WORLD TRADE ORGANIZATION

WT/DS320/R
31 March 2008

(08-0898)

Original: English

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

Report of the Panel

TABLE OF CONTENTS

LIST OF ANNEXES

ANNEX A

CORRESPONDENCE FROM THE PANEL TO THE PARTIES AND WORKING PROCEDURES

ANNEX B

REPLIES OF THE PARTIES TO QUESTIONS POSED BY THE PANEL AND OTHER PARTIES AFTER THE FIRST SUBSTANTIVE MEETING

ANNEX C

REPLIES OF THE PARTIES TO QUESTIONS POSED BY THE PANEL AND OTHER PARTIES AFTER THE SECOND SUBSTANTIVE MEETING AND COMMENTS BY THE PARTIES ON THE OTHER PARTIES' REPLIES

ANNEX D

REPLIES OF THE SCIENTIFIC EXPERTS TO QUESTIONS POSED BY THE PANEL

ANNEX E

REPLIES OF THE CODEX ALIMENTARIUS COMMISSION, THE JOINT FAO/WHO JECFA SECRETARIAT AND THE INTERNATIONAL AGENCY FOR RESEARCH ON CANCER TO CERTAIN QUESTIONS POSED BY THE PANEL TO INTERNATIONAL ORGANIZATIONS

ANNEX F

COMMENTS BY THE PARTIES ON THE REPLIES OF THE SCIENTIFIC EXPERTS, CODEX, JECFA AND IARC TO QUESTIONS POSED BY THE PANEL AND COMMENTS BY THE PARTIES ON THE OTHER PARTIES' COMMENTS

ANNEX G

TRANSCRIPT OF THE PANEL'S JOINT MEETING WITH SCIENTIFIC EXPERTS ON 27-28 SEPTEMBER 2006

TABLE OF WTO CASES CITED IN THIS REPORT

Short Title	Full Case Title and Citation
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
Argentina – Footwear (EC)	Panel Report, *Argentina – Safeguard Measures on Imports of Footwear*, WT/DS121/R, adopted 12 January 2000, as modified by Appellate Body Report, WT/DS121/AB/R, DSR 2000:II, 575
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
Brazil – Desiccated Coconut	Appellate Body Report, *Brazil – Measures Affecting Desiccated Coconut*, WT/DS22/AB/R, adopted 20 March 1997, DSR 1997:I, 167
Brazil – Desiccated Coconut	Panel Report, *Brazil – Measures Affecting Desiccated Coconut*, WT/DS22/R, adopted 20 March 1997, upheld by Appellate Body Report, WT/DS22/AB/R, DSR 1997:I, 189
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
Canada – Aircraft (Article 21.5 – Brazil)	Panel Report, *Canada – Measures Affecting the Export of Civilian Aircraft – Recourse by Brazil to Article 21.5 of the DSU*, WT/DS70/RW, adopted 4 August 2000, as modified by Appellate Body Report, WT/DS70/AB/RW, DSR 2000:IX, 4315
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
Canada – Dairy (Article 21.5 – New Zealand and US II)	Panel 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/RW2, WT/DS113/RW2, adopted 17 January 2003, as modified by Appellate Body Report, WT/DS103/AB/RW2, WT/DS113/AB/RW2, DSR 2003:I, 255
Canada – Periodicals	Appellate Body Report, *Canada – Certain Measures Concerning Periodicals*, WT/DS31/AB/R, adopted 30 July 1997, DSR 1997:I, 449
Canada – Periodicals	Panel Report, *Canada – Certain Measures Concerning Periodicals*, WT/DS31/R and Corr.1, adopted 30 July 1997, as modified by Appellate Body Report, WT/DS31/AB/R, DSR 1997:I, 481
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
Canada – Wheat Exports and Grain Imports	Panel Report, *Canada – Measures Relating to Exports of Wheat and Treatment of Imported Grain*, WT/DS276/R, adopted 27 September 2004, upheld by Appellate Body Report, WT/DS276/AB/R, DSR 2004:VI, 2817

Short Title	Full Case Title and Citation
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
Chile – Alcoholic Beverages	Panel Report, *Chile – Taxes on Alcoholic Beverages*, WT/DS87/R, WT/DS110/R, adopted 12 January 2000, as modified by Appellate Body Report, WT/DS87/AB/R, WT/DS110/AB/R, DSR 2000:I, 303
EC – Approval and Marketing of Biotech Products	Panel Report, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291/R, WT/DS292/R, WT/DS293/R, Corr.1 and Add.1, 2, 3, 4, 5, 6, 7, 8 and 9, adopted 21 November 2006
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 the United States 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 United States' 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 and 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)* (*EC – Hormones)*. The consultation request was circulated in document WT/DS320/1 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/DS320/6, 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/DS320/6, the matter referred to the DSB by the European Communities in that document, and to make such findings as will assist the DSB in making the recommendations or in giving the rulings provided for in those agreements."[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, Canada, China, India, Mexico, New Zealand, Norway and Chinese Taipei, 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, on 1 August 2005, the Panel decided that its meetings at which the parties were invited to appear, would be open for public observation through closed-circuit broadcast, provided the Secretariat could maintain satisfactory logistical arrangements. The Panel, however, after consulting the third parties, also decided that the session with the third parties would

[1] WT/DS320/6.
[2] WT/DS320/7.

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 dispue on *Canada – Continued Suspension of Obligations to the EC – Hormones Dispute* (WT/DS321) on 12-15 September 2005. The meeting with the parties was opened for public observation through closed-circuit broadcast. The Panel 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 the 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 parties, sought their advice as well as advice from 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 *Canada – Continued Suspension of Obligations to the EC – Hormones Dispute* (WT/DS321) on 27-28 September 2006. The expert from IARC served both as an individual scientific expert and as the representative of the IARC. 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 Dispute Settlement Body ("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" up to 13 May 1999 to comply with the recommendations. On 26 July 1999, the United States obtained from the DSB the authorization to suspend obligations up to the level of 116.8 million US 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 the United States at the time of its recourse to arbitration in May 1999. On 29 July 1999 and pursuant to the DSB's authorization, the United States introduced import duties in excess of bound rates on 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]

---

[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/DS320/8.

[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] These measures were published in the Federal Register Notice in Vol. 64, No. 143 of 27 July 1999.

2.2 The original measures in the *EC – Hormones (US)* 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 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 as well as the preceding scientific Opinions. In the same communication, the European Communities explained that it considered itself to have fully implemented the recommendations and rulings of the DSB in the *EC – Hormones* dispute, and as a consequence, it considers the United States' suspension of concessions vis-à-vis the European Communities to be no longer justified.[11]

2.6 The United States raised doubt in the DSB meeting held on 7 November 2003 on whether the new Directive was based on science and on whether the European Communities implemented the DSB's recommendations and rulings as well as the European Communities' obligations under the

[8] WT/DS26/R/USA, paras. 2.1-2.5.

[9] See Request for the Establishment of a Panel by the European Communities, WT/DS320/6.

[10] Ibid. *See also*, EC's second written submission, para. 139.

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

SPS Agreement.[12] The United States continued to impose retaliatory duties on certain products from the European Communities.

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 the Federal Register Notice in Vol. 64, No. 143 of 27 July 1999 and is enforced as of 29 July 1999. The EC's Directive 2003/74/EC was published and entered into force on 14 October 2003. The EC stated in its notification to the Dispute Settlement Body (DSB) that it had fully implemented the recommendations and rulings of the DSB in the dispute *European Communities – Measures concerning Meat and Meat Products (Hormones)* (WT/DS26/AB/R, WT/DS26/R/USA).[13]

III. PARTIES' REQUESTS FOR FINDINGS AND RECOMMENDATIONS

3.1 The European Communities requests that the Panel find that the United States continued suspension of concessions and related obligations under the covered agreements:

(a) violates Article 23.2(a), read together 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 the United States measure violates Article 22.8 of the DSU and Articles I and II of the GATT 1994.[15]

3.3 The United States requests the Panel to find that:

(a) the European Communities has failed to demonstrate that the United States has breached Article 22.8 of the DSU, and that the United States continued suspension of concessions to the European Communities is consistent with the requirements of that provision;

(b) the United States has not breached Articles 3.7, 21.5, 23.1 or 23.2(a) of the DSU; and

(c) the United States has not breached Articles I or II of the GATT 1994.[16]

[12] DSB, *Minutes of Meeting held on 7 November 2003*, WT/DSB/M/157, 18 December 2003, paras. 29-30.
[13] WT/DS320/6. WT/DS26/22.
[14] EC's first written submission, para. 149.
[15] EC's first written submission, para. 150.
[16] US's first written submission, para. 210.

