question 1 and 2.
[168] Replies by Norway to questions from the European Communities, questions 3, 4 and 5, para. 2.
[169] Replies by Norway to questions from the European Communities, questions 3, 4 and 5, para. 3.

5.100 Norway contends that the common concept in all the three elements is that continued suspension is related to continued non-compliance or lack of any other mutually satisfactory solution to the inconsistency. According to Norway therefore , the temporal condition is intrinsically linked to the substance of compliance. Norway posits that out of the three elements, the third one, "a mutually satisfactory solution", can in principle be achieved at any point in time and once achieved, would resolve the matter and no suspension may continue. Norway adds that this is even so if the original measure found to be inconsistent with a covered agreement is still in place.[170]

5.101 Norway considers that the first two elements are in reference to compliance, which can be achieved through the removal of the original measure or through another solution to the nullification or impairment of benefits, and the second element is the normal situation where one measure is replaced by another measure.[171]

5.102 Norway submits 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 obligations automatically lapses. Norway is of the view that similarly, once compliance has been established by a panel pursuant to Article 21.5 of the DSU, the previous authorization 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.[172]

5.103 Norway contends that once a measure taken to comply is notified by the original respondent, the question arises whether this amounts to full compliance or not. Norway submits that if the original complainant considers that the measure taken to comply falls short of what is required by the adopted rulings and recommendations, then the obligation to refer a "compliance dispute" to a panel according to Article 21.5 is incumbent upon them.[173]

3. Article 21.5 of the DSU

5.104 Norway argues that the situation addressed by Article 21.5 DSU occurs when the original respondent claims to have complied with the recommendation and ruling of the DSB, but the original complainant disagrees. According to Norway, Article 21.5 is competent both where the parties disagree as to the very existence of measures taken to comply, and where they disagree as to whether the measures taken to comply actually achieve compliance. Norway is of the view that the case at hand is typical in this respect, and falls squarely within the ambit of Article 21.5. Norway notes that neither Article 22.8 nor Article 21.5 sets forth time lines in this respect.[174]

5.105 According to Norway, the original complainant must be accorded a certain amount of time to assess the measure before going to a compliance panel. Norway posits that the length of time needed will vary from case to case, and it is hard to set a fixed dead-line. In Norway's view, the DSU does not include such a fixed dead-line, however, this does not mean that the original complainant can refuse to take action according to Article 21.5 within a reasonable time. Norway thus contends that in order to avoid such unreasonable delay, Article 21.5 allows the original respondent to have recourse to a compliance panel.[175]

5.106 Norway contends that the obligation to refer a "compliance dispute" to a panel according to Article 21.5 rests on both parties in the dispute. According to Norway, Article 21.5 does not specify

[170] Replies by Norway to questions from the European Communities, questions 3, 4 and 5, paras. 4 and 5.
[171] Replies by Norway to questions from the European Communities, questions 3, 4 and 5, para. 6.
[172] Replies by Norway to questions from the European Communities, questions 3, 4 and 5, para. 7.
[173] Replies by Norway to Panel questions, question 5 para. 10.
[174] Replies by Norway to questions from the European Communities, questions 3, 4 and 5, para. 8.
[175] Replies by Norway to Panel questions, question 5, paras. 11 and 12.

that it must be the original complainant to refer the matter to a "compliance panel". Norway submits that Article 21.5 is written in the passive form, concentrating on the result, specifically to place this obligation on all parties to the original dispute.[176]

5.107 Norway submits that the standard practice has been that the original complainant refers the matter to the panel. It argues that the one exception so far has been the referral to a compliance panel by the European Communities in *EC – Bananas III (Article 21.5 – EC)*.[177] According to Norway, the fact that the report remains unadopted and that the panel in that case refused to make any recommendations or rulings in the case, does not in itself prove that an original respondent may not invoke Article 21.5.[178] Rather, the position of the Panel in that case must be seen in the light of the fact that Ecuador also requested a separate compliance panel[179], and that the United States had submitted a request for retaliation that led to arbitration.[180] Norway submits that the panel in that particular case could thus justify not making any recommendations or rulings by pointing to these other proceedings.[181]

5.108 In Norway's view, a panel launched by the respondent cannot just make a declaratory judgment based on the presentation of the original respondent, but must make an objective assessment of the matter before it. The scope of the "terms of reference" would be to examine whether the measures taken to comply imply that there is now compliance with the rulings and recommendations of the original panel, *i.e.* that the original violation has been removed. Only the violations specifically addressed in the original report will be addressed by the compliance panel, not any other violations that the new measure may cause.[182]

5.109 Norway argues that where the original complainants refuse to participate, then any claim that the new measure is inconsistent with other provisions of the covered agreements will not be heard (will be outside of the "terms of the reference" for the compliance panel), and the original complainants risk a finding of compliance that does not take into account all the arguments that they would otherwise have presented. By not launching the Article 21.5 panel in a timely manner, the original complainants thus lose certain rights to present new claims that they would have had, had they themselves launched the panel request first. Such claims will thus have to await another panel. As such, the incentive structure that is created by allowing the original respondent to launch an Article 21.5 panel proceeding works to provide the original complainants with the incentive to go ahead themselves and launch the Article 21.5 panel first.[183]

5.110 In case a compliance panel is requested by the original respondent, the reference in Article 6.2 to "provide a brief summary of the legal basis of the complaint sufficient to present the problem

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[176] Joint reply by Norway to question 2 from the Panel and question 6 from the European Communities, para. 13.

[177] *European Communities – Regime for the Importation, Sale and Distribution of Bananas – Recourse to Article 21.5 by the European Communities*, Report by the Panel (WT/DS27/RW/EEC), 12 April 1999 – report never adopted.

[178] Joint reply by Norway to question 2 from the Panel and question 6 from the European Communities, para. 14.

[179] *European Communities – Regime for the Importation, Sale and Distribution of Bananas – Recourse to Article 21.5 by the Ecuador*, Report by the Panel (WT/DS27/RW/ECU), 12 April 1999.

[180] *European Communities – Regime for the Importation, Sale and Distribution of Bananas – Recourse to Arbitration by the European Communities under Article 22.6 of the DSU*, (WT/DS27/ARB), Report of the arbitrators dated 9 April 1999.

[181] See paras. 4.15 and 4.16 of the Panel Report in WT/DS27/RW/EEC.

[182] Joint reply by Norway to question 2 from the Panel and question 6 from the European Communities, paras. 16 and 18.

[183] Joint reply by Norway to question 2 from the Panel and question 6 from the European Communities, para. 16.

clearly" can be fulfilled by referring to the original panel report, together with the identification of the specific measure taken to comply and how it ensures compliance.[184] Where the original respondent has to request an Article 21.5 panel because the original complainants refused to do so, the original respondent may be considered as "complainant" for the purpose of Article 6.1 and "applicant" for the purpose of Article 6.2. The question who is "complainant" and who is "respondent" does not matter for the rest of the proceedings.[185]

H. SEPARATE CUSTOMS TERRITORY OF TAIWAN, PENGHU, KINMEN AND MATSU

1. Introduction

5.111 The Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu (Chinese Taipei) submits that it presents its views in this dispute because of the important systemic issues involved, in particular, the raised DSU provisions that are under negotiations in the Special Session of the Dispute Settlement Body. In its view, the resolution of certain issues in this case could significantly impact these negotiations.[186]

2. Opening Panel meetings for observation by the public

5.112 Chinese Taipei argues that in accordance with the procedures and customary practices developed over more than half a century under GATT, which are reflected in Articles 14.1, 18.2 and Appendix 3 of the DSU, panel proceedings are to be kept confidential. It argues that only Members by consensus can change the rules of confidentiality. According to Chinese Taipei, a panel, even with the consent of the parties does not have the legal authority to open the proceedings to the public.[187]

5.113 Chinese Taipei refers to Article VII of the Rules of Conduct which requires that each covered person shall at all times maintain the confidentiality of the dispute settlement deliberations and proceedings. According to it, the only exception to this confidentiality obligation is Article 18.2 of the DSU which states that nothing in the DSU shall preclude a party to a dispute from disclosing statements of its own positions to the public. Chinese Taipei is therefore of the opinion that this exception does not extend to the possibility of allowing parties to decide whether to open panel meetings to the public.[188]

5.114 According to Chinese Taipei, "panel deliberations" implies more than one form of deliberation, thus includes not only internal consideration among panelists, but also the entire process of the panel's consideration of the dispute.[189]

5.115 Chinese Taipei argues that the flexibility from Article 12.1 of the DSU to change Working Procedures in Appendix 3 cannot be extended to cover provisions in the Working Procedures that directly elaborate on the obligations of the DSU. It further argues that if the drafters had contemplated that the confidentiality requirement can be changed, they would have said so, just like in Article 18.2 of the DSU. In the absence of such language, only an amendment to the DSU by the Members through negotiations can change the requirement of confidential deliberations.[190]

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[184] Joint reply by Norway to question 2 from the Panel and question 6 from the European Communities, para. 18.
[185] Joint reply by Norway to question 2 from the Panel and question 6 from the European Communities, paras. 17 and 19.
[186] Third party submission of Chinese Taipei, para. 1.
[187] Replies by Chinese Taipei to Panel questions concerning open hearings, question 1, paras. 1 and 2.
[188] Replies by Chinese Taipei to Panel questions concerning open hearings, question 1, paras. 4 and 5.
[189] Replies by Chinese Taipei to Panel questions concerning open hearings, question 1, para. 3.
[190] Replies by Chinese Taipei to Panel questions concerning open hearings, question 1, paras. 6 and 7.

5.116 Chinese Taipei is of the opinion that the third party sessions be in closed session.[191]

3. Whether the DSB authorization remains in effect

5.117 Chinese Taipei contends that the new implementing measure is required to be confirmed by a multilateral determination that the measure is compliant with the DSB's recommendations and rulings. According to it, a unilateral claim of compliance together with the principle of good faith does not overturn the DSB authorization of suspension of concessions, and that suspension of concessions can continue until the conditions in Article 22.8 have been met.[192]

5.118 According to Chinese Taipei, the suspension of concessions can only be lifted after a multilateral determination of compliance, which involves an examination of the implementing measure against the recommendations and rulings of the DSB, or by mutual agreement of the parties. In its view, until then, the DSB authorization remains valid and the suspension of concessions may continue. Chinese Taipei further states that if none of the parties brings the implementing measure to the panel, whether through Article 21.5 or Article 22.8, the suspension of concessions may continue. It contends that without the initiation of a dispute that results in the examination of the implementing measure, the *status quo* would be considered as maintaining the existing balance of rights and obligations among WTO Members.[193]

5.119 Chinese Taipei does not consider that there is a need to justify the continuing suspension of concessions after the implementing Member's claim that it has complied with the DSB's recommendations and rulings.[194]

5.120 Chinese Taipei rejects the view that the lack of action for any period of time on the part of Canada constitutes an expression of Canada's determination. According to it, the existence of the determination by Canada cannot depend on such an indeterminate criteria as the length of time it takes for Canada to take action under Article 21.5 of the DSU. In its view, Article 22.8 of the DSU allows Canada to continue its suspension of concessions until one of the three conditions therein have been met.[195]

4. Article 21.5 of the DSU

5.121 Chinese Taipei considers that one of the ways to arrive at a multilateral determination in the current situation is through Article 21.5 of the DSU. With respect to the European Communities' argument that in absence of the initiation by Canada of an Article 21.5 compliance panel, the European Communities' implementing measure must be presumed to be compliant with WTO rules[196] and the continuation of the suspension of concessions by Canada would amount to a unilateral determination of a violation of WTO rules, it argues that Article 23.2(a) is valid only if two requirements are present in the text of Article 21.5,namely, (a) a deadline by which a 21.5 panel must be initiated, and (b) an obligation only on the original complaining party to initiate the proceeding.[197]

5.122 Chinese Taipei considers that neither one of these requirements currently exists in the text, nor is it reasonable to interpret their existence. It submits that it is up to the Member involved to choose whether and when to initiate the Article 21.5 proceeding. It opines that while it recognizes that the party suffering the suspension of concessions has an interest to lift such suspension as early as

[191] Replies by Chinese Taipei to Panel questions concerning open hearings, question 2, para. 12.
[192] Replies by Chinese Taipei to questions from the European Communities, question 1.
[193] Replies by Chinese Taipei to questions from the European Communities, question 4.
[194] Replies by Chinese Taipei to questions from the European Communities, question 5.
[195] Replies by Chinese Taipei to Panel questions, question 1.
[196] EC's first written submission, para. 61.
[197] Oral statement of Chinese Taipei, para. 2.

possible, that interest has to be balanced with the fact that the same party had originally been determined, through a lengthy WTO process, to be in violation of its obligations, and had a chance to implement, but failed to do so, within a reasonable period of time. Further, it argues that consistent with the text of Article 21.5, if the original respondent considers the conditions for the suspension of concessions to be no longer valid, the respondent may initiate the Article 21.5 proceeding at any time.[198]

5.123 Chinese Taipei stresses that as the DSU currently stands, there is no deadline and no designated party to initiate the Article 21.5 proceeding. Chinese Taipei agrees with the United States that just because the United States has not initiated the Article 21.5 proceeding does not mean that the European Communities automatically enjoys the presumption of compliance. In its view, at this stage, only a multilateral procedure can reach that conclusion, and one of the ways the European Communities can obtain such a multilateral determination is through its initiation of an Article 21.5 panel.

5.124 Chinese Taipei wishes to remind the Panel that the procedural issues involved in this case are currently under discussion in the negotiations on the improvement and clarification of the DSU. It argues that several competing proposals are on the table, including one from the European Communities. Chinese Taipei notes that it is a view widely shared by Members that the DSU procedures in this so-called "post-retaliation stage" are imperfect. According to Chinese Taipei however, it is not the task of the Panel, or indeed any Member, through litigation, to make up for such imperfection. Therefore, Chinese Taipei urges the Panel to avoid interpreting the current provisions in a way that would impose rules or requirements that are not written in the text.[199]

5. The relationship between Article 22.8 and Article 23 of the DSU

5.125 Chinese Taipei argues that Articles 23 and 22.8 apply to different situations and therefore should not be read together, as this would lead to a weakening of the WTO dispute settlement system. It contends that Article 22.8 differs from Article 23 in that it deals with the specific post-retaliation situation, outlining the conditions under which the suspension of the concessions pursuant to authorization from the DSB can be lifted. Chinese Taipei states that the general principle of resolving disputes under the multilateral system in Article 23 has been specifically modified by Article 22.8. Article 22.8 thus has its own independent set of requirements applicable specifically to the post-retaliation situation, apart from the general principles in Article 23.[200]

5.126 Chinese Taipei opines that the basis upon which European Communities builds its arguments for its interpretation of DSU Articles 23 and 22.8 is the general principle of good faith under which States are normally considered to act in conformity with their obligations.[201] Chinese Taipei agrees that Article 23.2(a) embodies that principle in prohibiting Members from making any unilateral determination to the effect that a violation has occurred.[202]

5.127 Chinese Taipei argues that by its title, Article 23 applies to the normal situations when the Member is responding to a perceived violation, nullification, impairment, or impediment, to which the Member is seeking remedy. It argues that this is the normal situation under which most cases begin and are first brought to the attention of the Dispute Settlement Body.[203]

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[198] Oral statement of Chinese Taipei, para. 3.
[199] Oral statement of Chinese Taipei, para. 4.
[200] Third party submission of Chinese Taipei, paras. 2 and 7.
[201] EC's first written submission para. 87.
[202] Third party submission of Chinese Taipei, paras. 2-4.
[203] Third party submission of Chinese Taipei, para. 5.