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 the 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 PUBLIC OBSERVATION

4.2 At the Panel's organizational meeting with 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 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 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 the 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 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 the 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 the United States

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

4.14 The United States notes that in the Panel's organizational meeting held on June 13, 2005, the United States, Canada and the European Communities agreed that the panel meetings in these disputes should be opened to interested Members and the public. In the view of the United States, open panel meetings are permissible under the DSU, including under Appendix 3 thereto.

4.15 The United States argues that whether substantive meetings of the Panel are open is not affected by Article 14.1 of the DSU, which provides that the deliberations of a panel shall be confidential. The United States agrees that any deliberations among the three panel members must be confidential. However, Article 14.1 of the DSU does not apply to the meetings of the panel with the parties. Therefore, DSU Article 14.1 does not prohibit opening panel meetings to the public.

4.16 The United States also argues that although Paragraph 2 of Appendix 3 states that a panel "shall meet in closed session", Article 12.1 of the DSU states that a panel may depart from the working procedures in Appendix 3 after consulting with the parties. In other words, the Panel has the ability to remove any provision of Appendix 3 that might be perceived as an impediment to accommodating the parties' decision to make their statements public by allowing the public to observe them as they are delivered. Second, Article 18.2 of the DSU, which is echoed in Paragraph 3 of Appendix 3, explicitly provides that "[n]othing in this Understanding shall preclude a party to a dispute from disclosing statements of its own positions to the public." Appendix 3 is part of the DSU and so, per Article 18.2, nothing in Appendix 3 prevents a party from disclosing statements of its own position to the public. Since each of the parties to this dispute agrees to the opening of panel meetings to the public, the United States considers that the parties should not be prevented from allowing the public to view the meetings at which the parties present their positions. The United States believes that the best way for the United States to disclose its statements to the public is to allow the public to observe those statements as they are being made.

4.17 The United States also argues that Article 17 of the DSU pertains to the Appellate Review process. As such, its provisions, including Article 17.10, do not apply to a determination of whether a panel can or will open its meetings to the public. A decision to open a panel meeting to the public would not have any bearing on any subsequent decision to open the Appellate Body proceedings to the public. Therefore, Article 17.10 of the DSU should not act as a bar to open panel meetings. The United States also believes that this dispute will have a substantial public interest, and permitting the public to observe the proceedings and be able to see first-hand the professional, impartial and objective manner in which they are conducted can only further enhance the credibility of the result.

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

4.18 The United States argues that the provisions in the Rules of Conduct that require panelists to maintain confidentiality apply only to information that is in fact confidential. For information that is

not confidential in the first place, there is no confidentiality to be "maintained." However, the parties to this dispute are affirmatively exercising their rights under Article 18.2 of the DSU to make their written and oral statements public. The parties have also agreed to open to the public the panel meetings in which these oral statements will be read and written submissions discussed. The parties believe that they have the ability under the DSU to have open proceedings and that nothing prevents the Panel from adapting its working procedures to reflect that ability. The United States considers that the opening of Panel meetings would not include the deliberations of the Panel, which would remain confidential under Article 14.1 of the DSU.

4.19 The United States further argues that while the Rules of Conduct state that covered persons "shall respect the confidentiality of proceedings,"[17] they also clarify that "[t]hese Rules shall in no way modify the rights and obligations of Members under the DSU nor the rules and procedures therein."[18] As already noted by the United States in its response to the Panel's question, the procedural rules of the DSU permit public hearings. Therefore, the confidentiality provisions of the Rules of Conduct do not prevent the opening of panel meetings to the public.

(c) Systemic and political impact of opening hearings

4.20 The United States argues that opening the panel meetings to the public is a natural extension of the discretion provided to the parties in Article 18.2 of the DSU for a party to disclose its statements to the public. In this dispute, the parties have agreed to waive their rights to keep written and oral statements confidential, and to open the meetings in which these submissions will be discussed to the public. It is not necessary or appropriate to consult the chairpersons of the Dispute Settlement Body ("DSB"), the General Council or the DSB Special Session, or the WTO Director-General, on whether or not panel meetings in this dispute will or can be opened to the public. In the view of the United States, Article 12.1 of the DSU provides for panels to adapt their working procedures after consulting the parties. Article 12.1 nowhere refers to consulting other WTO bodies and such consultation could be viewed as setting an unfortunate precedent since panels routinely adopt working procedures beyond or different from those in Appendix 3.

4.21 The United States believes that the third parties should be consulted, but only to determine if they would also choose to open portions of the third party session with the Panel to the public. The third parties need not be consulted regarding the opening of panel meetings with the parties.

4.22 The United States considers that opening panel meetings to the public will have a positive impact on the perception of the WTO dispute settlement system, but does not foresee a decision in this dispute to open panel meetings as having a political or systemic impact. For example, the opening of panel meetings in this dispute would not prejudice the ability of parties to other disputes to choose to open, or keep confidential, their respective panel meetings.

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

4.23 The United States believes that any portions of the Panel meetings dealing with confidential information would not be open to the public. Additional safeguards to provide against the disclosure of confidential information could be included in the working procedures. The United States notes that the issue of access to confidential information is not limited to the question of open panel meetings, but is one that panels have had to deal with in a number of disputes. For example, if meetings are

[17] *Rules of Conduct for the Understanding on the Rules and Procedures Governing the Settlement of Disputes* ("Rules of Conduct"), II.1; *see* Rules of Conduct, VII.1 ("Each covered person shall at all times maintain the confidentiality of dispute settlement deliberations and proceedings.").

[18] Rules of Conduct, II.1.

broadcast electronically, it may be possible to include a delay in the broadcast to ensure that there would be no inadvertent disclosure of confidential information.

4.24 The United States argues that the third parties would retain their ability to decide whether their submissions and statements are public. Any confidential statements would not be broadcast. It also considers that it is uncertain what information would come from a Member that is not a party or a third party to the dispute, but any such information that is confidential would be respected in the same manner as any other confidential information.

C. FIRST WRITTEN SUBMISSION OF THE EUROPEAN COMMUNITIES

1. Introduction

4.25 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

4.26 Following an authorization by the DSB, the United States suspended tariff concessions and other related obligations up to the level of US$ 116.8 million. Subsequently, the European Communities implemented the original DSB recommendations and rulings by adopting Council Directive 2003/74/EC. However, the United States 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

(a) The structure of Article 23 of the DSU

4.27 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.*

4.28 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: One, 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. Two, 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.

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

4.29 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.

4.30 It is obvious that when it suspended concessions in July 1999, the United States was seeking to redress a (WTO-determined) violation. Back then, the United States 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 authorisation under Article 22.2 (respectively 22.7) of the DSU, following which the United States decided on the imposition of additional duties at a rate of 100% *ad valorem* for the listed imports. The United States' way of proceeding back then is the very example of a "seeking to redress a WTO violation" in line with the rules and procedures of the DSU.

4.31 There can equally be no doubt that, if the United States is continuing the suspension of concessions to this day despite the European Communities' adoption of an implementation measure, it does so because it is still seeking to redress a WTO violation. This can be deduced from the fact that the July 1999 measure of applying duties in excess of bound rates is being continued without any modification. Because that measure was imposed as "a result of the EC's failure to implement the recommendations and rulings of the WTO," and since the United States has neither abolished nor changed the measure, nor modified its reasons for the imposition, the United States 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 the United States 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 the United States 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

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

4.33 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.

4.34 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 authorised 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 the United States 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.

4.35 Third, Article 23.2(a) of the DSU is violated if the determination to suspend concessions 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.

4.36 There exists obviously a disagreement as to whether, by adopting Directive 2003/74/EC, the European Communities has implemented the recommendations and rulings from the DSB in the *Hormones* case. Article 21.5 of the DSU requires that such a disagreement *shall* be decided through recourse to dispute settlement. The European Communities has invited the United States several times to initiate a compliance procedure under Article 21.5 (or, for that matter, any other dispute settlement procedure under the DSU), but to this date the United States refuses to do so. 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.

4.37 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) The United States' 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

4.38 Under Article 23.1 of the DSU, the United States 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:

4.39 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.

4.40 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 the violating WTO member to comply with its obligations. Indeed, in reaching this conclusion the arbitrators followed a suggestion by the United States (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 no longer be applied. 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.

4.41 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).

4.42 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.

4.43 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))*.