5.128 According to Chinese Taipei, Article 23.2 prescribes the actions Members may take in the normal situation described in Article 23.1. According to it, specifically, 23.2(a) prevents a Member from acting upon the unilateral perception of violation until it is validated under multilateral procedures. Chinese Taipei considers that this amounts to the presumption that a Member is normally considered to be acting in conformity with its obligations until a multilateral determination under the WTO says otherwise.[204]

5.129 Chinese Taipei posits that Article 22.8 on the other hand describes situations that depart from the norm. It submits that the general principle in Article 23 relating to normal situations therefore has limited application and must be modified by the specific requirements spelt out in Article 22.8. In its view, the situation at hand is one where the redress of violation has already been determined at least once through multilateral procedures and where suspension of concessions has been authorized. Chinese Taipei argues that the requirement is not that the suspension of concessions must be lifted in the absence of an adverse finding, but rather that the suspension shall be applied until the violation has been removed or any of the other two conditions in the provision have been met.[205]

5.130 According to Chinese Taipei, it therefore follows from this difference in situation and requirement that the normal presumption that a Member is considered to be in conformity with its obligations until proven otherwise in a multilateral determination does not apply. It contends that since Article 22.8 provides that the suspension of concessions can continue until the removal of the violation, the presumption here is that there is no removal of the violation until a multilateral determination says otherwise.[206]

5.131 Chinese Taipei contends that if the normal presumption were to apply to Article 22.8, despite the existence of a multilateral determination and authorization for retaliation, any offending Member can simply declare itself to have removed the violation. It submits that this would create the incentive for Members to implement partially or not at all, and drag the Member suspending concessions into an endless loop of Article 21.5 litigations.[207]

5.132 Chinese Taipei is of the view that under both normal and Article 22.8 situations, a multilateral determination is the prerequisite to any action that changes the existing balance of rights and obligations. It further notes that normally, a Member cannot seek redress of violation without a multilateral determination because a balance is presumed to exist. Similarly, Chinese Taipei argues that under the Article 22.8 situation where suspension of concessions is in place, that situation is the presumed balance, and that existing balance cannot be changed without another multilateral determination.[208]

5.133 Chinese Taipei thus argues that the suspension of concessions by Canada does not fall into the normal situation described in Article 23 and until a multilateral determination deems the European Communities' implementing measure to have removed the previously multilaterally determined inconsistency, the continuation of suspension of concessions by Canada does not violate the existing provisions of the DSU.[209]

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[204] Third party submission of Chinese Taipei, para. 6.
[205] Third party submission of Chinese Taipei, para. 7.
[206] Third party submission of Chinese Taipei, para. 8.
[207] Third party submission of Chinese Taipei, para. 9.
[208] Third party submission of Chinese Taipei, para. 10.
[209] Third party submission of Chinese Taipei, para. 11.

I. UNITED STATES

1. Introduction

5.134 The United States submits that for all of the reasons set out in the arguments presented by the United States in *United States – Continued Suspension of Obligations in the EC – Hormones Dispute* (WT/DS320)[210] the United States concurs that Canada's continued suspension of concessions to the European Communities is consistent with the obligations of Canada under the DSU and GATT 1994.[211]

2. Opening Panel meetings for observation by the public

5.135 A summary of the arguments of the United States on the opening of panel meetings for observation by the public is set out in Section IV.B.2 of the Panel's Report in *United States – Continued Suspension of Obligations in the EC – Hormones Dispute* (WT/DS320).

VI. INTERIM REVIEW

A. INTRODUCTION

6.1 Pursuant to Article 15.3 of the DSU, the findings of the final panel report shall include a discussion of the arguments made by the parties at the interim review stage. This section of the Panel report provides such a discussion. As is clear from Article 15.3, this Section is part of the Panel's findings.

6.2 The European Communities and Canada separately requested an interim review by the Panel of certain aspects of the interim report issued to the Parties on 31 July 2007.[212] The European Communities stated that it stood ready to attend an interim review hearing to discuss the issues raised in its letter, "should the Panel consider it useful". The Panel notes that it is not for it to decide whether holding an interim review hearing would be useful. Article 15.2 of the DSU provides that it is "[a]t the request of a party [that] the panel shall hold a further meeting with the parties on the issues identified in the written comments." The Panel does not understand the EC statement above as a request by the European Communities for the Panel to hold an additional meeting with the parties. Furthermore, the Panel notes that Canada did not request such a meeting. As a result, the Panel did not hold an interim review meeting.

6.3 In accordance with the Panel working procedures and timetable, the parties had, and used, the opportunity to submit further written comments on each other's requests for review of specific aspects of the interim report.[213] These comments are discussed, where relevant, together with the request to which they relate.

6.4 The Panel issued its final report to the parties on a confidential basis on 21 December 2007.

6.5 The Panel has structured its treatment of the Parties' requests below in the following manner:

(a) first, it addresses a comment made in relation to the descriptive part of the report (Section IV) that the Panel could not address at an earlier stage of the proceedings;

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[210] WT/DS320/6.
[211] Letter of 19 August 2005 to the Panel explaining the US third party submission.
[212] Letters of the parties dated 28 September 2007.
[213] Letters of the parties dated 19 October 2007.

(b) second, it discusses the comments of the parties relating to the findings of the Panel and, more particularly:

(i) the aspects of the report regarding procedural issues (Section VII.A);

(ii) the comments of the parties regarding the Panels findings of violation of Article 23.2(a) read together with Articles 21.5 and 23.1 of the DSU (Section VII.B); and

(iii) the comments of the parties regarding the compliance of the EC ban on meat and meat products treated with the six hormones at issue for growth promotion purposes with the *SPS Agreement* in relation to the Panel's findings on the EC claims on Article 23.1, read together with Articles 22.8 and 3.7 of the DSU (Section VII.C).

6.6 In addition, minor editing changes were made, which the Panel did not deem necessary to list in this section.

B. PARTIES' COMMENTS ON THE DESCRIPTIVE PART

6.7 The Panel considered and incorporated in its revised descriptive part the majority of the parties' comments. In one instance, however, the Panel rejected the modifications requested by the European Communities and deems it appropriate to provide its reasons in this section.

6.8 This instance relates to the EC request that the Panel incorporate in the descriptive part the parties' arguments on logistical issues relating to the opening to public observation of the Panel's substantive meetings with the parties and with the experts.

6.9 In its comments on paragraph 4.2 and following of the descriptive part of this report, the European Communities notes that, while the parties' answers of 20 June 2005 to a number of questions of the Panel have been reported in full, there is no reference to the parties' replies of 7 July 2005 to the additional questions of the Panel. This, in the opinion of the European Communities, raises a question of the completeness of the record of the parties' arguments. Inserting the replies of the parties of 7 July 2005 is also important according to the European Communities since the comments of the third parties on logistical matters have been reported in the descriptive part. Thus, the European Communities requests the Panel to reflect the parties' responses to these additional questions in its report.

6.10 The Panel notes that the parties' replies of 7 July 2005 essentially addressed technical questions of a logistical nature. The Panel did not deem it necessary to insert in its report any account of the logistical aspects of the opening of the hearings to public observation. The Panel notes in this respect that it did not include in the descriptive part of the report extracts from the replies of the parties of 20 June 2005 that related to logistical issues. Given that, among the third parties, only India and Mexico mentioned, in a general manner, the logistical implications of opening hearings to public observation, the discussion on logistical issues essentially took place between the parties themselves, or between the parties and the Secretariat. The Panel did not address the details of the logistical issues in its decision on opening meetings for public observation. This matter is, in the opinion of the Panel, purely administrative. It is neither procedurally nor factually relevant for the resolution of the dispute before us. The Panel is mindful that such an account might be useful from a practical point of view for future panels. However, it considers that the technical solutions found in this case may not necessarily be extended to other panel procedures, if only because the parties' expectations and constraints, e.g. in

terms of confidentiality, may be different in future cases.[214] Whereas the Panel provided a detailed account of the legal issues related to the opening of the Panel's hearings for public observation, for the reasons mentioned above, it decided not to follow the suggestion of the European Communities.

6.11 The Panel nonetheless wishes to confirm that the technical options available were extensively discussed with the parties and that the solution finally selected, i.e. the broadcast of the hearings into a separate room through closed-circuit television, was adopted in accordance with the positions expressed by the parties.

C. PARTIES' COMMENTS REGARDING THE FINDINGS OF THE PANEL

1. Preliminary remarks

6.12 As a preliminary remark, the Panel notes that the European Communities mentions in the introduction to its written request for the Panel to review precise aspects of the interim report that it:

> "[W]ill try to provide some examples of the numerous and serious errors in the reasoning of the Panel on the scientific issues underpinning this dispute. However, it is not possible in the time available to provide a detailed and complete list of all omissions and errors of the two interim reports as it would in reality require re-writing substantial parts of the Panel's report in order to rectify its analysis and reasoning... Therefore, the European Communities reserves the right to make all its comments at the appeal stage, if the Panel's findings on the issue were to be maintained."[215] (emphasis added)

6.13 This statement suggests that the European Communities did not identify all the precise aspects of the interim report with which it disagrees due to lack of time and because this would require rewriting substantial parts of the Panel report. It would, however, be able to make all its comments at the appeal stage. The Panel wishes first to make it clear that parties were free to request an extension if they needed more time to review the interim report and identify precise aspects that should be addressed by the Panel. The Panel notes in this respect that it is at the request of the European Communities that parties were granted several additional weeks to review the interim report. The Panel also notes that the European Communities gave as a justification for its request the expected length and complexity of the report. The Panel therefore regrets that the European Communities is now alleging lack of time as a justification for providing only "some examples" of errors in the reasoning of the Panel on the scientific issues underpinning this dispute.

6.14 In contrast, the European Communities mentions that it may make "all its comments" at the appeal stage. The Panel is surprised by the apparent choice of the European Communities to "make all its comments" before the Appellate Body rather than before the Panel, at the procedural stage expressly designed for the purpose of considering any and all comments on the interim report. This is because the decision of the European Communities to provide only "some examples" of errors of the Panel suggests that it has already decided to appeal the Panel report unless the Panel makes changes which the European Communities will not specify. It is also not clear whether the "examples" given by the European Communities exhaust all its factual comments or whether it intends to make further

[214] In the present dispute, after comparing different alternatives, the Secretariat was able to arrange open hearings through closed-circuit broadcast from one room to another utilizing the existing facilities of the Secretariat. The cost of open hearings was covered by the regular budget under the Secretariat arrangement. There may be different cost implications for future disputes in different circumstances but that consideration would fall outside the remit of this Panel.

[215] EC's written request of 28 September 2007, para. 5.

comments on factual issues before the Appellate Body. Having regard to Article 17.6 of the DSU, we consider this to be equivalent to depriving the interim review stage of its purpose.

6.15 The Panel therefore regrets that the European Communities did not request an extension so as to ensure that all the comments it deemed necessary on precise aspects of the interim report be made at the procedural stage of the dispute settlement process intended for that very purpose.

6.16 The Panel also notes that some of the EC comments are general statements on whole sections of the report, not a written request for the Panel to review *precise aspects* of the interim report. We recall that the panel in *Australia – Salmon*[216] stated as follows:

> "According to Canada, it is not open to the Panel to consider anything other than comments dealing with 'precise aspects' of the interim report. We agree with Canada and have therefore only reviewed our interim report in light of the comments made by the parties which relate to 'precise aspects' of the interim report."

6.17 We agree with the reasoning of the above-mentioned panel and therefore consider that the general comments by the European Communities did not require a specific reply from the Panel. We limited our replies to the portions of the report on which specific comments, in the form of precise requests for reconsideration of specific paragraphs, had been made by the European Communities. We addressed the EC general comments as part of our review of specific paragraphs.

2. Parties' requests for review related to aspects of the report on procedural issues

(a) Comments by the European Communities

6.18 The European Communities considers the Panel's reference to Article 17.10 of the DSU in paragraph 7.48 of the interim report is unnecessary and potentially detrimental as implicitly suggesting that the Appellate Body could be legally barred by Article 17.10 of the DSU from opening its own hearings to public observation. The European Communities requests that we remove that paragraph from our findings. We note that a similar request was made by Canada. Since this reference was only an additional argument, we accepted the parties' requests and removed our discussion of the term "proceedings" in Article 17.10 of the DSU.

6.19 The European Communities considers that the description of IARC contained in paragraph 7.76 footnote 370 is incomplete. It refers to Dr. Cogliano's statement in Annex G, paragraph 541. In paragraph 541, Dr. Cogliano essentially says that IARC monographs simply indicate which substances are carcinogenic or are probably not carcinogenic to humans. Monographs identify occurrence (i.e. exposure to a chemical through some particular pathway), but not the specific level of exposure for a particular population. Dr. Cogliano also says in paragraph 541 that different decision-making authorities will decide whether the evidence contained in IARC monographs sufficiently supports an SPS decision or whether they need to conduct further analysis. Thus it seems that IARC monographs provide information and serve in risk assessment. This said, the text in the footnote is a verbatim quote from the IARC website, describing what IARC does. Thus the Panel did not deem it necessary to augment the footnote.

6.20 The European Communities argues that the second sentence of paragraph 7.83 does not reflect reality, since the European Communities did not agree with the final decision on Working Procedures for Consultation with Scientific and/or Technical Experts adopted by the Panel. The Panel notes that, in a letter of 3 November 2005, the European Communities commented on the draft expert working procedures. One of the comments was that the experts should act as a single expert review

[216] Panel Report on *Australia – Salmon*, para. 7.3.

group in order to provide a consistent advice on the issues concerned. The European Communities also suggested that the experts should be independent from the industry or regulatory bodies which had a vested interest in the issue on which they would be consulted. The Panel rejected the EC request that experts should act as a single review group in its letter sent to the parties on 25 November 2005, together with its finalized Working Procedures for Consultation with Scientific and/or Technical Experts. We therefore modified paragraph 7.83 to reflect the absence of full agreement of the European Communities on the Panel's Working Procedures for Consultation with Scientific and/or Technical Experts.

6.21 The European Communities further requests us to redraft the fourth sentence of paragraph 7.83 to reflect better its concerns that two of the experts selected by the Panel participated in the preparation and drafting of the JECFA risk assessment of the hormonal substances at issue in this case, with which the EC risk assessment disagrees. The Panel sees no problem in clarifying the nature of the work of these two experts with JECFA It remains however puzzled by the EC suggestions that a scientist who worked with JECFA could be deemed to be biased in assessing the scientific evidence on which EC Directive 2003/74/EC relies and could be assumed to defend JECFA's work. 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 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 agrees with Canada in its comments on comments of 19 October 2007 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.

6.22 The Panel does not agree either with the EC arguments according to which the two experts at issue should not be described as "internationally recognized specialists". The Panel notes the arguments of Canada in this regard in its comments of 19 October 2007. The Panel recalls that these two experts 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 of the Panel to JECFA.[217] The Panel fails to understand why the JECFA selection would not be evidence of the international reputation of the scientists at issue.[218] The EC concerns about JECFA's work and the 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 their not having carried out experiments with the substances at issue and does not see any need for further substantial elaboration. The Panel has nevertheless made some clarifications, in response to the EC request, to paragraph 7.83.

6.23 The European Communities requests that we modify the first sentence of paragraph 7.85 to better reflect the content of its letter of 28 March 2006. We consider that the letter largely reiterated points which the Panel already addresses in paragraph 7.83, i.e. the involvement of experts in the preparation and drafting of JECFA's risk assessments and their alleged lack of scientific expertise. Besides this, the EC letter of 28 March deals exclusively with conflict of interest, which is the subject

[217] Annex E-2, pp. 115-116.

[218] See also Dr. Boobis, Annex G, para. 511; Dr. Tritscher, Annex G, para. 515; Dr. Wennberg, Annex G, para. 517.

addressed by the Panel in paragraph 7.85. While the Panel has modified the paragraph to reflect the fact that the EC letter addressed other issues already discussed in this report, it did not deem it necessary to modify the rest of the paragraph, except to clarify the elements on the basis of which the Panel considered that the experts concerned should be deemed to be the best among the very few individuals available.