4.44 Therefore, it is clear that the United States 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 the United States refuses to establish the contrary.

4.45 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.

4.46 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 a 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:

4.47 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.

4.48 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 the United States 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, the United States continues the suspension of concessions and related obligations on the basis of a unilateral determination regarding the WTO-inconsistency of the notified compliance measure.

4.49 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.

4.50 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 of Article 23.2(a), in conjunction with Article 21.5 of the DSU, as explained above.

4.51 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 concessions for the first time 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.

4.52 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. 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.

4.53 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.

4.54 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.

4.55 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.

4.56 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 it has been properly established that a Member's measure violates its WTO obligations, 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.

4.57 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.

4.58 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.

4.59 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.

4.60 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)*.

4.61 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.

4.62 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) The United States is in violation of Article I:1 of the GATT 1994 because of the continued suspension of concessions and related obligations

4.63 The United States 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) The United States is acting inconsistently with Article II of the GATT by the continued application of countermeasures on products originating in the European Communities.

4.64 The United States 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) The United States is violating Article 22.8 of the DSU because the measure found to be inconsistent has been removed by the European Communities

4.65 The United States 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, the United States 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.

4.66 The rulings of both the Panel and the Appellate Body 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 into 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."

4.67 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's 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's 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.

4.68 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 authorise 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.

4.69 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 these kind of substances in 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.

4.70 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 places 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.

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

(b) The United States is in violation of Articles I and II of the GATT 1994 following the continued application of suspension of concessions

4.72 As explained above, the illegal continued suspension of concessions and related obligations automatically entails a violation of Articles I and II of the GATT.

D. FIRST WRITTEN SUBMISSION OF THE UNITED STATES

1. Introduction

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

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

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

4.76 However, the EC, having made an Article 22.8 claim, bears the burden of establishing its claim of an inconsistency with Article 22.8 of the DSU. Accordingly, the issue presented to the Panel in this proceeding can be reduced to the simple question of whether the EC has established that it has come into compliance.

4.77 The EC has failed to even attempt to establish that it has come into compliance, and the EC's DSU Article 22.8 claim should be rejected on this basis alone. The EC's Article 21.5 of the DSU claim should likewise be rejected.

4.78 The EC's claims under Articles 23.1 and 23.2(a) of the DSU also fail. In compliance with Article 23.1 of the DSU, the United States has already sought and received multilateral authorization in relation to the EC's failure to comply with DSB recommendations and rulings. The United States has made no determination concerning whether the EC has come into compliance. Accordingly there is no basis for the EC's claims under these provisions.

2. Factual background

4.79 At the core of the matter described in the EC's panel request, and squarely within the Panel's terms of reference, lies the EC's assertion that it has removed the measure found to be inconsistent with its WTO obligations in the original *Hormones* dispute. In its panel request, the EC states: "The European Communities subsequently removed the measure found to be inconsistent with a covered agreement," and that "it considers itself to have fully implemented the recommendations and rulings of the DSB in the *EC – Hormones* dispute." The latter statement was confirming the EC's statement at the DSB meeting held on November 7, 2003, that the EC "consider[s] that with the entry into force of [Directive 2003/74, amending Directive 96/22], it [is] in conformity with the recommendations and rulings made by the DSB."

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

4.81 The EC complains of the "continued" US suspension of concessions to the EC "after the European Communities has removed the measure found to be inconsistent with WTO law in [the *EC – Hormones* dispute]." It suggests, in the wake of a declaration of its own compliance with DSB recommendations and rulings, that the United States' authorization to suspend concessions to the EC is no longer in effect or valid.

4.82 However, US suspension of concessions to the EC was, and remains, multilaterally authorized by the DSB. On 26 July1999, the DSB authorized the United States to suspend concessions or other obligations to the EC in the amount of $116.8 million as a consequence of the EC's failure to comply with its recommendations and rulings in the *EC – Hormones* dispute. To date, this authorization has not been revoked by the DSB, and the United States continues to act pursuant to that authority.

(a) The six hormones used for growth promotion purposes

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

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

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

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

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

4.88 As in the original *EC – Hormones* panel proceeding, the EC has neglected to present any new scientific evidence of a risk, or a risk assessment drawn from that evidence, which would contradict the reams of scientific evidence demonstrating that residues in meat from cattle treated with the six hormones for growth promotion according to good veterinary practice, are safe for consumers.

3. Legal arguments

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

4.90 The EC's theory is not contemplated by the text of the DSU and should be rejected. The EC's argument that an implementing Member may, through a unilateral declaration of compliance, invalidate the DSB's multilateral authorization would undermine the right of Members to obtain that authorization through operation of the negative consensus rule. According to the EC's logic, a Member could effectively invalidate another Member's authority to suspend concessions and force further litigation through a unilateral declaration of compliance the very day after the DSB grants that authority. According to the EC's approach, that implementing Member could then continuously force successive new rounds of litigation at will simply by asserting that it has complied. The EC's approach would create the very endless loop of litigation the DSU operates to prevent.

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

4.92 Before addressing the EC's claims, it is worthwhile to review the applicable burden of proof in this proceeding. It is well-established that the complaining Member in WTO dispute settlement bears the burden of proof. This means, as an initial matter, that the EC, as the complaining party,

bears the burden of coming forward with evidence and argument that establish a prima facie case of a violation. In establishing its prima facie case, the complaining party must set forth sufficient facts and arguments to establish each element of its case. Mere assertions are not sufficient. The EC has failed to meet this burden in these proceedings.

(a) The EC has failed to demonstrate that the United States has breached DSU Article 22.8 because the EC has neither demonstrated that it has "removed" the WTO-inconsistencies of the original hormones ban, nor demonstrated how the amended ban has provided a solution to the nullification or impairment of benefits to the United States

4.93 Article 22.8 states, in relevant part, that:

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

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

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

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

4.96 Article 22.8 nowhere provides that the issue of removal of a measure or providing a solution can be decided by a Member's simple assertion that it has developed a new, WTO-consistent measure, or that it alone has deemed that it has provided a "solution" to WTO nullification or impairment, without a DSB determination. Indeed the EC's proposed interpretation is directly at odds with the last sentence of Article 22.8 which makes it clear that these are questions for ongoing DSB surveillance. Article 22.8 stresses that "the DSB shall continue to keep under surveillance the implementation of adopted recommendations or rulings", in situations where "concessions or other obligations have been suspended but the [DSB] recommendations ... have not been implemented." This statement that the DSB's role is to monitor an implementing Member's compliance with DSB recommendations as well as the complaining Member's suspension of concessions further emphasizes that Article 22.8 is concerned with multilateral review of compliance. The EC simply errs in claiming that under Article 22.8 the US authorization to suspend concessions could be withdrawn in the absence of a DSB determination to that effect. Furthermore, the EC's approach would fundamentally undermine the operation of several critical DSU provisions, most notably the right of complaining parties to seek

authorization to suspend concessions through a DSB decision taken by negative consensus under Article 22.6 or Article 22.7 of the DSU.

4.97 The EC argues that the Panel should find that it has "removed" its WTO-inconsistent measure within the meaning of Article 22.8 analysis because it "must be presumed to have complied with its WTO obligations, if the United States refuses to establish to the contrary." However, the *EC – Bananas* compliance panel highlighted that there is simply no basis in the WTO Agreement for the EC's argument that it is presumed compliant with its obligations absent a finding against its measures. Similarly, there is no presumption of compliance for the EC's amended ban in this proceeding. Because compliance of the EC's amended ban is a condition precedent to several of the claims raised by the EC as a complaining party, the EC bears the burden in this proceeding of demonstrating its compliance.

(b) The EC has failed to demonstrate that its amended import ban on meat and meat products treated with hormones for growth promotion purposes is WTO-consistent

4.98 Whereas the EC claims in its Opinions and Directive 2003/74 to have developed a risk assessment and scientific evidence supporting its import ban on oestradiol-17β, it qualifies the ban on the other five hormones as "provisional." Consistent with this characterization, the EC invokes Article 5.7 of the *SPS Agreement* in its first written submission, alleging that the results of its Opinions provide "'the available pertinent information' on the basis of which the provisional prohibition regarding the other five hormones has been enacted." However, the EC fails to demonstrate how its ban satisfies Article 5.7's four cumulative elements, and it thereby fails to demonstrate how its ban is a legitimate provisional measure within the meaning of that Article.