6.24 Having reviewed the EC comments on paragraph 7.87 of the interim report**,** the Panel agrees that this paragraph did not directly relate to the issue of the alleged conflict of interest of two of the experts consulted by the Panel and has deleted it.

6.25 The European Communities argues that the statements in paragraph 7.115 and footnote 388 are not accurate as some of the subsequent evidence did expand and confirm the scientific basis of Directive 2003/74/EC. The European Communities refers to the replies of Dr. Guttenplan and Dr. Sippell. In paragraph 7.115 and footnote 388, the Panel states that nothing new was submitted after the adoption of Directive 2003/74/EC that differed *in any fundamental way* from previous evidence. This is not contradicted by the EC comment that subsequent evidence expanded and confirmed the scientific basis of its Directive, including the EC reply to question 5 of the Panel after the second substantive meeting.[219] The statements of Dr. Guttenplan referred to by the European Communities[220] do not support the EC argument. Dr. Sippell mentions in paragraph 611 of Annex G that he changed his opinion on exposure to exogenous oestrogens and precocious puberty because the acceptance of the significance of the ultrasensitive assays within paediatric endocrinology increased tremendously after he published his review article in 1999. However, the ultrasensitive assays he is referring to were not carried out or published after the adoption of Directive 2003/74/EC. In his written replies[221], where he discusses the ultrasensitive assay techniques, Dr. Sippell refers to *Klein et al (1994)* and *Larmore et al (2002)* and other studies dated 1999 or 2001. As a result, in the opinion of the Panel, the statement of Dr. Sippell cited by the European Communities is not about evidence that became available after the adoption of the Directive. Consequently the Panel did not modify paragraph 7.115 and footnote 388.

6.26 The European Communities also argues with respect to paragraph 7.116 that it had reserved its right to submit the finally published version of the study contained in Exhibit EC-107. According to the European Communities, this study was submitted in time and should have been accepted. The Panel notes that, when it submitted Exhibit EC-107 on 21 December 2005, the European Communities specified that it "reserve[d] its right to submit further evidence, if and to the extent this appears necessary for the purpose of commenting on any further submissions by the other parties as well as on replies of the panel's experts". The Panel does not read this reservation as reserving the EC right to submit the finally published version of the study. Moreover, the Panel recalls that the European Communities stated that it left it to the discretion of the Panel whether to forward the published version to the experts.[222] The Panel considers that it sufficiently explained in its report the reasons why the published version of this study had not been sent to the experts. In particular, it considered that submitting a modified study to experts at a relatively late stage of the expert consultation proceedings could generate confusion.

6.27 The European Communities also considers with respect to paragraph 7.124 that the Panel should accept that the European Communities submit the comments it wished to make in relation to some factual errors made by the United States[223] in its replies to the Panel questions posed after the

[219] Annex C, pp. 5-7.
[220] Annex G, paras. 709 and 713.
[221] Annex D, para. 319.
[222] See EC's letter to the Panel of 29 May 2006.
[223] Since the original request of the European Communities related to alleged factual errors in comments from the United States and Canada, and since the European Communities requests that we review

second substantive meeting. The Panel considers that its decision was clear. If inaccuracies resulting from US factual arguments had been reflected in the interim report, the European Communities could have identified them in its comments or in its comments on comments. There does not seem to be any need for the Panel to reverse its decision of 20 November 2006.

6.28 The European Communities also alleges, with respect to paragraph 7.126 *et seq.,* that one paragraph was added to the transcript of the experts' hearing annexed to this report compared with the version sent to the parties in January 2007. There are, indeed, more paragraph numbers. However, there is no additional text in Annex G as compared to the version sent to the parties in January 2007. In fact, the difference results from a correction to the paragraph numbers of the transcript. In the version sent to the parties for comments, there was a paragraph between paragraphs 29 and 30 that did not have a number. This paragraph became the new paragraph 30 in the final version of the transcript, and as a consequence, all the other paragraph numbers shifted by one. On the same subject, two more changes were made in paragraph numbers: paragraph 827 of the draft transcript was divided into two paragraphs, following a comment by the United States[224], and became paragraphs 828 and 829 in the final version of the transcript. Finally, another paragraph lacked a number, between paragraphs 926 and 927. This paragraph corresponded to a short statement by Dr. Boisseau clarifying that he had asked a question to Dr. Boobis, not to the European Communities. This unnumbered paragraph became paragraph 929. In conclusion, three additional paragraph numbers were added in the final version of the transcript compared to the draft version sent for comments to the parties. The draft version had 1069 numbered paragraphs; the final version has 1072 numbered paragraphs.

6.29 The European Communities also seems to request, with respect to paragraph 7.135**,** that the Panel specify the nature of the "editorial adjustments" made in the transcript. The Panel deems it appropriate to recall that the tapes of the meeting of the Panel with the experts were given to a typist who transcribed them. Two types of editorial adjustments were made to the transcript. First, the Secretariat proofread the transcript, identifying any words or passages the typist had misunderstood and checking these passages against the tapes. The type of errors identified were limited to confusions regarding technical terms (e.g. "N-point" instead of "endpoint"; "safe defactual" instead of "safety factor"[225] or "defactual threshold" instead of "de facto threshold"[226]). Other corrections involved minimal adjustments to sentences, for example to remove repeated words and occasionally adding punctuation marks. Once these corrections were made, the transcript was sent to the experts and subsequently to the parties in order to give each speaker the chance to verify that his or her own interventions had been accurately reflected. The experts' comments consisted of further corrections of technical words which had been improperly transcribed, or corrections of word order or colloquial expressions to make the transcript more legible. This is the reason why the Panel considered that these corrections did not go beyond "minimal editorial adjustments".

(b) Comments by Canada

6.30 With respect to the discussion of the procedural question of the opening of the Panel meetings with parties and experts for public observation, Canada requests that we remove our discussion of the term "proceedings" as it appears in Article 17.10 of the DSU. We note that the same request was made by the European Communities. Since this reference was only an additional argument, we accepted the parties' requests and removed our discussion of the term "proceedings" in Article 17.10 of the DSU.

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paragraph 7.124 of this report, the Panel deemed it appropriate to discuss this issue in this interim review section.

[224] See US's letter dated 14 February 2007.

[225] Annex G, para. 422.

[226] Annex G, para. 707.

6.31 Canada also requests that we modify paragraph 7.138. We see no reason not to adjust the description of the measure since it is actually the absence of recourse to the DSU by Canada which seems to be at the origin of the EC complaint. However, under the circumstances, we also deem it necessary to specify that the issue stems from the fact that Canada maintained the measure after the notification of Directive 2003/74/EC to the DSB and, accordingly, we have modified paragraphs 2.7 and 7.138.

6.32 Canada contests the conclusion of the Panel in paragraphs 7.149 and 7.151 that the European Communities narrowed the terms of reference of the Panel through the approach it followed in its first written submission. For Canada, the EC approach is a "choice of legal strategy" which is not binding on the Panel. The European Communities cannot constrain the terms of reference of the Panel by adopting a specific approach to its claims in its first written submission.

6.33 The Panel agrees that it is well established that a complainant cannot change the terms of reference of a panel in its first submission or subsequently. As stated by the Appellate Body in *EC – Bananas III*:

> "If a *claim* is not specified in the request for the establishment of a panel, then a faulty request cannot be subsequently 'cured' by a complaining party's argumentation in its first written submission to the panel or in any other submission or statement made later in the panel proceeding."[227]

6.34 However, the Panel does not believe that this is the issue in the present case. The European Communities did not try to cure a faulty request. It made its claims more specific. As the Panel itself noted[228], there could be several ways to find a violation of Article 23 of the DSU. The European Communities has clarified how it considered that this violation should be approached by the Panel. As stated by the Panel on *EC – Tube or Pipe Fittings*[229]:

> "In our view, it is in the nature of the Panel process that the claims made by a party may be progressively clarified and refined throughout the proceedings."

6.35 The Panel also quotes the Appellate Body in *US – Carbon Steel*.[230] It seems to be accepted that complainants can clarify their claims throughout the proceedings. In this instance however, it appears that Canada is concerned by the conclusion of the Panel that it is *bound* by these clarifications or that they are part of the Panel's terms of reference.

6.36 Panels are free to address claims in the order that they deem appropriate.[231] However, if a party specifies in its first written submission that a claim is raised in the alternative, can a panel disregard this clarification? To a lesser extent, can a panel disregard the fact that the complainant addressed the violation of a given provision in a particular way? Regarding the first question, it seems that panels should be bound by a claim made "in the alternative", as acknowledged by the Appellate Body.[232] Regarding the second question, the reply might be less clear and depend on the type of "clarification" made by the complainant. In the present case, the EC clarification had serious consequences on how the Panel could address the claims listed in the terms of reference. The European Communities did not claim a violation of Article 23 in general, but a violation of Article 23 as a consequence of a breach of Article 22.8 of the DSU. The Panel also notes the arguments of the

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[227] Appellate Body Report on *EC – Bananas III*, paras. 141-143; Appellate Body Report on *US – Lead and Bismuth II*, paras. 72 and 73.
[228] See para.7.159.
[229] Panel Report on *EC – Tubes and Pipes Fittings*, para. 7.10.
[230] See para. 7.148.
[231] Appellate Body Report on *Canada – Wheat Exports and Grain Imports*, para. 126.
[232] See, e.g., Appellate Body Report on *EC – Selected Customs Matters*, para. 308.

European Communities in its comments of 19 October 2007. The Panel recalls, in particular, that the rights of the respondent or its ability to defend itself were in no way affected by the "narrowing" of its claims by the European Communities. The Panel remains of the view that it is bound by the EC approach to its claims and, accordingly, has not modified paragraph 7.149 or paragraph 7.151.

3. Comments of the parties regarding the Panel's findings of violation of Article 23.2(a) read together with Articles 21.5 and 23.1 of the DSU and on the EC claims on Article 23.1, read together with Articles 22.8 and 3.7 of the DSU

(a) Comments by the European Communities

6.37 The European Communities disagrees with the interpretation the Panel makes, in paragraph 7.153, as well as in paragraph 7.288**,** of the EC claims as set out in its first written submission. The European Communities insists in its comments that "it did not argue [in its main claims] that there was a violation of Article 22.8 itself, but rather one of Article 23.1". In other words, the European Communities seems to suggest that the Panel should not have addressed the conformity of Canada's measure under Article 22.8 of the DSU – even though this Article was listed in the EC request for establishment of a panel – but only under Article 23.1. Yet, the European Communities alleges a violation of Article 22.8 in various parts of its first submission and subsequently.[233]

6.38 In the opinion of the Panel, the use of the term "in conjunction with" or "read together with" is not indicative that the European Communities only claims a violation of Article 23. In Section III.E.3 of its first written submission, the European Communities alleges a violation of Article 3.7 even though in its conclusions it states that the United States' and Canada's unilateral conduct "violates Article 23.1 of the DSU read in conjunction with Article 22.8 and 3.7 of the DSU". One cannot conclude either that the European Communities draws a conclusion of violation of Article 22.8 from the violation of Article 23.1 since its allegation of violation of Article 23.1 stems from the obligation to withdraw the measure if the violation has been removed. Rather, one must conclude the opposite, i.e. that the European Communities draws a conclusion of violation of Article 23.1 from a violation of Article 22.8. For those reasons, the Panel does not agree with the argument made by the European Communities at the interim review stage that it never made a claim of violation of Article 22.8 of the DSU, and that its claims related only to violations of Article 23.

6.39 The European Communities also contests the qualifications made by the Panel of its second series of main claims (i.e. its claims of violation of Article 23.1 of the DSU in conjunction with Article 22.8 and Article 3.7 of the DSU) as claims "premised on compliance by the European Communities with the DSB recommendations and rulings in the *EC – Hormones* case" in paragraph 7.163. The Panel notes that it has clearly explained in paragraphs 7.293-7.294 why it believes that this claim was premised on compliance with the DSB recommendations and rulings in the *EC – Hormones* case.

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[233] See, for instance:
- EC's first written submission, para. 71: "Under Article 23.1 of the DSU, Canada is obliged to have recourse to, and abide by, the rules and procedures of this Understanding. This encompasses, *inter alia*, Articles 22.8 and 3.7 of the DSU";
- EC's first written submission, Section III.E.2, title: "The obligation not to apply suspension of concessions or other obligations under Article 22.8 of the DSU";
- EC's first written submission, Section III:E.3, title: "Canada's violation of Article 23.1 and Article 22.8 of the DSU necessary entails a violation of Article 3.7";
- EC's first written submission, para. 123: "For these reasons, Canada, by violating Articles 23.1, 22.8 of the DSU, also acted contrary to Article 3.7 of the DSU";
- EC's oral statement at first meeting, para. 56: a "systemic claim under Article 22.8, *in conjunction with Article 23.1*";
- EC's second written submission, para. 174.

6.40 Consequently, and having regard to Canada's comments of 19 October 2007, the Panel will not delete the section of its report considering the allegedly non-existent EC claim under Article 22.8 of the DSU.

6.41 The Panel, however, deems it appropriate to clarify paragraph 7.163, and to make a modification with respect to paragraph 7.357 in order to make clear that it is not reviewing the EC claim of violation of Article 22.8 in isolation.

6.42 The European Communities also argues that, even though the obligation of the respondent clearly emerges from the Panel's reasoning, the Panel should clarify its recommendations. This could be done either by removing from the findings any consideration of the second series of main EC claims (i.e. its claim of violation of Article 23.1 of the DSU in conjunction with Articles 22.8 and 3.7 of the DSU) or, if necessary, through suggestions under Article 19.1 of the DSU, or through clarifications in the Panel's reasoning. A somewhat similar request for clarification has been made by the respondent in its request for review of precise aspects of the interim report. However, the European Communities suggests that the Panel should clarify that Canada must remove its suspension of concessions, whereas Canada requests that we clarify that our findings under Article 23.1 and 23.2(a) have been rendered moot by the current proceedings and the Panel's findings regarding Canada's compliance with Article 22.8 of the DSU.

6.43 The Panel is mindful of its duty to assist the DSB in making recommendations or rulings aimed at achieving a satisfactory settlement of the matter. The Panel notes that the parties have both requested that the Panel make suggestions or concluding remarks aimed at clarifying what is expected from Canada. The Panel notes, however, that their proposed suggestions or concluding remarks are divergent. The Panel wishes to recall its conclusion in paragraph 7.244. This conclusion is based on the terms of Article 23.1 and 23.2(a). Those provisions require that recourse should be had to "the rules and procedures of the [DSU]" (Article 23.1) or, in the case of Article 23.2(a), that recourse be had to "dispute settlement in accordance with the rules and procedures of this Understanding". Moreover, for reasons explained in this report, the Panel does not believe that recourse by the European Communities to dispute settlement exempts the respondent from its obligations under Article 23.1 and 23.2(a) of the DSU. The Panel has clarified this point in paragraph 8.3.

(b) Comments by Canada

6.44 The Panel accepted Canada's suggestion regarding paragraph 7.225.

6.45 Canada requests that we clarify our statement in the first sentence of paragraph 7.292 by confirming that the present proceedings and the Panel's findings in respect of Article 22.8 of the DSU, while technically not findings under Article 21.5 of the DSU, involve the same legal questions and legal conclusions as a compliance panel under Article 21.5 of the DSU. While recognizing that, indeed, its review of a breach of Article 22.8 by Canada involved in this case assessments resembling those that could have been performed by an Article 21.5 panel called upon to review the compatibility of Directive 2003/74/EC, the Panel notes a fundamental difference. The matter before it is not the conformity of Directive 2003/74/EC, but the conformity of the continued suspension of concessions or other obligations by Canada *vis-à-vis* the European Communities. The fact that the European Communities may have the possibility in practice to achieve, by initiating a panel procedure like the present one, a result similar to that which could be achieved by Canada having recourse to Article 21.5 does not exempt Canada from its obligation under Article 23 to have recourse to dispute settlement. Moreover, there is no telling which claims would be brought by Canada if it had recourse

to Article 21.5 of the DSU. We also note the EC comments of 19 October 2007.[234] As a result, the Panel does not deem it necessary to modify paragraph 7.292.

6.46 Canada requests that the Panel modify paragraph 7.358 so as to state that reviewing alleged violations of the *SPS Agreement* falls within the Panel's mandate and constitutes an integral part of its findings in this report.

6.47 The European Communities, in its comments of 19 October 2007[235], disagrees with the comments of Canada to the extent that, unlike in the case referred to by Canada where there was an express reference to another provision in the article allegedly breached, there is no reference in the term "removed" in Article 22.8 to any other provision. The European Communities considers that if Canada's interpretation prevailed, the responding party would effectively be free to refer to any provision of the covered agreements and the terms of reference would become meaningless.

6.48 The Panel considers that it has extensively explained why it believes that, while making actual findings regarding the compatibility of the EC Directive 2003/74/EC with the *SPS Agreement* is not part of its mandate, it has jurisdiction to address the compatibility of the Directive with the *SPS Agreement* to the extent necessary to make findings in relation to Article 22.8 of the DSU, which is part of its mandate. The Panel notes that this is part of its duty to make an objective assessment of the matter pursuant to Article 11 of the DSU and a sentence has been added to that effect in the findings.[236] The Panel also believes that its approach is consistent with the scope of a panel mandate as confirmed by the Appellate Body.

6.49 Moreover, the Panel considers that the Appellate Body report in *Argentina – Footwear (EC)*[237] does not support the view that the Panel could make actual findings with respect to the compatibility of the EC measure with the *SPS Agreement*. First, the EC implementing measure (Directive 2003/74/EC) is not part of the terms of reference of the Panel. Second, the Appellate Body report in *Argentina – Footwear (EC)* confirms the reasoning of the Panel:

> "We have examined the specific paragraphs in the Panel Report cited by Argentina, and we see no *finding* by the Panel that Argentina acted inconsistently with Article 3 of the *Agreement on Safeguards*. In one instance[238], the Panel referred to Article 3 parenthetically in support of its reasoning on Article 4.2(a) of the *Agreement on Safeguards*. Every other reference to Article 3 cited by Argentina was made by the Panel in conjunction with the Panel's reasoning and findings relating to Article 4.2(c) of the *Agreement on Safeguards*. None of these references constitutes a legal finding or conclusion by the Panel regarding Article 3 itself."[239]

6.50 In that case, the panel had reviewed Article 3 of the *Agreement on Safeguards* as part of its review of Article 4.2(a), not as a finding on Article 3. Article 3 was not mentioned in the terms of reference of the panel. The Appellate Body agreed with the panel that it had to consider Article 3. It even concluded that it had an obligation to do so. But it also noted that the panel made no findings under Article 3. Rather, its consideration of Article 3 was made in support of its reasoning on Article 4.2(a).

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[234] Paras. 14-16.
[235] Para. 21.
[236] Para. 7.374.
[237] Appellate Body Report on *Argentina – Footwear (EC),* paras. 74-75.
[238] (*footnote original*) Panel Report, para. 8.238.
[239] Appellate Body Report on *Argentina – Footwear (EC)*, para. 73.

6.51 Finally, Canada requests a modification to paragraph 8.2 and the addition of a new paragraph confirming that the Panel's finding of a breach of Article 23.1 and 23.2(a) has been rendered moot by the current proceedings and the Panel's findings regarding Canada's compliance with Article 22.8 of the DSU. Regarding paragraph 8.2, having duly considered the EC comments on comments, we nonetheless decided to replace the term "legislation" with the term "measure", consistent with Article 19.1 of the DSU. Indeed, the measure at issue has been previously defined in paragraph 7.138.

6.52 Regarding Canada's request for the addition of a new paragraph, we do not agree with Canada that, through our comment in the first sentence of paragraph 7.350, we have recognized that recourse to Article 21.5 of the DSU has become unnecessary by virtue of the current proceedings. What we meant was that this dispute was an alternative to a recourse to Article 21.5 *by the European Communities*, not that it was an alternative to Canada complying with its obligations under Article 23.1 and 23.2(a) of the DSU. We have clarified this point in paragraph 8.3.

4. Comments of the parties on the compliance of the EC ban on meat and meat products treated with the six hormones at issue for growth promotion purposes with the *SPS Agreement* in relation to the Panel's findings on the EC claims on Article 23.1, read together with Articles 22.8 and 3.7 of the DSU

(a) Comments by the European Communities

(i) Introductory comments

6.53 In an introduction to its specific comments, the European Communities alleges:

(a) that the Panel has dismissed the 1999, 2000 and 2002 Opinions as not constituting a proper risk assessment based on an alleged absence of specific evidence which, the European Communities claims, is impossible to provide;

(b) that the Panel dismissed the Opinions as not having presented sufficient evidence to call into question the conclusions of JECFA;

(c) that the Panel should have scrutinized JECFA's evaluations, which are based on old studies which were not publicly available and were not communicated to the Panel or the Panel's experts for review;

(d) that the Panel has reached its conclusions on the EC implementing measure (Directive 2003/74/EC) by relying selectively, for a number of important issues, on the statements of two experts in a group of six. The European Communities recalls that those two experts had participated in the drafting of the JECFA's assessments contradicted by the EC Opinions and were obviously defending their own work and the methodology applied by JECFA and Codex. Comparatively, the other four experts had overall validated and supported the conclusions of the EC Opinions; and, finally,

(e) that the Panel's methodology and reasoning are contrary to established principles on burden of proof and standards of review of genuine scientific questions by WTO panels and ordinary courts of law.

6.54 Regarding the argument under (a) above, the Panel will address this question when it addresses the EC comments on the Panel's findings under Article 5.1 of the *SPS Agreement*. As a preliminary remark, however, the Panel wishes to clarify that it did not "dismiss the opinion of a relevant committee constituted of highly regarded, independent scientific experts". The Panel

concluded that the European Communities had not evaluated specifically the possibility that the adverse effects related to the association between excess hormones and neurobiological, developmental, reproductive and immunological effects, as well as immunotoxicity, genotoxicity and carcinogenicity coming into being, originating or resulting from the consumption of meat or meat products which contain veterinary residues of oestradiol-17β as a result of the cattle being treated with this hormone for growth promotion purposes. The Panel also found that the scientific evidence referred to in the Opinions does not support the EC conclusions on genotoxicity, or the conclusion that the presence of residues of oestradiol-17β in meat and meat products as a result of a cattle being treated with this hormone for growth promotion purposes leads to increase cancer risk. Nor does the scientific evidence support the EC conclusions about the adverse immunological and developmental effects of consuming meat and meat products from cattle treated with oestradiol-17β for growth promotion purposes. This does not put into question the results of the studies and research relied upon by the SCVPH, nor the conclusions reached by the scientists, but simply the conclusions drawn by the European Communities on the basis of the science.

6.55 Regarding the argument under (b) above, it 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*[240], as well as with the presumption of compliance under Article 3.2 of the *SPS Agreement*.

6.56 As far as the argument under (c) is concerned, the Panel explained in its findings why it relied on JECFA's work without questioning it.[241] First, using JECFA's risk assessments as "benchmarks" did not mean that the Panel had to examine the scientific evidence supporting JECFA's conclusions. Second, none of the parties contested that JECFA and Codex work on the hormones at issue (with the exception of MGA) constitute international standards, guidelines and recommendations within the meaning of Article 3.2. Because sanitary measures which conform to international standards, guidelines or recommendations are deemed to be consistent with the provisions of the *SPS Agreement*, the Panel had no reason to scrutinize the evaluation made by JECFA. The only benefit of such an evaluation would have been to determine whether JECFA's risk assessment met the conditions of Article 5.1. However, the question before the Panel is not to review the validity of international standards – the Panel has no mandate to do that. It is not to review whether JECFA's risk assessments are compatible with Article 5.1, but whether the EC implementing measure is compatible with Article 5.1 as far as oestradiol-17β is concerned or justified under Article 5.7 for the other five hormones at issue. The Panel also notes in this respect that, whereas Members have, pursuant to Article 3.3, a right to introduce or maintain sanitary measures which result in a higher level of sanitary protection than would be achieved by measures based on the relevant international standards, guidelines and recommendations, the way to do this is not by seeking to demonstrate that those standards, guidelines and recommendations are flawed or outdated, which would simply show that they have become insufficient and would not justify the EC measure, but by providing positive evidence or information supporting the conformity of the measure at issue with Article 5.1 and/or Article 5.7. It was, thus, for the European Communities to provide convincing evidence, in line with the requirements of Article 3.3 of the *SPS Agreement*, to justify its definitive ban on oestradiol-17β and that relevant scientific evidence was insufficient for the other five hormones.

[240] Appellate Body Report on *Japan – Apples*, para. 179.
[241] Paras. 7.621-7.625.

6.57 Regarding the argument according to which the two experts involved in the drafting of JECFA's risk assessments were defending their own work and the methodology applied by JECFA and Codex, the Panel wishes to add to what it has already said above 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.[242] The purpose was not to check whether JECFA's risk assessments were supported by sufficient scientific evidence or carried out in accordance with Article 5 of the *SPS Agreement*, but to identify to what extent the concerns raised by the European Communities in its submissions had been considered in the development of its risk assessments by JECFA (e.g. how the risk to prepubertal children had been taken into account by JECFA). 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.[243] JECFA also regularly reassesses its risk assessments, normally at the request of Members of Codex, and evidence before the Panel suggest that the European Communities did not request JECFA to reassess the hormones at issue on the basis of the new evidence it had gathered. Instead, the European Communities relied on its own risk assessment. 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. For instance, Dr. Boobis stated that:

> "[S]cience moves on, and it would be complacent for a risk assessment body to assume that it knew everything about a substance at a particular point in time. We have to work within the available information, and the question we ask is: do we have sufficient information at this point to conduct a risk assessment? – not: is the data complete and are there no scientific questions remaining to be answered."[244]

6.58 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. The Panel also notes that other experts referred to JECFA's work in their replies, just as they also referred to studies commissioned by the European Communities.[245]

6.59 The European Communities also argues that the remaining four experts "overall validated and supported the conclusions of the [SCVPH] Opinion[s]". The Panel does not share this point of view. First, not all experts expressed their views on all the issues. The experts who expressed their views often agreed with each other. Second, the impression that a majority of experts overall validated and supported the conclusions of the SCVPH Opinions is incorrect. With respect to the five provisionally banned hormones, to different degrees, the experts agreed that new studies would be useful. This does not mean, however, that they considered them useful for the reasons advocated by the European Communities. The four experts agreed regarding the hazard related to hormones, or the risk attached to high doses. But so did the two experts with JECFA experience.

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[242] In order to assess the appropriateness for the Panel to seek advice from experts involved in the preparation of JECFA's risk assessment, it is also important to recall that the experts are being consulted in the context of an assessment of the EC implementing measure under Articles 5.1 (and accessorily 5.2 in WT/DS320), 5.7 and 3.3 of the *SPS Agreement*, and of the presumption of conformity with the *SPS Agreement* of measures based on international standards.

[243] JECFA's reply to question 14 of the Panel. See also Dr. Boobis, Annex G, para. 511; Dr. Tritscher, Annex G, para. 515; Dr. Wennberg, Annex G, para. 517.

[244] See Annex G, para. 346.

[245] See, e.g. Dr. Guttenplan, Annex D, para. 145.

6.60 As to the argument that the Panel's methodology and reasoning are contrary to established principles on burden of proof and standards of review of genuine scientific questions by WTO panels and ordinary courts of law, the Panel wishes to recall its findings at paragraphs 7.377-7.383 and 7.403-7.418 on the standard of review and burden of proof. The Panel has also explained why it gave particular relevance to JECFA's risk assessments and why, to the extent that the European Communities disagreed with JECFA, it had to prove that its measure was based on a risk assessment consistent with Article 5.1 and Annex A(4) of the *SPS Agreement*, or that the relevant scientific evidence was insufficient.

6.61 The European Communities argues that the statement originally found in paragraph 7.368 was not accurate as the European Communities was allegedly replying to a hypothetical question and stated that it was not necessary to look into the scientific issues. The Panel notes that the European Communities stated in its reply to question 74 of the Panel[246] that "it did not believe that it [was] necessary to look into the scientific issues". The European Communities did not formally *object* to the Panel seeking scientific opinion even if the Panel proceeded with reviewing the *SPS Agreement*. Indeed, the European Communities added in its reply to the same question 74:[247]

> "However, the European Communities does not believe that the Panel would have the expertise to decide on such issues itself, should the Panel decide to go down [the road] of deciding the scientific issues at stake. In such a scenario, the European Communities believes that the consultation of scientific and technical advice would be absolutely necessary."

6.62 The European Communities argues that it was replying to an hypothetical question. Yet, the European Communities uses the affirmative and not the conditional in its reply when it states that "New experts will have to be chosen".[248] The Panel concludes that, whereas the European Communities was not of the view that it was necessary to look into the scientific issues, it was nevertheless in favour of the consultation of scientific experts if the Panel decided to address the scientific issues at stake. Paragraph 7.368 was modified accordingly.

6.63 The European Communities suggests that the Panel contradicted itself in paragraph 7.371 when it stated, on the one hand, that parties had had sufficient opportunity to comment on the other party's allegations and, on the other hand, in paragraph 7.124, refused to allow the European Communities clarify the nature of a number of factual errors allegedly made by the United States and Canada. In paragraph 7.124, the Panel took the view that the European Communities should not be allowed to make further comments, lest the other parties would also comment and this would launch an endless exchange of arguments. The Panel notes that parties were allowed to comment on the experts' responses and to comment on the comments of the other party. In addition, the parties were allowed to comment on each other's replies to the questions of the Panel after the second substantive meeting. This is fully consistent with usual panel procedures. Moreover, the European Communities could correct any factual error appearing in the interim report by requesting the Panel to review precise aspects of the interim report, if the allegedly erroneous information provided by the United States and Canada had been used in the findings. The Panel notes that the EC request to correct some factual statements made by the other parties was limited to factual aspects, not to legal issues such as allegations of inconsistency with the *SPS Agreement*, which was the subject of this paragraph. The Panel nonetheless decided to clarify paragraph 7.371**.**

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[246] EC's replies to Panel questions after the first substantive meeting, Annex B, para. 274.

[247] EC's replies to Panel questions after the first substantive meeting, Annex B, para. 275.

[248] The Panel also notes that the European Communities made an alternative claim of violation of Article 22.8 of the DSU and Articles I and II of the GATT 1994, in isolation from its claim under Articles 23.1 and 3.7 of the DSU which was based on an allegation of actual compliance with the recommendations and rulings of the DSB in the *EC – Hormones* case.

6.64 The European Communities argues that, in paragraphs 7.373-7.374, the Panel states that its approach was a "pragmatic solution" and the "most logical way forward" without further explanation. The European Communities considers that the approach of the Panel is arbitrary and negatively affects the interests of the parties and reverses existing case law and established practice. The Panel first notes that the European Communities does not specify which "existing case law" and "established practice" it refers to, and that it does not make any reference to its previous submissions. Second, the Panel notes that these paragraphs contain only additional arguments. The Panel has amply justified its decision to address the compatibility of the EC implementing measure with the *SPS Agreement* throughout the preceding paragraphs. The Panel also explains the reason why it follows this approach in paragraph 7.374, emphasizing the need to assist the parties and the DSB in solving this dispute and the need to determine whether there is a violation of Article 23.1 in conjunction with Article 22.8 and Article 3.7 of the DSU. The Panel's choice was directed by the requirement to make an objective assessment of the matter before it, in accordance with Article 11 of the DSU, having regard to the particular circumstances of this case, as recalled in Section VII.C.2.(a) of this report.