4.99 Specifically, the EC: (1) fails to demonstrate that its "provisional" ban on meat and meat products from cattle treated with five of the hormones for growth promotion purposes is maintained in a situation where "relevant scientific evidence is insufficient"; (2) fails to demonstrate how its "provisional" ban has been adopted on the "basis of available pertinent information"; (3) has not sought "to obtain the additional information necessary for a more objective assessment of risk"; and (4) has not "reviewed [its] ... measure accordingly within a reasonable period of time" within the meaning of Article 5.7.

4.100 In addition, the EC fails to demonstrate that its amended ban is "based on" a risk assessment within the meaning of Article 5.1 since: (1) the EC's Opinions do not appear to be risk assessments within the meaning of Article 5.1, and (2) the results of the EC's Opinions do not rationally relate to or reasonably support its import ban.

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

4.102 Furthermore, the EC's Opinions and their underlying studies identify theoretical risks from oestradiol-17β generally, but fail to address the relevant risk – that arising from the presence in meat of residues resulting from the administration to animals, according to good veterinary practice, of any of the six hormones for growth promotion purposes. Therefore, the EC's Opinions fail to sufficiently warrant or reasonably support the EC's ban on meat from cattle treated with hormones for growth

promotion purposes according to good veterinary practice. As a result, the EC's ban is not based on a risk assessment within the meaning of Article 5.1 of the *SPS Agreement*.

4.103 Finally, the EC fails to demonstrate that its amended ban, which is not based on international standards, satisfies the conditions of Article 3.3 of the *SPS Agreement*. Specifically, the EC maintains its amended ban in breach of Article 3.3 because it fails to base its amended ban on a risk assessment within the meaning of Article 5.1 of the *SPS Agreement*.

(c) The United States has not breached any other WTO obligations by continuing to suspend concessions to the EC

4.104 The EC argues that the United States has breached Articles 3.7, 21.5, 22.8, 23.1 and 23.2(a) of the DSU. There are two cornerstones to this argument, through which the EC seeks to avoid having to demonstrate how its amended ban in fact cures the WTO-inconsistencies of the original ban. First, the EC argues that the original complaining party, in this case the United States, is obligated to seek recourse to dispute settlement in order to continue to suspend properly-authorized concessions. In particular the EC cites to the United States' failure "to initiate dispute settlement proceedings pursuant to Article 21.5 of the DSU." The EC links this failure to initiate a compliance proceeding to breaches of Articles 23.2(a) and 23.1 of the DSU, and asserts that a US failure to initiate an Article 21.5 proceeding equates to a presumption of EC compliance. As discussed below, Article 21.5 does not, among other things, obligate the original complaining party to seek immediate recourse to dispute settlement to evaluate a Member's unilateral declaration that it has taken a measure to comply.

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

(i) The United States continues to satisfy its obligations under Article 23 of the DSU

4.106 Prior to addressing the EC's intertwined claims alleging breaches of several DSU provisions, it is first necessary to examine an alleged DSU breach common to each of those claims – that the United States has breached its obligations under DSU Article 23. Notwithstanding the EC's claim that by continuing to suspend concessions the United States seeks redress of a perceived violation on the part of the EC, the United States does not now, and did not at the time of the EC's unilateral declaration of compliance, "seek" anything within the meaning of Article 23.1 with respect to the EC's declaration. The United States did not make a determination that the EC's amended hormone ban is in violation of a covered agreement (the current proceeding provides an opportunity for the WTO to resolve that question), nor did the United States try to obtain or bring about compensation or remedy for some new wrong or alleged WTO violation.

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

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

(ii) The US suspension of concessions does not breach Articles 23.2(a), 21.5 and 23.1 of the DSU

4.109 The EC argues that the United States "should have introduced a compliance procedure under Article 21.5 of the DSU," and in failing to do so "violated the specific prohibition of unilateral conduct set out in Article 23.2(a) of the DSU." The EC argues that the alleged breach of Articles 23.2(a) and 21.5 further constitutes a breach of Article 23.1 of the DSU. To the contrary, the United States continues to satisfy its obligations under each of these Articles, and the EC has failed to demonstrate the contrary.

4.110 As discussed above, the United States has not, through its continued application of the DSB's authorization to suspend concessions, sought redress for another Member's violation, in breach of Article 23.1. This also means the United States is not breaching Article 23.2(a). Likewise, the United States is not breaching Article 23.2(a) because it did not make a "determination" within the meaning of Article 23.2(a).

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

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

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

4.114 First, the United States has continued to evaluate the EC's claim, and at the time of panel establishment had been awaiting the EC's response to the US request under Article 5.8 of the *SPS Agreement*. The United States has continued to evaluate the EC's claim, including its 19 May 2005 response to the US request. The US evaluation depends to a large extent on the EC's response to

questions such as those posed in this submission, including why the EC believes that scientific evidence has now become insufficient to perform a risk assessment for five of the six hormones. To date the EC has been less than thorough in its responses. Article 21.5 only applies "[w]here there is disagreement."

4.115 Next, the EC interpretation of Article 21.5 as requiring immediate resort to litigation by a complaining party would definitively prevent that complaining party from exercising any judgment as to the fruitfulness of dispute settlement, and would preclude Members from seeking mutually agreeable solutions through negotiations. The aim of the dispute settlement system is to secure a positive solution by whatever means possible, and not simply through litigation. In the absence of any obligation in Article 21.5 to immediately resort to litigation, the fact that the United States had not done so by the time the EC initiated this proceeding cannot constitute a breach of Article 21.5.

4.116 Thirdly, contrary to the EC's argument, the text of Article 21.5 assigns no obligation to the *complaining* party to seek recourse to "these dispute settlement procedures" in the event that there is a disagreement "as to the existence or consistency with a covered agreement of measures taken to comply." The text does not require that the original complaining Member, in this case the United States, initiate dispute settlement proceedings in the event of a disagreement. Thus, the mere fact that the United States had not yet decided to invoke Article 21.5 proceedings before the EC undertook the present challenge is not in itself grounds for concluding that the United States breached Article 21.5, any more than the EC's failure to do so was.

4.117 Finally, it is important to recognize that the text of Article 21.5 refers to "these dispute settlement procedures," without specifying any particular subset of WTO dispute settlement procedures. The panel in the *US – Certain EC Products* dispute recognized that the ordinary meaning of this phrase covers any dispute settlement procedure provided in the DSU "that could be used to assess the compatibility of the new implementing measure, including Article 25 or Article 22 of the DSU". In other words, there is no basis in Article 21.5 for excluding any WTO dispute settlement procedure that could be used to assess the WTO-compatibility of a new implementing measure. In bringing these proceedings, the EC availed itself of one such means, though, as discussed above, it has failed to meet its required burden to prevail. Also, in bringing these proceedings, the EC has conceded that an Article 21.5 compliance panel is not the exclusive means to resolve a "disagreement" even if one existed. If it were the exclusive means, then the EC itself would have invoked Article 21.5, as it has done in the past. However, it did not, nor did it seek to have the matter that is the subject of this proceeding referred to the "original panel" as provided in Article 21.5. None of the original panelists are serving on this Panel. Thus the EC's approach in this proceeding itself refutes the EC's Article 21.5 claim.

(iii) The United States has not violated Article 23.1 of the DSU, read together with Articles 22.8 and 3.7 of the DSU

4.118 The EC claims that the United States violates Article 23.1 of the DSU, when read together with Articles 22.8 and 3.7 of the DSU. The EC asserts that these three Articles, together, demonstrate "that a WTO Member shall not apply the suspension of concessions or other obligations in the presence of an implementation act, which has not been found to be inconsistent following an Article 21.5 proceeding." Contrary to this claim, the United States continues to satisfy its obligations under each of these Articles.

4.119 As discussed above, the United States does not seek to redress a WTO violation within the meaning of Article 23.1 of the DSU, and it continues to act pursuant to its multilateral authorization to suspend concessions to the EC. Therefore, the EC's claim that the United States has violated DSU Article 23.1, read together with Articles 22.8 and 3.7 of the DSU fails.

(iv) The United States has not breached its obligations under Article I or II of the GATT 1994

4.120 Finally, the EC claims that the United States acts in breach of Articles I and II of the GATT 1994. However, the DSB has specifically authorized the United States to suspend concessions under Articles I and II of the GATT 1994. Until the DSB withdraws its authorization or the conditions of Article 22.8 have been found to have been met, the United States cannot be found in breach of GATT 1994 Articles I or II.

4. Conclusion

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

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

1. Introduction

4.122 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

4.123 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.

4.124 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 of the 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?

4.125 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

4.126 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.

4.127 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.

4.128 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.