6.65 The European Communities states that paragraph 7.401 and footnote 506 are factually inaccurate. This comment can only relate to and be limited to the refusal of the Panel to let the European Communities correct alleged *factual* errors in the comments of Canada and the United States on the EC replies to the questions of the Panel after the second substantive meeting. First, the European Communities never identified the factual errors at issue. Second, the Panel explained its position in its letter of 20 November 2006. The Panel recalls that it followed the standard practice of panels in terms of procedure, allowing comments on replies to the questions of the Panel. The Panel felt justified in not allowing further comments. The Panel stressed that the European Communities could address these factual errors at the interim review stage, if they were reflected in the findings of the Panel. It appears that the European Communities did not take advantage of this opportunity as no such factual corrections were made. Thus, the Panel sees no reason to correct paragraph 7.401 and footnote 506.

6.66 The reference to Article 5.2 of the *SPS Agreement* in paragraph 7.434 has been removed.

6.67 The European Communities argues, with respect to paragraph 7.411, that the Panel misconstrued its role by engaging in settling a scientific debate and arbitrating the opinions expressed by the scientific community by "picking and choosing" from individual replies of experts without any valid explanation. The Panel explained in its findings in paragraph 7.69 why it deemed it preferable to consult experts individually. The Panel had also explained in its letter to the parties of 25 November 2005 how it understood its role in terms of assessment of scientific opinions. The Panel believes that weighing the scientific evidence before it was necessary to reply to the two main legal questions in relation to the *SPS Agreement*, i.e. whether the European Communities had performed a risk assessment within the meaning of Article 5.1 for oestradiol-17β and if the relevant scientific evidence was sufficient within the meaning of Article 5.7 as far as the other hormones were concerned. In fact, the Appellate Body confirmed the discretion of Panels in weighing evidence in *EC – Asbestos*.[249] This is also part of the role of panels under Articles 11 and 13 of the DSU. The Panel also considers that 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. If panels were not to weigh the scientific evidence before them, then the DSU would have mandated the recourse to experts review groups. The Panel also notes that the Appellate Body took the view in *EC – Hormones*, that both the *SPS Agreement* and the DSU leave to the discretion of a panel the determination of whether the establishment of an expert review group is necessary or appropriate.[250] The Panel explained its approach in detail in paragraph 7.411 and thus does not believe that it engaged into "picking and

[249] Appellate Body Report on *EC – Asbestos*, para. 161.
[250] See para. 7.72.

choosing" without any valid explanation. The Panel notes that some replies to its questions were more detailed than others and supported by bibliographical references. The Panel believes 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. Therefore, having also considered the comments of the respondent of 19 October 2007, the Panel did not deem it necessary to revise paragraph 7.411.

6.68 The European Communities considers that, in paragraphs 7.414-7.418, the Panel missed the point made by the European Communities, namely that neither the United States, Canada nor JECFA have provided conclusive proof that the methods used to generate the outdated evidence on which they based and continue to base their risk assessment were validated. The Panel first notes that the paragraphs at issue are part of an introductory section, not one where the validity of the evidence actually relied upon by JECFA is being discussed. Second, the purpose of the discussion contained in the paragraphs at issue is clearly stated in paragraph 7.418. The point made by the Panel is that a study is not *ipso facto* irrelevant because it is old. The Panel makes two points in paragraph 7.418: (i) that accuracy is a problem when one is at the limits of detection of the older methods and (ii) that in any event an essential question is whether a given method has been validated.

6.69 Second, the European Communities' comment raises the question whether there is a need for the United States and Canada to prove that JECFA's risk assessments were based on validated studies. In the opinion of the Panel, this is not a question that needs to be addressed in order to resolve this dispute. JECFA's risk assessments were used as the bases for Codex recommendations which are, pursuant to Article 3.1 and Annex A(3) of the *SPS Agreement*, "international standards, guidelines or recommendations". Pursuant to Article 3.3, it is for the WTO Member wishing to introduce or maintain sanitary measures which result in a higher level of sanitary protection than would be achieved by measures based on the relevant international standards, guidelines and recommendations to provide scientific justification in support of such measures. In that context, the question before the Panel is not whether JECFA's risk assessments were based on validated studies[251], but whether the European Communities' permanent ban on meat and meat products containing veterinary residues of oestradiol-17β derived from cattle treated with this hormone for growth promotion purposes is based on a risk assessment within the meaning of Article 5.1 and, for the five provisionally banned

[251] The Panel did not use the quotation from Dr. Wennberg in paragraph 7.417 to argue that JECFA's studies were actually validated, but to stress that if a study used a validated method, there is no reason to reject it simply because it is old. The problem with some of the more recent studies on which the European Communities relies is that they have not been validated. The European Communities also refers to statements of Dr. De Brabander (Annex G, paras. 670, 675, 681 and 687) and Dr. Sippell (Annex G, para. 689). The Panel understands from Dr. De Brabander's comments that there would be reasons to re-do certain assessments, *inter alia* because the separation power of components has increased considerably since the 1980s (see para. 681). However, the Panel notes that Dr. De Brabander insists on the fact that one cannot say that the "old" data are not correct on not valid until they are checked with modern analytical methods, which, according to him, has not been done. Dr. Sippell states that, for infant and young children, a standard commercially available radioimmunoassay is not able to pick up the real concentrations, because there are numerous other cross-reacting steroids. Dr. Sippell concludes that "one should really look at the new data". Whereas this statement suggests that old data are not valid, Dr. Sippel stops short of formally concluding that they are not valid. We also note Dr. Boobis' comment following Dr. Sippell's intervention (Annex G, para. 691):

> "I would make the point that a method that is used to measure low levels of oestrogens in infants is a different question from a method that is being used to measure residues in food. The analytical challenges are quite different and the methods that were developed in the 1980s for the residues were fit for that purpose, and that is what they were used for. If you ask the question about the circulating concentrations, that is a different issue. So in terms of residues the methods were suitable."

hormones, whether there exists *validated* studies that sufficiently put into question the evidence on which JECFA's risk assessments are based, so as to support a conclusion that the relevant scientific evidence is insufficient to permit the assessment of risk.

(ii) General comments on the Panel's analysis regarding oestradiol-17β

6.70 The European Communities argues that the use of the term "measure" in paragraphs 7.432 and 7.490 to describe the Panel's function is unfortunate because "it is clear that a panel does not measure anything (which implies that there is something quantitative to measure), but simply examines the conformity of the measure with the relevant provisions."[252] The Panel notes that it used the term "measure" in the sense, as defined by the Oxford English Dictionary, to "judge or estimate the greatness or value of (a person, a quality, etc.) by a certain standard or rule; appraise by comparison with something else."[253] The Panel believes that judging or appraising something, in this case the SCVPH Opinions, against a certain standard or rule, in this case Article 5.1 and Annex A(4) of the *SPS Agreement*, is precisely examining the conformity of the measure with the relevant provisions. Therefore, the Panel will not change the term. However, the Panel wishes to clarify here that it did not intend to use the term "measure" to imply any sort of quantitative analysis.

6.71 The European Communities also states that it did not understand the Panel's use of the term "objective measures" in the paragraph of the interim report corresponding to paragraph 7.432. The European Communities correctly points out an error in the paragraph. The fourth sentence should read "The Panel must objectively measure the Opinions against the relevant standard for whether a risk assessment has been conducted, which can be found in the texts of Articles 5.1 as well as Annex A(4) of the *SPS Agreement*." Again, the Panel notes that it is using the term "measure" in the sense of a qualitative appraisal of the SCVPH Opinions against a standard or rule, namely the *SPS Agreement*.

(iii) Comments on "risk assessment techniques"

6.72 The European Communities argues that the discussion by the Panel of risk assessment techniques in paragraphs 7.435-7.459 is irrelevant and unnecessary given that no relevant international risk assessment techniques for veterinary drug residues have been agreed upon.[254]

6.73 The Panel notes that Article 5.1 requires that Members take into account the risk assessment techniques of the relevant international organizations when ensuring that their sanitary and phytosanitary measures are based on a risk assessment. Therefore, the Panel believes that an analysis of whether such techniques exist and whether the European Communities took them into account is necessary and appropriate to an analysis of whether the European Communities has removed the previously found inconsistency of its ban on the importation of meat and meat products treated with oestradiol-17β for growth promotion purposes with Article 5.1 of the *SPS Agreement*.

6.74 The Panel notes in paragraph 7.438 that no specific techniques or guidelines has thus far been formally adopted by Codex for use by national governments in conducting risk assessments of veterinary drug residues. However, there are relevant definitions of the phases of a risk assessment as well as guidelines and practices for conducting a risk assessment in the general sense and the Panel, therefore, analyses whether the European Communities took these into account when it adopted Directive 2003/74/EC.

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[252] EC's comments on interim report, para. 50.
[253] *Shorter Oxford English Dictionary*, 5th edition (1993), p. 1730.
[254] EC's comments on interim report, para. 51.

6.75 The European Communities also argues that these passages convey the erroneous message that the concept of risk assessment as defined in the *SPS Agreement* is the same as in Codex Alimentarius.[255]

6.76 The Panel is surprised by this comment, because it states in paragraph 7.457:

> "[T]he Panel must concur with the reasoning of the panel in *Japan – Apples*, that the requirement to "take into account" the risk assessment techniques of international organizations:
>
> > '[D]oes not impose that a risk assessment under Article 5.1 be 'based on' or 'in conformity with' such risk assessment techniques. This suggests that such techniques should be considered relevant, but that a failure to respect each and every aspect of them would not necessarily, *per se*, signal that the risk assessment on which the measure is based is not in conformity with the requirements of Article 5.1.'"[256]

6.77 The Panel finds that this quotation adequately conveys the Panel's opinion that although the risk assessment techniques of the relevant international organizations must be considered by the Members, they are not binding on Members and that not following them would not necessarily lead to the conclusion that the risk assessment did not conform with Article 5.1 and Annex A(4) of the *SPS Agreement*. However, to avoid confusion, the Panel clarified paragraph 7.457 and added paragraph 7.458.

6.78 The European Communities also takes issue with paragraph 7.444. In that paragraph the Panel summarizes the arguments of the European Communities as follows:

> "The **European Communities** agrees that the risk assessment techniques developed by Codex are relevant and contemplated in Article 5.1's requirement to take into account the risk assessment techniques developed by relevant international organizations."

6.79 The European Communities argues that this paragraph is misleading because the European Communities has followed the four steps of risk assessment described by Codex. The European Communities asserts that it has followed the four steps because its legislation so provides, not because it is required to do so under the *SPS Agreement*, since such techniques do not exist.

6.80 The Panel notes that it does not discuss in any way in paragraph 7.444 whether the European Communities has complied with the four steps. In addition, the Panel notes in paragraph 7.446 that "the European Communities argues that the risk assessment at the basis of Directive 2003/74/EC precisely follows the four steps of risk assessment as defined by Codex ..."

6.81 It is irrelevant for the Panel whether the EC internal legislation mandates that the European Communities follow the four steps or whether the European Communities complied with its own legislation. The Panel's analysis focuses on whether the European Communities "took into account" the relevant risk assessment techniques of the relevant international organizations as required by Article 5.1 of the *SPS Agreement* and, in paragraph 7.459, the Panel finds that it has.

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[255] EC's comments on interim report, para. 51.
[256] Panel Report on *Japan – Apples*, para. 8.241.

6.82 The European Communities asks the Panel to more fully summarize its arguments in paragraphs 7.474 and 7.475.[257] The Panel has, therefore, modified those paragraphs.

(iv) Assessment of the scientific arguments

6.83 The European Communities, argues that paragraphs 7.476-7.509 are incoherent and confused. Specifically, the European Communities believes that they do not adequately present the debate on the "threshold approach" which it believes is the central scientific debate.[258] The Panel notes that the content of paragraphs 7.476-7.509 contains the reasoning of the Panel on whether the Opinions satisfy the definition of a risk assessment set forth in Annex A(4) of the *SPS Agreement*. This section of the Panel's reasoning is not the appropriate place to present a debate between the parties about a particular scientific issue.

6.84 The Panel, however, is mindful that the parties did expend a significant amount of argument on the relevance of "thresholds" to the risk assessment process and that perhaps it would provide further clarity to include more explanation of the various arguments. Therefore, the Panel made modifications to the summaries of the parties' arguments. The Panel believes that the debate over the "threshold" issue can be divided into two main components. First, whether all four of the risk assessment steps as defined by Codex should be followed when the substance under review exhibits no threshold. Second, whether oestradiol-17β is such a substance that exhibits no threshold because it is genotoxic *in vivo* and therefore would lead to adverse effects even at the doses found in meat as a result of treatment of cattle with oestradiol-17β for growth promotion purposes.

6.85 The Panel also feels that it would be helpful to include some additional information provided by the experts with respect to this matter. Therefore, the Panel inserted a new paragraph after paragraph 7.454. The Panel also changed the first sentence of paragraph 7.457.

6.86 With respect to whether oestradiol-17β, in particular, is genotoxic *in vivo* and has no threshold, the Panel finds that the issue arises in two different contexts: first, in the context of what such a conclusion means for evaluating whether the SCVPH Opinions constitute a risk assessment within the meaning of the *SPS Agreement*; second, in the context of the analysis of whether the science supports the conclusions reached by the European Communities with respect to the genotoxic properties of oestradiol-17β. To address both of these issues the Panel edited paragraph 7.469.

6.87 The Panel also feels that it would be helpful to include some additional information provided by the experts with respect to this matter. Therefore, the Panel inserted a new paragraph after paragraph 7.501.

6.88 With respect to whether the science supports the conclusion that oestradiol-17β is a substance that exhibits no threshold, the Panel has added Dr. Cogliano's response to question 19 from the Panel[259] as paragraph 7.527.

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[257] EC's comments on interim report, para. 52.

[258] EC's comments on interim report, para. 53.

[259] Panel question 19, Annex D, p. 34 ("The European Communities states that '... it is generally recognized that for substances which have genotoxic potential (as is the case with oestradiol-17β) a threshold can not be identified. Therefore it cannot be said that there exist a safe level below which intakes from residue should be considered to be safe. Therefore the fact that doses used in growth promotion are low is not of relevance'. Does the scientific evidence referred to by the European Communities support these conclusions? Would your reply have been different at the time of adoption of the EC Directive in September 2003? If so, why? [see para. 201 of EC Rebuttal Submission (US case), paras. 120-122 of EC Rebuttal Submission (Canada case), paras. 73 and 86-98 of Canada Rebuttal Submission, paras. 87-91 and 153-156 of US First Submission and paras. 35-40 and 46 of US Rebuttal Submission]")

6.89 The European Communities argues that paragraphs 7.487 and 7.488 of the interim report are a misinterpretation of what the Appellate Body found in the original *EC – Hormones* case about the concept of risk assessment and its significance in the *SPS Agreement*.[260] The European Communities does not provide any specific parts of the analysis that it feels are a misinterpretation, neither does it provide what it believes is the correct interpretation. The Panel can only assume that the European Communities maintains its position as summarized in paragraph 7.489.

6.90 The Panel based its reasoning in paragraphs 7.487 and 7.488 of the interim report on several passages in the Appellate Body Report on *EC – Hormones*. Paragraph 181 of the Appellate Body Report reads as follows:

> "The second preliminary consideration relates to the Panel's effort to distinguish between 'risk assessment' and 'risk management'. The Panel observed that an assessment of risk is, at least with respect to risks to human life and health, a 'scientific' examination of data and factual studies; it is not, in the view of the Panel, a 'policy' exercise involving social value judgments made by political bodies.[261] The Panel describes the latter as 'non-scientific' and as pertaining to 'risk management' rather than to 'risk assessment'.[262] 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, which it apparently employs to achieve or support what appears to be a restrictive notion of risk assessment, has no textual basis. The fundamental rule of treaty interpretation requires a treaty interpreter 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."