4.129 Finally, the United States claims that there is no obligation for the retaliating complainants 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

4.130 As regards the EC' claim under Article 23.1 in conjunction with Article 22.8, 3.7, 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.

4.131 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.

4.132 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.

4.133 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.

4.134 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.

4.135 It is therefore also absurd, and indeed turns 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.

4.136 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.

4.137 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*.

4.138 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.

4.139 Second, the DSB authorization is even more fundamentally changed in the 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 "Bananas" dispute the DSB Chairman explicitly stated that the sequencing of a determination of (non-)compliance and the suspension of concessions should be treated in a "logical way forward".

4.140 As it happened, the logical way forward at the time was to assess first whether 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's compliance measure, pretending that this is not necessary becuase they have a DSB authorization.

4.141 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's compliance measure which is in obvious contradiction to Article 23 and Article 21.5 of the DSU.

4.142 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.

4.143 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.

4.144 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.

4.145 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.

4.146 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.

4.147 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.

4.148 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

4.149 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.

4.150 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.

4.151 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 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.

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

4.153 The EC would recall some essential points which have been discussed by the parties:

4.154 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 the EC's 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".

4.155 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's 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 to accept that the EC may rely on this principle in a "post-implementation" scenario. The United States even wants to go so 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 consistently 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.

4.156 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 measure 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 has actually done in this case after a most thorough review of its measure involving a comprehensive review and assessment of the available scientific evidence.

4.157 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.

4.158 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.

4.159 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.

4.160 We hope that we have assisted you in your important task and look forward to helping you in any further way that we can in coming weeks.

F. ORAL STATEMENT OF THE UNITED STATES DURING THE FIRST SUBSTANTIVE MEETING

1. Introduction

4.161 There are two central facts in this dispute. The first is that the WTO's Dispute Settlement Body authorized the United States to suspend concessions against the European Communities in the *EC – Hormones* dispute over five years ago because the DSB found that the EC lacked a scientific risk assessment to justify its ban on imports of meat in connection with hormones and that the EC then failed to implement the DSB's recommendations and rulings. The second is that the EC has made no effort to demonstrate that the conditions in the WTO's DSU for ending that DSB-authorized suspension have been met. Those conditions are set forth in DSU Article 22.8. While the EC has alleged that the United States is breaching this provision, the EC apparently considers that it can simply assert that those conditions have been met, that it can unilaterally declare itself to be in compliance and that it can thereby invalidate the multilateral authorization of the DSB.

4.162 This position is not sustainable. The EC is alleging that the United States is breaching its WTO obligations, and there can be no dispute that the EC bears the burden of demonstrating this – including demonstrating that it has removed the measure or provided a solution to the nullification or impairment suffered by the Member suspending concessions.

4.163 Despite this burden, the EC has insisted that this proceeding should not reach the question of whether it has actually complied with its WTO obligations in the *EC – Hormones* dispute. We can understand the EC's reluctance to deal with this issue, since we do not see how the EC can credibly claim it is in compliance with those obligations. Nevertheless, the EC's failure to make any effort at all to demonstrate its compliance is by itself grounds for rejecting the EC's claims, since this question goes to the heart of those claims.

2. The European Communities' amended ban

4.164 It is notable what the EC has not argued in these proceedings – how and why it has come into compliance with the DSB's recommendations and rulings. The absence of this argument is odd since the majority of its claims are premised on the assertion that its ban is now WTO-consistent. Let us look for a moment at what, exactly, the EC has done. As far as the United States can tell in the

absence of any explanation by the EC, the EC's "amended" ban simply preserves the *status quo* of its original ban found by a WTO panel and the WTO Appellate Body to violate the *SPS Agreement* in 1997 and 1998, respectively. Under the ban, found in Directives 96/22/EC and 2003/74/EC, the same products that were prohibited entry into the EC almost ten years ago when we first challenged the measure still may not enter the EC today.

3. The six hormones used for growth promotion purposes according to good veterinary practices

4.165 The six hormones at issue are oestradiol-17β, testosterone, progesterone, zeranol, trenbolone acetate and melengestrol acetate (or "MGA"). These hormones have been used for growth promotion purposes in cattle for decades in several countries, and meat from treated animals has been consumed by millions of people, without any evidence of risk or harm to human health.

4.166 In terms of human food safety, the six hormones have been studied extensively, by national authorities and by Codex, the relevant international standard-setting body with scientific expertise in this area. In fact, the study of these hormones dates back over twenty years. The consensus throughout the course of this study is that meat from cattle treated with these six hormones for growth promotion purposes according to good veterinary practices is safe.

4.167 In stark contrast to the several reviews finding the use of these hormones to be safe, there is one view that the EC portrays as dissenting – that of its Scientific Committee on Veterinary Measures Relating to Public Health ("SCVPH"), contained in the SCVPH's 1999 and 2002 Opinions and 2000 Review, ostensibly supported by several (17) studies commissioned by the EC. It is this view which the EC now asks the Panel to accept wholesale without any explanation or analysis.

4.168 It is therefore not surprising that the EC has been unable to convince several of its own agencies of the conclusions set out in its Opinions and studies. For example, in 1999, a sub-group of the United Kingdom's Veterinary Products Committee dismissed the methodology and conclusions of the EC's 1999 Opinion. Recently, in a May 2005 draft report reviewing the EC's 2002 Opinion and the 17 studies, the Veterinary Products Committee ("UK Group") again concluded that it was "unable to support the conclusion reached by the SCVPH that risks associated with the consumption of meat from hormone-treated cattle may be greater than previously thought." The UK Group also stated that, regarding estradiol 17β, "there is ample information to show that zoo-technical and therapeutic uses of oestradiol-17β do not pose any risk to humans unless an active implant site is ingested."

4.169 Regarding the other five hormones, the majority of the U.K. Group determined that the "available evidence on genotoxicity, tumorigenicity, hormonal activity and endocrine disrupting effects was supportive of the view that eating meat from animals treated with these five hormones was unlikely to be harmful to human health."

4.170 In addition, the EC's own Committee for Veterinary Medicinal Products ("CVMP"), which in 1999 evaluated the conclusions of the 1999 Opinion and the new EC studies on oestradiol and progesterone, determined that the EC had not presented sufficient new evidence to cause the CVMP to conduct a new risk assessment on either hormone or alter its previous conclusions on their safety.

4.171 Let me reiterate: these are internal criticisms of the work produced by the EC and of the very documents it now asserts bring its measure into compliance with DSB recommendations and rulings. Despite these criticisms, and despite the extensive history of study of these hormones finding their use to be safe, the EC would have this Panel endorse its assertion that its new measure is WTO-consistent without a demonstration of why this is so. A determination of an Article 22.8 breach absent a thorough evaluation of these documents would not only ignore the rules of burden of proof in WTO dispute settlement, it would cast aside the substantial history of review of these hormones – a history

that has, time and again, demonstrated that their use for growth promotion purposes according to good veterinary practices, is safe for consumers.

4. The EC's assertion of its own compliance

4.172 Contrary to the EC's argument, a WTO Member may not, in effect, revoke DSB authorization to suspend concessions, and consequently establish a breach of Article 22.8 of the DSU, by simply asserting that it has brought its measure into compliance. This interpretation ignores the rules of burden of proof in WTO dispute settlement as well as the Article's text and context.

5. Burden of proof

4.173 As a threshold matter, the EC fails to meet its burden of proving that the United States has breached Article 22.8 of the DSU. As the complaining party, it shoulders the burden of proving each element of its claims against the United States. Article 22.8 requires that a Member either remove its WTO-inconsistent measure or provide a solution to the nullification or impairment suffered by the Member suspending concessions in order to demonstrate a breach. In other words, for purposes of its Article 22.8 claim, the EC must demonstrate how it has in fact accomplished either of these two conditions.

4.174 The EC's bald assertion of compliance in the context of this scientific and factual landscape highlights the fact that it has made no effort to demonstrate how its new import ban satisfies the conditions of a "provisional" ban under Article 5.7 of the *SPS Agreement* or "rationally relates" to or is "reasonably supported" by a risk assessment for purposes of Article 5.1 of the *SPS Agreement*. Its mere assertion that it can invoke Article 5.7 for the five hormones, and that it has developed a proper risk assessment for the sixth and that its ban is now based on such an assessment is not sufficient to demonstrate that it has removed its WTO-inconsistent measure or provided a solution to the EC's nullification or impairment of benefits, and thereby does not satisfy its burden of proof and make its prima facie case.

6. "Presumption of good faith"

4.175 In lieu of an attempt to satisfy its burden of proof, the EC argues the existence of a presumption or principle of good faith. Or, at least such a presumption applied selectively on the EC's terms. For the EC, the presumption applies to its unilateral declaration of compliance, but apparently does not apply to a Member's suspension of concessions in accordance with a DSB authorization.

4.176 In support of its argument, the EC cites dicta from WTO disputes in which panels, arbitrators, and the Appellate Body are simply elaborating on the appropriate burdens of proof in WTO dispute settlement. It is unexceptional and uncontested that, in a dispute, the complaining party bears the initial burden of proof to establish its claims of a WTO violation, and that there is no presumption of bad faith with respect to the responding party. Were it otherwise, complaining Members would not have to mount any case whatsoever to demonstrate a WTO violation. They could simply allege that it was so and prevail.

7. The EC's interpretation of the DSU

4.177 The EC claims that the United States has breached Articles 21.5 and 23 of the DSU by continuing to suspend concessions to the EC despite its claim of compliance. However, the EC's analysis of these provisions is not consistent with their terms, nor does it reflect the fact that the United States' DSB authorization remains valid.

(a) Article 21.5

4.178 For instance, the EC reads into Article 21.5 of the DSU an obligation that a Member duly authorized to suspend concessions must request an Article 21.5 panel the moment that another Member declares its own compliance with DSB recommendations and rulings. However, nothing in Article 21.5's text hints at such an obligation. Indeed, the DSU simply does not prescribe the particular procedures to follow in a situation where the DSB has granted authorization to suspend concessions to a Member, and the implementing Member later claims to have complied. Rather, it leaves open to the parties to choose one of various means to proceed, including bilateral consultations, use of good offices, conciliation and mediation under Article 5 of the DSU, recourse to DSU Article 21.5, arbitration under Article 25 of the DSU, and recourse to normal panel proceedings such as we are party to here.

4.179 Despite this fact, the EC would instead remove all alternatives except an Article 21.5 compliance proceeding and would read into that Article a deadline that is not there. The EC would also read into Article 21.5 an obligation for the complaining Member, and only that Member, to invoke Article 21.5. The EC does not base its proposed approach on the actual text of the Article, but rather constructs a series of policy arguments as to why the DSU should be re-written in the manner it desires.

4.180 There are three basic shortcomings in the EC's Article 21.5 analysis. First, Article 21.5 only applies in situations where there is a disagreement regarding the WTO-consistency of a measure taken to comply. Prior to the EC's request for the establishment of this Panel (and so by definition prior to the EC's request for consultations), the United States had not formulated an opinion as to the WTO-consistency of the EC's ban.

4.181 Second, Article 21.5 does not contain any time limitation or deadline by which a Member must initiate dispute settlement proceedings – a point emphasized by the fact that there is often substantial delay between claims of compliance and the initiation of Article 21.5 proceedings (presumably responding Members normally welcome such delays since they would not be in a hurry to have their claims of compliance questioned before a panel). The EC's interpretation of Article 21.5 would prevent Members such as the United States from exercising any judgment as to the fruitfulness of dispute settlement prior to finding themselves obligated to do so and would similarly preclude Members from seeking mutually agreeable solutions through negotiations.

4.182 Third, and finally, the EC argues that the United States was obligated to seek recourse to an Article 21.5 compliance panel, and only such a panel, upon hearing the EC's declaration. However, the text of Article 21.5 simply refers to "these dispute settlement procedures," without specifying any particular subset of procedures. Therefore, the EC's argument that the United States was specifically obligated to initiate a compliance proceeding under Article 21.5 is groundless.

(b) Article 23

4.183 In addition to its claim of a US breach of Article 21.5, the EC also contends that the United States has breached Article 23.1 by seeking redress of a perceived WTO violation without recourse to dispute settlement and made a "determination" of the WTO-consistency of the EC's ban in breach of Article 23.2(a). We have done neither.

4.184 The United States was not obligated to seek recourse to dispute settlement pursuant to the general rule set out in Article 23.1 once the EC declared its own compliance at the DSB. The United States adhered to the letter of Article 23.1 by seeking redress of the nullification or impairment caused by the EC's import ban through recourse to the provisions of the DSU. The multilaterally-authorized suspension of concessions stemming from US recourse to dispute settlement remains valid to this day.

It is unaffected by the EC's unilateral declaration of compliance, and the EC has failed to demonstrate to the contrary.

4.185 Similarly, the United States has made no Article 23.2(a) determination as to the WTO-consistency of the EC's amended ban. Since receiving authorization to suspend concessions to the EC, we have simply continued to act according to that authorization. Contrary to the EC's claims in this panel proceeding, we have made no determinations regarding the WTO-consistency of its import ban, amended or not. We did not have to make any further determinations in order to continue to suspend concessions. Article 22.8, discussed earlier, sets the parameters for when we would no longer have been authorized to do so. The EC has made no effort to demonstrate that any of the conditions of that Article have been met.

8. Conclusion

4.186 For all the reasons discussed above and in its first written submission, the United States respectfully requests the Panel to reject the EC's claims in their entirety.

9. Concluding statement of the United States

4.187 The United States has actively engaged in this week's debate, examined in detail provisions of the DSU and the facts of this dispute. Taking into account all of these discussions and facts, it becomes clear that we find ourselves here today for a simple reason: the EC, a WTO Member who claimed to have come into conformity with DSB recommendations in the *EC – Hormones* dispute, did not want to undertake the effort of explaining why this was indeed the case. It chose not to attempt to satisfy its burden despite its eagerness to have the suspension of concessions lifted, and despite its possession of new Opinions and studies it so confidently alleged to support its ongoing ban. It has chosen not to make this attempt despite several avenues available to it in the current text of the DSU, including Article 22.8 (as well as Articles 5 and 25).

4.188 Instead, it chose to seek a suspension of sanctions in the most roundabout way possible – by alleging that the United States, by not lifting its suspension of concessions, breached its obligations under elaborate, intertwining interpretations of the DSU. This choice is remarkable given the fanfare that the EC attached to its ban and Opinions. One would have thought that an Article 22.8 finding that it had removed the ban or provided a solution to nullification or impairment would have been a logical and simple approach.

4.189 Yet, the EC did not pursue this straightforward course. Instead, it alleged that the United States had made a unilateral determination that the EC's new ban was not WTO-consistent. In this, it ignored the fact that the United States has been suspending concessions to the EC pursuant to DSB authorization. Moreover, having eschewed Article 22.8, the EC could not identify a standalone provision in the DSU regarding which it could allege a US breach. So, rather than looking to Members' obligations as they currently exist in the text of the DSU, the EC concocted two claims, melding and rewriting provisions of the DSU, and contending that it has demonstrated that the US suspension of concessions can no longer be applied.

4.190 The EC asserts that these claims are a "refinement" of the individual claims described in its panel request. However, rather than becoming more clear or "refined", the EC's claims blending multiple DSU provisions have become more and more muddled. I would like to take a moment to discuss a few of these "in conjunction with" claims.

4.191 I would first reiterate a question raised in Tuesday's session, and add one additional question for future consideration. In that meeting, the United States asked the EC whether it still alleged a US breach of Article 21.5 of the DSU *per se*. I would now ask a further question: does the EC still allege

that the United States has breached Article 22.8 of the DSU? Why do I ask if there is a violation of these provisions *per se*? Because the EC has failed to identify, anywhere in the text of either Article, an obligation breached by the United States, and those are the only breaches possible under the DSU as currently written. Instead, the EC cloaks its alleged claims of breach "in conjunction" with claims of breach of other DSU provisions, ranging from Article 3.7 to Article 23.

4.192 The EC's repeated invocation of the phrase "in conjunction with" does not make the EC's interpretive approach any more credible. To the contrary, the phrase should be viewed as a signal that the argument which follows is based not on the text of the DSU, but on how the EC would like to see the DSU rewritten. Or, at least, how it would like to see the DSU rewritten for purposes of this dispute.

4.193 From our standpoint, it is impossible to tell if, through these "in conjunction with" claims, the EC still alleges an actual US breach of these provisions (Articles 21.5 and 22.8). Ironically, the EC refers to our attempts to respond to their jumbled claims on an individual, article-by-article basis as "obfuscat[ion]", yet it has told us all that, if the Panel makes a finding in its favour on one of these "in conjunction" claims, it expects very real, individual, un-conjoined breaches of Articles 21.5 and 22.8 to be an integral part of those findings.