6.91 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 to carry out is the responsibility of the regulator and not of the scientific bodies."[263]

6.92 This Panel, following the advice of the Appellate Body, has adhered strictly to the text of Article 5.1 and Annex A(4) of the *SPS Agreement* in its interpretation. In analysing the European Communities' compliance with Article 5.1 and Annex A(4) of the *SPS Agreement*, the Panel is also cognisant of the Appellate Body's finding that:

> "The listing in Article 5.2 begins with 'available scientific evidence'; this, however, is only the beginning. We note in this connection that the Panel states that, for purposes of the EC measures in dispute, a risk assessment required by Article 5.1 is 'a *scientific* process aimed at establishing the *scientific* basis for the sanitary measure a Member intends to take'.[264] To the extent that the Panel intended to refer to a process characterized by systematic, disciplined and objective enquiry and analysis, that is, a

[260] EC's comments on interim report, para. 55.
[261] (*footnote original*) US Panel Report, para. 8.94; Canada Panel Report, para. 8.97.
[262] (*footnote original*) US Panel Report, para. 8.95; Canada Panel Report, para. 8.98.
[263] EC's second written submission, para. 116.
[264] (*footnote original*) US Panel Report, para. 8.107; Canada Panel Report, para. 8.110.

> mode of studying and sorting out facts and opinions, the Panel's statement is unexceptionable.[265] However, to the extent that the Panel purports to exclude from the scope of a risk assessment in the sense of Article 5.1, all matters not susceptible of quantitative analysis by the empirical or experimental laboratory methods commonly associated with the physical sciences, we believe that the Panel is in error. Some 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. Furthermore, 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. 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 actual potential for adverse effects on human health in the real world where people live and work and die."[266]

6.93 Therefore, the Panel finds that a risk assessment consistent with Article 5.1 need not be limited to empirical or experimental laboratory methods commonly associated with the physical sciences. However, the Panel also agrees with the Appellate Body's statement that a requirement that a risk assessment be "a process characterized by systematic, disciplined and objective enquiry and analysis, that is, a mode of studying and sorting out facts and opinions" is unexceptionable.

6.94 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."[267] 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*.

6.95 To avoid any confusion or misunderstanding the Panel modified paragraphs 7.490 through 7.492.

6.96 The Panel is aware that the experts responded to the Panel's questions with respect to what the European Communities had evaluated in its Opinions by using a terminology that is standard for risk assessments conducted according to the process outlined in the Codex Procedural Manual. Although the scientific experts' responses may include terms such as "hazard characterization" or "exposure assessment", the Panel is at all times aware that the relevant standard against which it is assessing the European Communities' measure is that of the *SPS Agreement*. In order to emphasize this point, the Panel added a new paragraph before paragraph 7.494.

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[265] (*footnote original*) "The ordinary meaning of 'scientific', as provided by dictionary definitions, includes of, relating to, or used in science', broadly, having or appearing to have an exact, objective, factual, systematic or methodological basis', of, relating to, or exhibiting the methods or principles of science' and of, pertaining to, using, or based on the methodology of science'. Dictionary definitions of science' include the observation, identification, description, experimental investigation, and theoretical explanation of natural phenomena', any methodological activity, discipline, or study', and knowledge attained through study or practice'". (footnotes omitted) *United States' Statement of Administrative Action, Uruguay Round Agreements Act*, 203d Congress, 2d Session, House Document 103-316, Vol. 1, 27 September 1994, p. 90.

[266] Appellate Body Report on *EC – Hormones*, para. 187.

[267] EC's reply to question 24 of the Panel after the first substantive meeting, Annex B-1, para. 137.

6.97 The European Communities takes issue with the reliance of the Panel on certain statements by the experts in paragraphs 7.494-7.500 and cites to various other statements by the same experts which it claims stand for the opposite proposition.[268] The Panel takes note that Annex D, which contains the replies of the experts to the Panel's questions is 116 pages long and Annex G which contains the transcript of the Panel's meeting with the experts is 170 pages long. This does not include the various comments and comments on comments of the parties on the experts' responses and on the transcripts. With this volume of information, every comment by the experts could not be included in the Panel findings and, for that matter, did not have to be.[269] Therefore, the Panel made a decision to select quotations that are representative of a particular expert's opinion on a given topic. The Panel has reviewed the specific paragraphs referred to by the European Communities in an attempt to determine if it misunderstood or misrepresented a particular expert's opinion.

6.98 With respect to Dr. Guttenplan, the European Communities objects to the Panel's reliance on paragraph 145 of the experts replies to the Panel's questions and refers the Panel to paragraphs 366, 393, 713, and 716-718 of Annex G as well as his written reply to Panel question 17 which is at paragraph 176 of Annex D.[270]

6.99 With respect to the Panel's reliance on paragraph 145 of Annex D, which is Dr. Guttenplan's response to Panel question 13, cited in paragraph 7.495, the Panel amended the paragraph to better reflect Dr. Guttenplan's complete response to the question.

6.100 Additionally, to more fully reflect Dr. Guttenplan's written answer to question 52 of the Panel, the Panel modified paragraph 7.500.

6.101 With respect to Dr. Guttenplan's other interventions cited by the European Communities, the Panel did not deem it necessary to make any additional changes in this section.

6.102 Paragraph 366 of Annex G refers to Dr. Guttenplan's opinion that oestrogen is genotoxic, but that it may not be possible to "really estimate the risk at this point from such low levels of genotoxic effects."[271] Paragraph 393 of Annex G refers generally to the issue of conducting risk assessments of genotoxic substances with no threshold.[272] The Panel believes it has dealt with these issues in the amendments mentioned above.

6.103 Paragraphs 713 and 716-718 of Annex G reflect Dr. Guttenplan's opinion that although, because anything is possible, there may be a risk from consumption of meat derived from cattle treated with oestradiol-17β for growth promotion purposes, it is so low that it is not susceptible to calculation. It also reflects an interjection by the European Communities asking Dr. Guttenplan to confirm his statement that, although the risk is small and cannot be evaluated or calculated, it is not zero.

6.104 The Panel does not believe that these statements are directly relevant to the Panel's reasoning on whether the European Communities conducted a risk assessment consistent with the definition set forth in Annex A(4) of the *SPS Agreement*. As the Panel has noted, the purpose of the risk assessment is to evaluate the possibility that an identified adverse effect comes into being, originates, or results from the presence of the identified additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs. It is not to guarantee that said possibility will be below the Member's appropriate level of protection or indeed will be zero.

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[268] EC's comments on interim report, para. 56.
[269] Appellate Body Report on *EC – Hormones*, para. 138; see also Section VII.C.3.(d)(iii) of this report.
[270] EC's comments on interim report, para. 56.
[271] Transcript of the Panel meeting with the experts, Annex G, para. 366.
[272] Transcript of the Panel meeting with the experts, Annex G, para. 393.

6.105 Finally, the European Communities cites Dr. Guttenplan's written response to question 17 of the Panel. In that paragraph, Dr. Guttenplan states that the absence of catechol metabolites in meat from treated animals does not imply that the meat is without risk for genotoxicity. Dr. Guttenplan was being asked to evaluate a particular argument by Canada. The Panel does not read this statement as implying that the residues of oestradiol-17β in meat from treated cattle are definitely genotoxic. However, 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. Again, the Panel believes it has addressed this point with the additions and edits suggested above.

6.106 The European Communities also refers the Panel to various interventions by Dr. Cogliano at the Panel meeting with the experts, namely, paragraphs 400, 404, 406, 409, 870, and 1021-1025 of Annex G.[273] In paragraphs 400, 404, and 406 of Annex G, Dr. Cogliano provides the Panel with general background information on the issue of thresholds and linear dose response curves. The comments are not specific to the Opinions of the European Communities and therefore are not relevant to the analysis the Panel is undertaking in this particular section. Paragraph 409 of Annex G contains a question from the Chairman. The Panel is unsure whether the European Communities meant to refer to paragraph 408 or paragraph 410.[274] In any event, in both those paragraphs Dr. Cogliano provides general background information on what is meant by a linear dose response curve.

6.107 Dr. Cogliano, in paragraph 871 of Annex G[275], states that the data are not sufficient to conduct a "JECFA-style" risk assessment if oestradiol-17β has no threshold. The Panel finds this statement unremarkable for two reasons. First, the Panel is not evaluating whether the European Communities has done a "JECFA-style" risk assessment, but whether it has done a risk assessment consistent with the definition set forth in Annex A(4) of the *SPS Agreement*. Second, the European Communities has not argued that there is insufficient data to conduct a risk assessment of oestradiol-17β, it has argued that it has conducted a risk assessment of oestradiol-17β that is consistent with the *SPS Agreement*, that its measure is based on that risk assessment and that, consequently, it has acted consistently with Article 5.1 of the *SPS Agreement*. Dr. Cogliano's statement, in the paragraph cited by the European Communities, is not directly relevant in this context.

6.108 Paragraphs 1021 through 1025 of the transcript of the panel meeting with the experts report a discussion where both Drs. Boobis and Cogliano confirm that the fundamental difference between the JECFA study and the SCVPH Opinions is the willingness to assume a threshold and interpret the data from that standpoint. The Panel has now cited these interventions in the new paragraphs 7.455-7.456 and paragraph 7.502.

6.109 In its comments on the interim report, the European Communities argues that if the Panel had properly looked at Dr. Cogliano's interventions in these paragraphs of the transcript the Panel would have had to conclude that the European Communities' risk assessment has followed one side of a legitimate debate while JECFA has followed another.[276] The European Communities seems to imply that if the Panel recognizes this it would also conclude that the European Communities' ban on the importation of meat and meat products from cattle treated with oestradiol-17β for growth promotion purposes was based on a risk assessment within the meaning of Article 5.1 and Annex A(4) of the

[273] EC's comments on interim report, paras. 56-58.

[274] Because the specific paragraph references by the European Communities in its comments on the interim report frequently tend to differ from the version in Annex G, the Panel believes that the European Communities must have prepared its interim comments with a different version of the transcript than the one contained in Annex G. In each instance of mistaken citation, the Panel has read the paragraphs in the transcript surrounding those cited by the European Communities to ensure that it has correctly identified and is responding to the concerns expressed by the European Communities.

[275] Paragraph 870 is the Chairman giving the floor to Dr. Cogliano.

[276] EC's comments on interim report, paras. 57-64.

SPS Agreement. The Panel does not see the issue in quite the same manner as the European Communities. The issue is not whether a risk assessment following the four steps as defined by Codex could or should have been completed. The issue is whether the European Communities has conducted a risk assessment within the meaning of Article 5.1 and Annex A(4) of the *SPS Agreement*.

6.110 The Panel does not take a position on the science or on how to evaluate data when a particular substance exhibits no threshold.[277] However, whatever approach the European Communities adopts in its assessment of the risks, it is obligated to conduct a risk assessment that is consistent with the definition set forth in Annex A(4) of the *SPS Agreement*. The Panel finds that the *SPS Agreement* requires an analysis that goes beyond the identification of a potential adverse effect. The 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-17β in meat and meat products derived from cattle treated with the hormone for growth promotion purposes. The Panel will not prescribe a particular manner or approach for how the analysis should be conducted, but the analysis must be conducted.

6.111 The intervention by Dr. Sippell in paragraph 576 of Annex G cited by the European Communities mentions a scientific study cited in the 1999 Opinion which posits that the radioimmuno assays originally used to calculate daily endogenous production levels of the hormones may have overestimated these levels. The Panel addressed this issue by inserting in paragraph 7.507 quotations from the 1999 SCVPH Opinion on this issue directly, and a new paragraph 7.508.

6.112 Additionally, the Panel felt that more direct quotation from the Opinions with respect to the other identified potential adverse effects would provide greater clarity. Therefore, the Panel modified paragraphs 7.506 and 7.507.

6.113 The European Communities also refers to a statement by Dr. Boobis at paragraph 725 of Annex G. [278] The Panel has reviewed the surrounding paragraphs and found that, like Dr. Guttenplan, Dr. Boobis had engaged in an exchange with the European Communities about the concept of zero risk. Again, Dr. Boobis confirms that science cannot provide absolute assurance of the absence of risk or an absolute guarantee of safety. Dr. Boobis also states "it is not clear to me how you would ever conduct a risk assessment and guarantee that, without ensuring zero exposure, and of course that would cease all use of all compounds where there is any risk whatsoever, and they all have some risk."[279]

6.114 As with the citations to Dr. Guttenplan's statements at the meeting with the Panel, the Panel is unclear what the European Communities believes this reference to certain statements by Dr. Boobis will add to the Panel's reasoning on whether it conducted a risk assessment consistent with the definition set forth in Annex A(4) of the *SPS Agreement*. The Panel notes again that the purpose of a risk assessment is to evaluate the possibility that an identified adverse effect comes into being, originates, or results from the presence of the identified additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs, not to guarantee that said possibility will be below a Member's appropriate level of protection or indeed will be zero.[280]

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[277] EC's comments on interim report, para. 78. Contrary to the assertion of the European Communities, the Panel does not endorse any one particular way to approach risk assessment.

[278] Paragraph 725 is an interjection by Canada. See transcript of the Panel meeting with the experts, Annex G, para. 725.

[279] Transcript of the Panel meeting with the experts, Annex G, paras. 723 and 729.

[280] The Panel notes that the Appellate Body in para. 186 of its report on *EC – Hormones*, asked "if a risk is not ascertainable, how does a Member ever know or demonstrate that it exists?"

6.115 The European Communities argues that in paragraphs 7.525-7.534 the Panel relies solely on the responses of Drs. Boobis and Boisseau and does not reflect the opinions of the other experts.[281]

6.116 The Panel notes that the relevant section is from paragraphs 7.520-7.540 and that the Panel cites Dr. Cogliano and Dr. Guttenplan in paragraph 7.536 and Dr. Guttenplan again in paragraph 7.537. Nevertheless, the Panel has examined the written answers of the other experts to the same questions of the Panel as well as the transcript of the Panel meeting with the experts and made additional references to experts' statements.

6.117 The European Communities argues that the Panel is in error in paragraph 7.538 when it states that the only study cited with respect to susceptible populations was one having to do with *in utero* exposure to DES, which is banned in the United States.[282] The Panel has reviewed the paragraphs in the 1999 Opinion referenced by the European Communities. Although the European Communities is correct that other studies regarding susceptible populations are referenced in section 2.2.2.4 entitled "Potential adverse effects of exogenous sex hormones on growth and puberty upon exposure of prepubertal children," the Panel, in paragraph 7.538, was specifically referring to the link between *cancer* and consumption of hormone treated meat. With respect to that specific identified potential adverse effect, the only study mentioned in section 2.3.2.4 under susceptible populations with respect to oestrogen is one involving *in utero* exposure to DES. The Panel modified the third sentence of paragraph 7.538.

6.118 Additionally, based on the European Communities' comment, the Panel also reviewed the paragraphs in the interim report which dealt with section 2.2.2.4 of the 1999 Opinion. In order to ensure that the Panel fully reflects the science the European Communities relied upon in this section, the Panel amended paragraph 7.505.

6.119 The European Communities argues with respect to paragraph 7.540 that, because the Panel based its findings on the views expressed by the "most convincing" experts, the Panel has failed to make an objective assessment of the matter, failed to take properly into account the totality of the available evidence and failed to give proper weight to different scientific views which are based on genuine and legitimate scientific grounds. The European Communities also argues that the Panel's "most convincing" experts are the ones it had alleged had a conflict of interest.

6.120 The Panel bases its analysis in this section on its own reading of the plain language in the Opinions which was corroborated by the views expressed by the experts and this combination leads the Panel to its conclusions. Additionally, the Panel disagrees with the European Communities that it fails to examine the totality of the evidence or to give proper weight to particular scientific views. As the Panel notes, it does not disregard any of the statements by the experts. However, the Panel could not possibly provide full quotations of every answer or statement of every expert. The fact that the Panel may have cited specific passages from specific experts does not mean that the Panel did not consider and weigh all of the responses.