4.194 According to the EC, an analysis of the black-and-white text of Articles 22.8 and 21.5 is "obfuscation," since these can only be analysed "in conjunction with" other provisions. In particular, I would highlight the following quotes from the EC's oral statement:

> "This Panel is asked to find whether, under Article 23, in conjunction with Article 21.5, a Member has an obligation ..." but that "[i]t is not relevant for this dispute what obligations can be found directly in 21.5 in the absence of such unilateral conduct."
>
> "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 ..."

4.195 The EC's non-textual approach appears to be an attempt to distract from the fact that it does not wish to attempt to make its prima facie case of an Article 22.8 breach by demonstrating, pursuant to the actual, current, text of that provision that it has either removed its WTO-inconsistent measure or provided a solution to the nullification or impairment. Likewise, it seeks to avoid any analysis of what obligations are actually found in the text of Article 21.5, since that provision does not in fact obligate the United States to bring an Article 21.5 proceeding, nor does it contain a time limitation for doing so.

4.196 Rather than a "refinement" of the EC's case, these "in conjunction" arguments only make the EC's case all the more obtuse – creating in essence a moving target for responding parties. We are forced to defend ourselves against accusations that we are in breach of provisions that do not, in fact, exist. We have exposed in the question and answer session the potentially confusing outcome of recommendations and rulings on some of the EC's claims – an outcome that would result from the EC's inability to demonstrate a US breach of any of these provisions standing alone. Fortunately, there is a simple way to avoid this confusing outcome – to look instead to the text of the DSU as it is currently written, not as a single Member's policy would have it rewritten.

4.197 We have demonstrated in our submissions that Article 21.5 does not contain any obligations that the United States could theoretically have breached. For example, there is no obligation that the United States bring a compliance proceeding upon learning of the EC's declaration of compliance.

Further, there is no time period, whether that period is immediate or is unspecified, indefinable and unwritten "reasonable delay" championed by the EC. Pursuant to this fictional new Article 21.5 requirement developed by the EC, if a Member requests an Article 21.5 panel "a month or two – rather than two years – into implementation" it has satisfied its imaginary deadline to do so. Maybe I have not been looking hard enough at the text of Article 21.5, but I have not been able to locate the "reasonable delay" deadline yet. This is not surprising, because the EC makes every effort to avoid the actual text of Article 21.5. According to the EC, the fact that we can demonstrate that we have not breached the provisions of Article 21.5 is not the point – because "[i]t is not relevant for this dispute what obligations can be found directly in 21.5."

4.198 We have demonstrated in our submissions that we have not breached Article 22.8, which requires that the suspension of concessions "only be applied until such time as the measure found to be inconsistent with a covered agreement has been removed, or the Member that must implement recommendations or rulings provides a solution to the nullification or impairment of benefits, or a mutually satisfactory solution is reached." We have shown that the EC has failed to demonstrate that any of these three conditions have been met. There is no satisfactory solution, no removal of the measure, and no provision of a solution to US nullification or impairment. Indeed, the EC does not engage in a discussion of whether or not it has satisfied these conditions whatsoever. In the eyes of the EC any substantive analysis of Article 22.8 would involve analysis of a "(direct) violation" of Article 22.8. Evidently, a direct analysis of a direct violation of the actual text of Article 22.8 is not relevant to this proceeding. This is the case because, for the EC, its reference to Article 22.8 in Part I of its submission is only to be read "in conjunction with" Article 23. As a result, the United States is evidently left to rebut an "indirect" claim. Indirect, that is, in that it evidently does not involve analysis of the obligations specifically set out in Article 22.8. Not so indirect in that, through this Article 22.8 "in conjunction with" Article 23 claim, the EC seeks a finding of a very full-fledged, very direct US violation of Article 22.8.

4.199 So, finally, we come to the "central provision" of the EC's claims against the United States – Article 23. Like it did for Articles 21.5 and 22.8, the United States set out clear arguments, based on the text of this provision as it is currently set out in the DSU. We demonstrated that, at the appropriate time, we sought recourse to dispute settlement and obtained the proper DSB authorization. We continued to suspend those concessions pursuant to this authorization.

4.200 It is critical to note that, just because the DSU does not set out an explicit path for Members to pursue in this "post-suspension" scenario, it provides several options by which, pursuant to its text as currently written, the EC may have sought review of its measure. The EC, contrary to what it would apparently have this Panel believe, was not without avenues for obtaining a multilateral determination that its measure was or was not WTO-consistent. For example, I should reiterate that, as we have indicated on several occasions, we find ourselves in a perfectly suitable panel proceeding to examine the EC's compliance pursuant to DSU Article 22.8. While the EC would argue that an Article 22.8 claim against the United States, and a need to make a prima facie case that it has either removed its offending measure or provided a solution to nullification or impairment is only raised in its Part II claim, we would note that it is also squarely before this Panel in the Part I claims set out in the EC's first written submission, only in the form of the opaque "23 in conjunction with 22.8" claim, which evidently sets out an "indirect" Article 22.8 claim.

4.201 We have also commented that an Article 21.5 compliance panel could be a possible avenue for determining whether or not the EC has brought its measure into compliance with DSB recommendations and rulings. The EC has raised various issues concerning a Member bringing a compliance proceeding against itself. Among these, it has argued that the *EC – Bananas (Article 21.5)* proceeding does not demonstrate that a Member may do so. In the third party session, it responded to another party's comment that, by the very fact that the EC composed an Article 21.5 panel, it demonstrated that this is a possible avenue. However, the EC's dismissal of this comment

because the report was not adopted ignored the point being made. Apart from the fact that the report was not adopted for the simple reason that the EC never requested its adoption, it is unclear why adoption or lack of adoption of the report has any bearing on the simple fact that the EC was indeed able to request the Article 21.5 panel.

4.202 I would now like to turn to Part II of the EC's argument.

4.203 Part II of the EC's argument, its "direct" Article 22.8 claim against the United States, is the embodiment of what this case would look like if the EC chose to put its amended measure forward for multilateral review. That the EC has brought this claim is testament to the fact that it is possible to do so, that it is possible for an implementing Member to put its measure squarely before an Article 6 panel and to seek multilateral review and findings of the WTO-consistency of that measure.

4.204 The issue of burden of proof came up in yesterday's meetings, and I think that we should touch upon it at this point. Yesterday, the EC expressed its concern regarding what would be involved in setting out a prima facie case of removal of its measure or providing a solution to nullification or impairment for purposes of an Article 22.8 claim against the United States. I think that everyone here would agree that this is not exactly an insurmountable task, in particular, for a Member like the EC who has just spent the last six years producing studies on these hormones and developing Opinions evaluating those risks. The EC believes its ongoing ban is tied neatly to these studies and Opinions, and one would think it of little consequence for the EC to explain why it felt justified in declaring itself to be in compliance with the DSB's recommendations and rulings, why it believes that its ban on oestradiol-17β is based on a risk assessment within the meaning of Article 5.1 of the *SPS Agreement*, and whether its provisional ban on the five other hormones satisfied the conditions of Article 5.7. The EC could, for example, have addressed its alleged compliance with specific panel and Appellate Body findings. But the EC did not do so, and instead relies on unsupported assertions.

4.205 It is worth noting that the question of the precise level of evidence and argumentation necessary to establish a prima facie case is rarely at issue in WTO dispute settlement, for the simple reason that both sides typically engage on the merits, allowing the panel to evaluate the totality of the evidence presented to determine whether the responding party has adequately rebutted the complaining party's arguments. Indeed, the United States in this proceeding has engaged on the substance of the EC's new studies as if the EC had attempted to make its prima facie case. The EC's failure to actually do so, and its reliance in this dispute on creative redrafting of the DSU, says more about the EC's lack of confidence in its own scientific evidence than it does about the supposed difficulty of understanding how to establish a prima facie case.

G. SECOND WRITTEN SUBMISSION OF THE EUROPEAN COMMUNITIES

1. Introduction

4.206 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. 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).

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

(a) The United States is in violation of Article 23.1 and 23.2(a) read together with Article 21.5

4.207 The existence of a DSB authorization does not exclude that a WTO Member is still seeking the redress of a violation within the meaning of Article 23.1. The very fact of applying sanctions implies that a Member is seeking to redress a violation. Such an application of 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 never found to be WTO-inconsistent or which has not even been challenged. In such case, 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. 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, i.e. violation. Conversely, the *present* application of sanctions to a *past*, no longer existing measure is not justified just as it would be unjustified to link the *present* application of sanctions to a *future*, not yet existing measure.