6.121 The Panel, after reading the Opinions, the experts' answers to questions, the transcript of the meeting with the experts, and the parties submissions and comments, made a determination about which experts had provided the Panel with answers that responded to the questions asked in a clear and consistent manner supported by expertise and evidence. This determination is the essence of weighing the evidence. As the Panel noted above, in paragraphs 7.520-7.540, the section to which paragraph 7.540 belongs, the Panel cited Dr. Boisseau, Dr. Boobis, Dr. Cogliano, and Dr. Guttenplan. These are the experts who answered the relevant questions and who had identified expertise in risk

[281] EC's comments on interim report, footnote 11.
[282] EC's comments on interim report, footnote 11.

assessment, toxicology, studies of carcinogens, and biochemistry.[283] The Panel regrets if it caused any confusion by using the phrase "most convincing" and accordingly clarified paragraph 7.540.

6.122 The European Communities fails to see why the Panel, after having concluded that there is no risk assessment, goes on to examine whether the science supports the conclusions in the Opinions and asks for more explanation than previously provided for. The Panel modified paragraph 7.510 in order to provide additional explanation.

(v) Comments on the Panel analysis regarding the other five hormonal substances

6.123 The European Communities argues that paragraph 7.583 is unclear and seems irrelevant for the further analysis of the Panel. The European Communities first argues that, in its oral statement, it spoke about whether a risk assessment can reach a definitive conclusion, not whether or not it is possible to perform a definitive risk assessment. First, the Panel recalls that the EC reference to a "definitive risk assessment" is found in the EC second written submission.[284] Second, the Panel does not see any real difference between "reach[ing] a definitive conclusion" and making a "definitive risk assessment". Its reasoning in paragraph 7.583 thus applies equally to both statements.

6.124 Second, the European Communities considers that the Panel should have referred to what the experts said at the hearing about the issue of whether scientific data can ever allow for a definitive conclusion to be reached. This seems to suggest that the European Communities no longer argues that what matters in order to justify the application of Article 5.7 is whether a definitive conclusion can be reached or whether a definitive risk assessment can be made. If this is correct, the Panel does not believe that it is entitled to address new arguments at the interim review stage. The Panel nevertheless reviewed the comments of Dr. Cogliano referred to by the European Communities. In paragraph 776 of Annex G, Dr. Cogliano suggests that there can be different types of risk assessments, depending on the specificity of the risk one wishes to identify. The Panel fails to see in what respect this statement affects its finding in paragraph 7.583. As recalled by the Panel in its findings[285], the type of risk assessment requested under Article 5.1 is a risk assessment within the meaning of Annex A(4) of the *SPS Agreement*, which is not one of the types of risk assessment identified by Dr. Cogliano. It is in the context of the completion of a risk assessment within the meaning of Article 5.1 and Annex A(4) of the *SPS Agreement* that the Panel discussed the EC argument regarding a "definitive risk assessment" or a "risk assessment reach[ing] a definitive conclusion". The other comment of Dr. Cogliano referred to by the European Communities[286] suggests that data may be sufficient to do one type of risk assessment (e.g. "the JECFA-style ADI") but not one based on a theory according to which it is not possible to identify a dose below which there is no risk, because there is a risk at any dose level, even the low doses one might find in hormone-treated meat. The Panel notes in this regard that this is different from arguing that one should be able to invoke Article 5.7 because one cannot make a "definitive risk assessment". As mentioned by the Panel, the Appellate Body in *Japan – Apples* did not say that relevant scientific evidence would become insufficient if a Member could not perform a particular type of risk assessment, but only if it would be unable to perform a risk assessment within the meaning of Article 5.1 and Annex A(4) of the *SPS Agreement*.

6.125 The Panel did not deem it necessary to delete or modify paragraph 7.583.

6.126 The European Communities makes a general reference to its second written submission and takes issue with the assessment of the Panel in paragraphs 7.627-7.698 by stating that the Panel did

[283] Transcript of the Panel meeting with the experts, Annex G, paras. 54-72.
[284] *Inter alia* in paras. 137 and 143.
[285] See paras. 7.432-7.433.
[286] Annex G, para. 871.

not properly and fully examine the reasons contained in the Opinions and relied exclusively on certain statements of a minority of the experts it had chosen to advise it, while ignoring pertinent statements of the other experts. The Panel notes that it addressed the EC comments on its findings where they were directed at precise aspects of the interim report. This was the case regarding comments on the Panel's reliance on the views expressed by some of the experts it consulted and for comments regarding the existence of sufficient relevant scientific evidence. The Panel does not deem it necessary to address those issues in general terms here.

6.127 The European Communities finds the Panel reference to a risk assessment "in substance" in paragraph 7.606 to be "entirely unclear". In the opinion of the Panel, one can always follow each of the Codex steps provided for the gathering and analysis of scientific evidence. However, in order to be a risk assessment within the meaning of Article 5.1, that exercise must reach scientific conclusions that are supported by the scientific evidence therein.[287] Thus, the possibility to complete a risk assessment depends on whether the relevant scientific evidence is sufficient to support a conclusion on whether the identified adverse effect arises from, comes into being, or occurs as a result of the presence of the substance at issue in food, beverages, or feedstuffs.

6.128 The European Communities seems to suggest, in substance, that whether a risk assessment can be completed depends on the level of protection chosen by a given Member. The European Communities seems to link the conduct of the risk assessment with the desired outcome of a given SPS measure; i.e. to ensure zero risk. The Panel believes that this is not what the *SPS Agreement* requires. The Panel considers that the European Communities' interpretation is not supported by the text of Article 5.7, which only refers to the insufficiency of relevant scientific evidence. There is no indication that this insufficiency is to be assessed in relation to the Member's level of protection. Otherwise the negotiators would have stated "in cases where relevant scientific evidence is insufficient in the light of the level of protection chosen by the Member adopting of maintaining a sanitary measure". Nothing in the context of Article 5.7 suggests this interpretation either. Articles 2.2, 3.3 and 5.1 provide relevant contextual support for the proposition that the purpose of the *SPS Agreement* was to ensure that Member's SPS measures are "objectively justified"[288] by science. This purpose would be defeated if a Member could invoke Article 5.7 whenever relevant scientific evidence is insufficient to objectively justify the type of measure that would achieve a particular desired level of protection. The Panel modified paragraph 7.606 in order to clarify what it meant.

6.129 Regarding paragraphs 7.608-7.615, the European Communities argues that the Panel's discussion does not do justice to the role genuine scientific uncertainty plays in risk assessment. It contests the Panel's exclusive reliance on the opinions of Dr. Boisseau and Dr. Boobis and refers to statements by experts other than those quoted by the Panel. As far as the Panel's reliance on Dr. Boisseau and Dr. Boobis is concerned, it should be recalled that this is a risk assessment issue and these two scientists were selected by the Panel *inter alia* because of their expertise on risk assessment. Yet, Dr. Boisseau and Dr. Boobis were not the only ones with the same view. Dr. Tritscher's remarks on the subject also support the Panel's conclusion.[289]

6.130 None of the interventions of experts cited by the European Communities in its comments contradicts the conclusions reached by the Panel in its interim report, which are clearly spelled out in paragraph 7.615. More particularly, none of Dr. Cogliano's statements cited by the European Communities contradicts the Panel. In the paragraphs cited by the European Communities, Dr. Cogliano mainly explains the role of IARC and whether there is uncertainly about genotoxicity. Similarly, in the paragraphs cited by the European Communities, Dr. Guttenplan says that there is uncertainty about certain scientific issues, but he does not address the role of uncertainty in risk

[287] Panel Report on *Japan – Apples (Article 21.5 – US)*, para. 8.136.
[288] Appellate Body Report on *EC – Hormones*, para. 190.
[289] Annex G, para. 348.

assessment. Dr. Sippell addresses an issue unrelated to risk assessment. Dr. De Brabander addresses the quality of data and improved methods. Regarding the alleged misinterpretation of some of the statements of Dr. Boobis on the existence or not of genuine scientific uncertainty, it seems that the paragraph referred to by the European Communities (Annex G, paragraph 1049) deals with a different issue: that of scientific uncertainty in relation to U-shaped dose-response curves, not how scientific uncertainty is treated in risk assessment.

6.131 The European Communities argues, with respect to paragraph 7.622**,** that the risk assessments performed by JECFA do not contain the specific evidence that the Panel allegedly found to be missing in the EC Opinions and, therefore, cannot constitute proper risk assessments. The Panel notes that there is no reference to the JECFA risk assessment of oestradiol-17β in the Panel's analysis of the consistency of the European Communities' permanent ban on meat and meat products derived from cattle treated with oestradiol-17β for growth promotion purposes, because the European Communities claimed that it completed its own risk assessment for oestradiol-17β. The Panel thus conducted an analysis of the SCVPH Opinions and sought to determine whether they complied with the definition of a risk assessment in Annex A(4) and whether the science contained therein supported the European Communities' decision to institute a total ban. Unlike the analysis under Article 5.7, with respect to oestradiol-17β the Panel was not trying to determine whether there was sufficient scientific information to conduct a risk assessment. The Panel recalls that the fault it found with the Opinions was not that any particular piece of evidence was missing, but rather that the Opinions did not specifically analyse the risk of the identified adverse effects *arising from* the presence of oestradiol-17β in food, beverages, or feedstuffs. Therefore, whether JECFA relied on the same evidence as the European Communities in its analysis of oestradiol-17β is irrelevant. The Panel notes that JECFA did take into account the dose levels in meat and meat products and attempted to calculate the risk to humans from consuming typical amounts of meat. JECFA used a series of assumptions regarding meat consumption, circulating levels of oestrogen in the blood for various sub-groups of the population, etc. The European Communities may very well be right that there are other ways to analyse the risk than those JECFA utilized. The Panel does not take a position on that issue. What the Panel has said, is that such an analysis is required by Article 5.1 and Annex A(4) of the *SPS Agreement*.

6.132 With respect to the Panel's reference to the concept of "critical mass" in paragraph 7.626, the European Communities request that we provide an explanation of where this criterion comes from and whether it is in conformity with the findings of the Appellate Body in *EC – Hormones*.

6.133 The Panel used the term "critical mass" in full knowledge of its meaning.[290] 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.*

[290] In 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 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.

6.134 The European Communities takes issue with paragraph 7.640. The European Communities contests the Panel's approach in defining a list of general issues common to all five hormones. The European Communities argues that it has identified exactly, for each hormonal substance, the sections in the 1999 Opinion that deals individually with that substance and suggests that the Panel's list of "general issues" common to all five hormones is arbitrary.

6.135 The Panel first recalls that, as a general principle, panels are free to structure the order of their analysis as they see fit.[291] The Panel does not deny that the EC Opinions addressed each hormone individually. However, as explained in paragraphs 7.637-7.639, some issues were common to all five hormones and the evidence provided was not always sufficiently specific to address a particular issue in relation to each hormone individually. The Panel modified paragraphs 7.629-7.640 and the title to Section VII.C.3.(f)(vi) to reflect the fact that what is discussed are issues common to all hormones for which hormone-specific evidence was not provided.

6.136 The Panel also clarified that certain insufficiencies identified in the EC Opinions had not as such been discussed by the European Communities in its submissions. The Panel concluded that the European Communities was not arguing that these particular insufficiencies were what made it impossible to complete a risk assessment. Therefore, the Panel decided not to address these insufficiencies. This may have prompted the EC comment that the Panel analysis on the individual hormonal substances in paragraphs 7.699-7.816 was incomplete. The clarification brought by the Panel demonstrates that it did not draw a random list of issues common to all hormones and explains the reasons why a more limited number of issues was discussed compared with what had been identified in the Opinions. The Panel has also clarified this point in the sections relating to each hormone individually and did not follow the request of the European Communities that it address each and every issue of insufficiency raised in the Opinions.[292]

6.137 The European Communities contests the conclusions of the Panel in paragraph 7.642**,** footnote 739 as inaccurate, but without specifying why. In that footnote, the Panel refers to a new method and new assays to detect small amounts of hormones in meat, mentioned in the 2002 Opinion. From what is mentioned in the 2002 Opinion, the studies were on the subject of hormone levels in meat, not in people. Whereas it might be possible to apply these method and assays to detect endogenous levels of hormones in humans, the European Communities does not argue this in its comments, and this is not what the method and assays are about. It also appears that, according to the 2002 Opinion, the method and assays mentioned were not exactly successful or trustworthy. The conclusion in section 4.1.1 of the 2002 Opinion, where the new method is discussed, reads: "[D]espite a number of positive analytical results in this study, the low number of samples does not allow a qualified validation of typical characteristics such as sensitivity, specificity, accuracy and reproductibility." (2002 Opinion, page 9). The conclusion of section 4.1.2, where the bioassays are discussed, is that: " [T]he obtained results suggest that the use of recombinant yeast and rainbow trout hepatocytes to detect oestrogenic compounds is not justified in view of their lack of sensitivity". (2002 Opinion, page 9). It seems that, even if they were relevant in the context of paragraph 7.642 this new method and assays do not contribute to a critical mass of evidence that would put into question existing knowledge. The Panel, therefore, did not modify footnote 739.

6.138 With respect to paragraphs 7.644-7.647, the European Communities argues that the Panel reduces the discussion to only two quotations and draws a conclusion that is not based on the debate with the experts at the hearing. The European Communities argues that "much more was said about this issue" at that hearing.[293] The Panel notes, however, that the discussion related to the sensitivity of children to hormones in general, without drawing any direct link with any of the five hormones at

[291] Appellate Body Report on *Canada – Wheat Exports and Grain Imports*, para. 126.
[292] EC's comments on Sections VII.C.3(f)(vii), (viii), (ix), (x), (xi).
[293] Annex G, para. 561 *et seq*.

issue in this section, and to the validation of methods, particularly of the new ultrasensitive assay (the "Klein" methodology). The only hormone expressly discussed in relation to this assay was oestradiol-17β. The Panel notes that it concludes in this section that (a) the studies using the new ultrasensitive assay were limited to oestradiol-17β; and (b) that the ultrasensitive assay had not been validated. Thus, the Panel does not agree with the European Communities that its conclusions are not based on the debate referred to above.

6.139 The European Communities requests that we clarify the first sentence in paragraph 7.647. More particularly, the European Communities requests that we specify whether this is a legal argument or a scientific argument. The Panel considers that the finding that the evidence relates only to oestradiol is not an argument but a factual consideration. The Panel considers that, since the new detection method measured oestradiol only[294] and since no evidence was provided that suggested that extrapolation had been made or could be made to other hormones, the evidence is insufficient to conclude, with respect to the five hormones subject to a provisional ban under Article 5.7 of the *SPS Agreement*, that existing knowledge has been put into question.

6.140 With respect to the EC comment on the second sentence of paragraph 7.647, the Panel confirms that, indeed, its understanding is that the ultrasensitive detection method used by Klein and subsequently relates only to oestradiol and has not been validated. This has been confirmed by Dr. Boobis at the hearing.[295] As a result, the Panel cannot conclude that existing knowledge and evidence have been put into question by the results of the ultrasensitive assay with regard to the impact of the five hormones on prepubertal children if the available evidence relates only to oestradiol.

6.141 Even if the ultrasensitive assay had been validated and had demonstrated lower levels of the five hormones at issue in this section – and not only oestradiol – in sensitive populations, the Panel notes that the 1999 Opinion itself states that "[A] corollary is that perhaps the hormones residues in beef, which are also low and which have also been determined by RIA are equally variable and over representative of the actual hormone concentrations."[296]

6.142 In its comments regarding paragraphs 7.649-7.652 the European Communities considers that the Panel's approach to the issue of dose response is flawed and circular.

6.143 The European Communities bases its contention that the Panel's reasoning is circular on the assumption that the Panel rejected the EC approach based on an absence of a dose response analysis. Even though it rejected that approach in this particular case for oestradiol-17β, the Panel did not exclude that there could be situations where dose response would not apply. The Panel believes, on the contrary, that it is the European Communities that is making contradictory arguments. The European Communities cannot argue that "the Appellate Body clearly judged that a risk assessment [could] be either qualitative or quantitative"[297] and that a dose response is not *required* in order to complete a risk assessment and, at the same time, argue for the five hormones at issue that relevant scientific evidence is insufficient to perform a risk assessment because the data available do not allow a dose response assessment. Yet, this is what appears to be concluded in the 1999 Opinion as far as the five hormones are concerned. The Panel nonetheless clarified the paragraphs at issue.

6.144 The European Communities argues that, in paragraph 7.654, the Panel declines to discuss bioavailability on the basis that the studies relied upon by the European Communities do not relate to the five hormones in question, but only to oestradiol and that there is no indication that the

[294] See para. 7.645 quoting Dr. Sippell. See, also, Dr. Sippell's statement in Annex G, para. 588.
[295] Annex G, para. 572.
[296] 1999 Opinion, section 3.2, p. 30.
[297] See EC's reply to question 26 of the first series of questions of the Panel, para. 153, Annex B.

conclusions can be applied to hormones other than oestrogens. The European Communities considers that this assertion by the Panel is without foundation.

6.145 In order to reach its conclusion, the Panel examined most particularly the portions of the 1999 and 2002 Opinions quoted by the European Communities in its reply to question 28 of the questions of the Panel after the first substantive meeting[298] and in its second written submission.[299] The two extracts quoted by the European Communities address only oestradiol, while making references to oestrogens. Furthermore, the extract of the 1999 Opinion quoted by the European Communities is part of the section of the Opinion regarding oestradiol. The Panel notes that the European Communities argued that "similar findings [had been] made for all the other five hormones."[300] However, the European Communities did not specify where such findings had been made. This allegation has to be considered in relation to the comments of the experts. The Panel nonetheless deemed it necessary to clarify the section on bioavailability.

6.146 In its comments on the interim report, the European Communities also refers to the experts' replies to question 43. The Panel first notes that this question concerns bioavailability in general, not the sufficiency of evidence regarding bioavailability. The Panel has included quotations of the relevant passages of the experts' replies in its findings. The European Communities also refers to paragraphs 132 *et seq.* of the transcript of the hearing (Annex G). The Panel reviewed the comments of the experts on bioavailability and found that those comments address neither the bioavailability of the five hormones at issue, nor the sufficiency or insufficiency of evidence on it.

6.147 With respect to paragraphs 7.662 to 7.677, the European Communities argues first that the discussion on long latency of cancer and confounding factors should have been in the Panel's analysis under Article 5.1 of the *SPS Agreement*. We note that the Panel addressed this question to the extent this was necessary for its analysis under Article 5.1. The question of the latency period of cancer and of the epidemiological survey of the occurrence of cancer in various populations was addressed in paragraphs 7.535 *et seq.* The Panel also deemed it necessary to address the latency of cancer in its section under Article 5.7 because the European Communities argued that the long latency period of cancer made it impossible to demonstrate positively the existence of clear harm in relation to the hormones at issue. The Panel first determined whether long latency of cancer was relevant for the performance of a risk assessment for the hormones at issue. It then proceeded to determine whether relevant scientific evidence in relation to the latency of cancer was insufficient to the point of making it impossible to perform a risk assessment within the meaning of Article 5.1 and Annex A(4) of the *SPS Agreement*. In order to do this, it assessed whether it could be considered that a "critical mass" of new information or evidence was now available which could unsettle the way long latency of cancer has been taken into account in risk assessment so far. The Panel clarified the part of Section VII.C.3.(f)(vi) dealing with long latency of cancer and confounding factors in order to better present its analysis.

6.148 The European Communities also argues that the section on long latency of cancer and confounding factors is evidence that we applied a "double standard" of evidence for the removal as compared to the approval of the hormones at issue. We did not argue that JECFA or the respondent performed the epidemiological studies necessary to demonstrate an absence of long term effect of the hormones at issue in terms of cancer. We note that the long latency of cancer has been acknowledged. We also note that confounding factors make it difficult to assign a particular cancer to specific circumstances of ingestion of hormone residues. We recall that JECFA's risk assessments take into account the long latency of cancer through the ADI. To the extent that the European

[298] Annex B-1, paras. 155-159.
[299] Paras. 131-166.
[300] EC's reply to question 28 of the questions of the Panel after the first substantive meeting, Annex B-1, para. 158.

Communities disagrees with the approach followed by JECFA, it is for the European Communities to provide a "critical mass" of evidence – not a "positive evidence" – that this approach is no longer valid.[301] We conclude that, in these proceedings, the European Communities has not pointed at evidence suggesting that long latency of cancer has not been appropriately taken into account in existing risk assessments.

6.149 The European Communities also takes issue with the Panel's discussion on the immunological effect of the five hormones in paragraphs 7.678-7.685. The European Communities seems to raise two issues in its comments. The first one is related to the question of whether a threshold approach must be followed. The second one is whether the Panel dismissed the EC arguments on the basis that the scientific evidence relates to oestrogens only.

6.150 Regarding the first issue, the Panel notes that all three experts who answered question 59[302] stated that there is no evidence of effects on the immune system from doses such as those resulting from consumption of meat from treated animals. If the point the European Communities wishes to make in its comments is that the approach based on a "threshold" is not required to assess the effect of the five hormones at issue on the immune system, then the Panel fails to understand why, under those circumstances, the relevant scientific evidence on the effect of the five hormones on the immune system is insufficient for the European Communities to perform a risk assessment for those hormones.

6.151 With respect to the second issue, the Panel notes that Dr. Boobis and Dr. Guttenplan address the effect of oestrogen/oestradiol on the immune system (Dr. Boobis refers to "hormones such as oestradiol"). As the Panel mentions in paragraph 7.681, the main reason for dismissing the EC arguments on insufficiency of evidence regarding the effect of hormones on the immune system is the fact that the evidence made available to the Panel relates exclusively to the effect of oestrogens. The European Communities has not identified any evidence that specifically addresses any of the five hormones at issue in this section. The European Communities has not explained either to the Panel why it thinks the evidence on oestrogens would be relevant for the other hormones. The Panel notes in this respect that the Opinions do not identify any evidence with respect to the five hormones that residue levels in meat might have an effect on the immune system. The Panel nonetheless clarified paragraphs 7.683-7.684.

6.152 Regarding paragraphs 7.686-7.698, the European Communities argues that the Panel quotes Dr. Sippell as identifying adverse effects, but does not discuss his statement. The European Communities adds that there is also no discussion of the other experts' views put forward at the hearing.

6.153 Regarding Dr. Sippell's statement in paragraph 7.691, the Panel has further discussed the points raised by the experts on this matter in paragraphs 7.692 through 7.698.

6.154 With respect to paragraphs 7.674 to 7.687 of the interim report, the European Communities argues 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. 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

[301] In this respect, the Panel inserted a footnote in para. 7.626 to address the EC argument on standard of proof.

[302] Annex D, paras. 443-448.

oestradiol-17β, 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 are 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 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-17β 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.

6.155 Having regard to the point made by the European Communities that misuse and abuse in the administration of hormones is an aspect of risk assessment within the meaning of Article 5.1 to 5.3, the Panel reflected further on whether this issue related at all to the question of insufficiency of relevant scientific evidence under Article 5.7. In the view of the Panel, the question of whether JECFA properly took into account misuse and abuse in its risk assessments is irrelevant to the question whether the European Communities can take this matter into account in its own risk assessment, since it has full discretion to do so pursuant Article 5.2 and to the Appellate Body finding in *EC – Hormones*. In that context, whether evidence exists of misuse or abuse in the administration of hormones 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.

6.156 For these reasons, the Panel decided to delete the section regarding misuse or abuse in the administration of hormones from its final report and modified paragraph 7.578.

6.157 The European Communities argues that the Panel's analysis on the issue of carcinogenicity of progesterone in Section VII.C.3(f)(vii) is flawed. However, the European Communities does not explain specifically in what respect it is flawed. The Panel therefore did not modify its reasoning.

6.158 The European Communities argues that the Panel's analysis on the issue of carcinogenicity and genotoxicity of testosterone in Section VII.C.3(f)(viii) is clearly incorrect and flawed. The European Communities refers to a statement by Dr. Tritscher allegedly admitting that JECFA found that there was scientific uncertainty about genotoxicity of testosterone.[303] The Panel consulted the transcript and noted that Dr. Tritcher discussed the genotoxicity of oestradiol, not that of testosterone. She did say that "all information is being looked at, in particular with compounds that have a genotoxic potential", but she did not mention that progesterone had a genotoxic potential.

6.159 The European Communities argues that the approach and analysis of the Panel on the issue of metabolism and carcinogenicity of trenbolone acetate in Section VII.C.3(f)(ix) is flawed, *inter alia*, because JECFA's assessment defended by Dr. Boobis and Dr. Boisseau dates back to 1988 and is clearly outdated. The Panel has already discussed this argument and considers that a risk assessment does not become invalid merely because it is "old". The Panel believes that, in order to demonstrate that a risk assessment is "outdated", a party must provide studies showing that the data on which the risk assessment is based are no longer valid.

6.160 The European Communities argues that the reasoning of the Panel regarding carcinogenicity of zeranol is flawed, *inter alia*, because if the extrapolation to meat consumption mentioned by Dr. Guttenplan was necessary, as the Panel seems to require in paragraph 7.783, this would have amounted to a complete risk assessment in the sense of Article 5.1 of the *SPS Agreement*. The

[303] Statement of Dr. Tritcher, Annex G, para. 463.

European Communities argues that this is not the relevant standard in the context of Article 5.7. We agree with the European Communities that being able to perform a risk assessment compatible with Article 5.1 is not the standard applicable in the context of Article 5.7 and we do not consider that we applied any such standard in this case. Indeed, the reason why the Panel paraphrased Dr. Guttenplan's statement was not to say that the European Communities could demonstrate that relevant scientific evidence was insufficient only if it were able to extrapolate some genotoxic effect of zeranol to meat consumption. The point that the Panel wanted to make was that the extrapolation of the study commented by Dr. Guttenplan would have entailed, according to Dr. Guttenplan, a "myriad of uncertainties". As a result, this study could hardly serve as a basis to put in question existing knowledge. We clarified this in paragraph 7.783.

6.161 As regards the alleged application of a similar standard in paragraphs 7.787-7.788, the Panel recalls that what has to be demonstrated for Article 5.7 to apply is that no risk assessment within the meaning of Article 5.1 and Annex A(4) of the *SPS Agreement* can be performed. Our reference to Dr. Guttenplan means that we consider, as mentioned in paragraph 7.615, that not just any form of scientific uncertainty can justify a recourse to Article 5.7. As previously noted, we consider that when scientific evidence has been sufficient, it may only be considered as insufficient if a critical mass of scientific information and evidence exists, in terms of quantity and quality, to put into question existing knowledge and evidence. We therefore did not consider it necessary to modify our reasoning.

6.162 In paragraph 7.798, the European Communities expresses its disagreement with the Panel's approach consisting of applying a presumption of conformity with the *SPS Agreement* to JECFA's risk assessment on melengestrol acetate (MGA), even though that risk assessment has not yet been endorsed by Codex. The Panel has explained in paragraph 7.799 why some degree of relevance should be given to JECFA's work, even though it is not formally a "standard, guideline or recommendation" within the meaning of Article 3.2 of the *SPS Agreement*. The Panel also notes that the European Communities does not specify in which respect the Panel's analysis of the issue of the residue data used by JECFA on carcinogenicity is flawed, except for suggesting that the residue data is "outdated", a question already addressed by the Panel in paragraphs 7.800-7.803.

6.163 Finally, the European Communities requests the Panel to clarify the meaning and extent of its conclusion in paragraph 7.823. This paragraph simply states that, because relevant scientific evidence is not insufficient, the European Communities cannot invoke Article 5.7. The corollary is that the European Communities should be able to complete a risk assessment under Article 5.1. The European Communities argues that the Panel should clarify further how the risk assessment could be completed in the presence of the gaps identified in the EC Opinions with respect to oestradiol-17β. The gaps identified in the EC Opinions for oestradiol-17β are:

(a) that the European Communities has not evaluated specifically the possibility of the adverse effects related to the association between excess hormones and neurobiological, developmental, reproductive and immunological effects, as well as immunotoxicity, genotoxicity and carcinogenicity coming into being, originating or resulting from the consumption of meat or meat products which contain veterinary residues of oestradiol-17β as a result of the cattle being treated with this hormone for growth promotion purposes;

(b) The scientific evidence referred to in the Opinions does not support the European Communities' conclusions on genotoxicity, or the conclusion that the presence of residues of oestradiol-17β in meat and meat products as a result of cattle being treated with the hormone for growth promotion purposes leads to increased cancer risk. The scientific evidence does not support the EC conclusions on the adverse

> immunological and developmental effects of consuming meat and meat products from cattle treated with oestradiol-17β for growth promotion purposes.

6.164 Thus, the problems identified by the Panel are not related to the fact that a risk assessment cannot be performed, but rather that the European Communities did not conduct a risk assessment pursuant to Article 5.1 and Annex A(4) and that the scientific evidence did not support the conclusions which the European Communities reached. The European Communities' comment apparently underlines an approach to risk assessment that seems to consist of identifying a risk from a particular substance and if there is any possibility, no matter how remote, of that risk occurring because of that substance, deciding that there is no need to further study whether the risk could arise from the levels of that substance found in food, beverages, or feedstuffs. As discussed in paragraph 6.107 above, the purpose of a risk assessment under Article 5.1 and Annex A(4) is not to provide guarantees that risks will be below a particular appropriate level of protection or even zero, but to objectively determine the possibility for the risk to arise from the presence of the substance under review in food, beverages, or feedstuffs. The Panel therefore, does not believe that the European Communities' approach to risk assessment, whereby the desired level of protection informs the risk assessment rather than the risk assessment providing objective data to be utilized by a government in determining how to achieve its appropriate level of protection, is consistent with the object and purpose of Article 5 of the *SPS Agreement.*

(b) Comments by Canada

6.165 Canada points out that the first sentence of paragraph 7.509 states that "the European Communities has assessed the general risk of the identified potential adverse health effects ..." (emphasis added). Canada requests, given the specific definition of risk assessment in the *SPS Agreement*, that the Panel replace the phrase "has assessed the general risk" with the phrase "has identified a hazard in relation to".[304] The European Communities, in its comments of 19 October 2007[305], argues that the Appellate Body has already found, in *EC – Hormones*, that the EC risk assessment at that time had indeed shown the "existence of a general risk of cancer".[306]

6.166 Considering that it was necessary to ensure clarity, the Panel decided to modify paragraph 7.509. However, the Panel will not use the term "has identified a hazard in relation to" as this too has very specific meanings as set forth in the Codex Procedural Manual and cited in paragraph 7.437. Instead, it will modify paragraph 7.509 to read:

> "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-17β as a result of the cattle they are derived from being treated with the hormone for growth promotion purposes."

6.167 The Panel also considers this correction to be in line with the finding of the Appellate Body in paragraph 200 of its report on *EC – Hormones* referred to above by the European Communities.

6.168 Canada also requests that we replace, in paragraph 7.842(a), the phrase "to the extent that" by the term "because". The Panel does not deem it appropriate to accept Canada's suggestion since the reason for the violation of Article 22.8 in this case is only one of the reasons that can lead to a violation of that Article.

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[304] Canada's comments on interim report, p. 4.
[305] Para. 23.
[306] Appellate Body Report on *EC – Hormones*, para. 200.