4.208 The US counter-argument would lead to the absurd result that the United States 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 the United States applies sanctions merely because of the existence of a DSB authorization and irrespective of a subsequent compliance measure, they are neither inducing nor rebalancing anything. The United States fails to acknowledge that the situation has changed by the adoption of the EC implementing measure. Yet, since the United States has adopted a negative position on the EC compliance measure and since the United States has been under no obligation to continue the suspension of concessions, the very fact that it nevertheless continues the application of sanctions proves that despite its claim to the contrary the United States is indeed drawing a causal link between the continuation of the suspension and the determination of inconsistency of the EC compliance measure.

4.209 The opposite US view would lead to the conclusion that the United States is currently applying sanctions against a no longer existing measure, because it is uncontested that the original measure which the DSB found inconsistent has been removed by the EC. However, the true reason for the US application of sanctions is that it considers the existence of an "import ban" as such as a violation. The United States does so on the basis of a unilateral determination since the current import ban is a totally new measure which has never been found WTO-inconsistent. Thus, in the presence of a compliance measure the United States assumes a right to determine unilaterally whether this measure is sufficient or not. Furthermore, the fact that the United States seeks redress is also evidenced for instance by its statement in the 2005 Trade Policy Agenda whereby the United States openly links the continued application of sanctions to the EC compliance measure. Conversely, the United States did *not* state that it continues to apply sanctions because of the DSB authorization.

4.210 The United States has also made a unilateral "determination" that a violation has occurred. 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*. 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.

4.211 Moreover, the interpretation of the word "determination" should be guided by the context of Article 23.2(a), which is 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 also confirmed by the title of this provision. The crucial importance of Article 23 has also been acknowledged by the Panel in *US – Section 301*. 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, 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 the United States has made a unilateral "determination" of non-compliance of the EC measure. This is demonstrated by the 2005 Trade Policy Agenda and, for instance, the US statement in the DSB meeting of December 2003. In addition, it deliberately *continues* to apply sanctions against the European Communities. Contrary to what the US purports, this continuation is also a positive action and not just some "inaction".

4.212 The European Communities adopted and notified its compliance measure over two years ago. To these two years one could add another three years since the European Communities notified its legislative proposal to the SPS Committee in November 2000. Against this time lag it is not credible for the United States to argue that it has still not made a determination. Rather the US attitude is explained by the attempt to declare its rights sacrosanct and to refuse any responsibility for a prompt resolution (see Article 3.3) of the dispute.

4.213 Finally, Article 23 in conjunction with Article 22.8 obliges a retaliating Member to take note of a compliance measure and to decide if the continued application of sanctions is still justified. Furthermore, Article 23 prohibits making a unilateral determination of *non-compliance*. Conversely, nothing prevents the United States under Article 23 to make a unilateral determination of *compliance*. Thus, unlike what the United States pretends Article 23 does not prohibit any "determination".

4.214 The European Communities considers that, by refusing to initiate a compliance proceeding in this situation, the United States is in breach of Article 21.5. Contrary to what the United States purports, there exists a "disagreement" between the European Communities and the United States. The term "disagreement" is defined as "a refusal to accord or agree, difference of opinion, quarrel". The US attitude towards the EC compliance measure cannot escape this basic definition in the light of its statements and the continuation of sanctions. There is no contradiction between Articles 21.5 and 23. Article 23 does not apply to any sort of "disagreement' but only in case of a "determination" of a violation which a Member is "seeking to redress". This is exactly what the United States is currently doing. In any event Article 23 contains an explicit reference to dispute settlement proceedings, which includes Article 21.5 of the DSU. Thus, had the United States invoked a procedure under Article 21.5 of the DSU, it would have fully satisfied Article 23.2(a) of the DSU.

4.215 Finally, it is appropriate to read into Article 21.5 a reasonable timeframe until which a retaliating Member can be expected to decide whether an implementing member is WTO consistent and whether to launch a compliance proceeding. This is not to be confused with a "deadline" as the United States asserts. According to Article 3.3, disputes should be settled "promptly". Also, every treaty must be performed in good faith, according to Article 26 of the Vienna Convention. Moreover, Article 21.5 provides that a Panel has 90 days to determine whether an implementing measure is WTO-consistent. If a Panel can be asked to decide in 90 days whether there is compliance, it is not acceptable that a retaliating Member argues eight times as long that it cannot determine the consistency of the measure. This is even more relevant in a case like this one which involves the continued application of sanctions.

4.216 Regarding the US argument about alternative procedures other than Article 21.5 the US conceptual approach is not clear. In any case, Article 21.5 literally provides for a specific panel proceeding in case there is a disagreement about the WTO consistency of a compliance measure. This

is consistent with Article 3.3. Contrary to what the United States asserts, Article 21.5 is therefore not purely a matter of political opportunity in particular if at the same time it assumes the right to continue to sanction the implementing WTO Member. As explained in detail in its second written submission, the European Communities considers that the US examples in this respect demonstrate an extraordinary denial of any responsibility for the well-functioning of the dispute settlement system and the prompt settlement of disputes. This is also corroborated by the US reply to Questions 46 and 42 of the Panel where the United States first mischaracterizes the correct implementation in this case and, second, where the United States contradicts itself regarding its alleged interest for a quick resolution of the dispute. Finally, the special procedure under Article 21.5 is also not overridden by any alternative means such as good offices, conciliation, mediation or arbitration under Articles 5 and 25 which are neither enforceable nor legally binding.

4.217 Regarding the self-initiation of an Article 21.5 proceeding the European Communities demonstrated that also in the light of the *Bananas* case, the whole approach does not work and it would be inconsistent to the logic of the DSU as well as specific provisions such as Article 6 or 1.1.

(b) The United States' continued suspension of concessions and related obligations is in violation of Article 23.1, read together with Articles 22.8 and 3.7

4.218 The European Communities disagrees with the US assertion that the continued application of the sanctions is unrelated to the EC compliance measure. Since the original EC measure has been removed, the US argument would mean that the US is currently applying sanctions against a non-existing measure. Such a conclusion would not only be illogical it would also be in plain contradiction with the purpose of sanctions, namely to rebalance rights and obligations and to induce compliance in the light of a *current* WTO violation. As explained several times, it is obvious that the United States continues to apply the 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 new measure has never properly been found to be WTO-inconsistent.

4.219 Contrary to what the United States asserts the prohibition to continue the application of sanctions under Article 22.8 does not depend on whether the DSB authorization has been formally removed. Article 22.8 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. In addition, Article 22.8 subjects the application of sanctions to a measure which has been found inconsistent. Yet, this can only occur through a proper proceeding under WTO but not through a unilateral determination. Article 22.8 is also of self-executing nature and 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" automatically stop.

4.220 Finally, the European Communities does not agree with the US that the principle of good faith is not relevant for WTO proceedings in general or only relevant for the issue of burden of proof. This radical position is not supported by the general public international law, which also applies to the WTO, as for instance expressed in Article 26 of the Vienna Convention. In this context, the European Communities also considers that due to the specific circumstances for the adoption of its compliance measure as explained in detail in its various submissions and in the absence of a concrete challenge by the United States and in the light of the time that has passed since the measure was prepared and adopted, it is fully entitled to invoke the principle of good faith and the presumption of compliance.

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

4.221 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.

4.222 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.

4.223 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 authorised "over the counter", as is the situation in the United States.

4.224 Turning to the legal arguments, the European Communities disagrees with the US 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 the US 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 the United States, 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.

(a) Article 5.7 of the *SPS Agreement*

4.225 In respect of the provisional prohibition of the relevant hormones under Article 5.7 SPS the European Communities considers that the compliance measure fully respects the respective standard. As regards the "insufficiency" of the scientific evidence for conducting a risk assessment 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 *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.

4.226 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 results were published from the women's health Initiative Randomised Controlled Trial 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 the US and Codex/JECFA) that residues of these hormones in meat from animals treated for growth promotion pose no risk to human health.

4.227 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 factors 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.

4.228 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.

4.229 As regards progesterone, the US has not pointed to relevant evidence to rebut the SCVPH conclusions. The US instead merely relies on old JECFA conclusions which have been overtaken by

more recent studies in 2002. Equally erroneous is the US' reference to the CVMP's opinion which is irrelevant for the purposes of this dispute as it concerns an assessment of progesterone for zootechnical and therapeutic purposes. In any case, even the CVMP's assessment pointed out that only few recent data were available for re-evaluation of the carcinogenic and/or genotoxic properties of progesterone and had concluded that the compound (1) is not genotoxic in most of the tests performed and (2) increases tumor incidences in animals at exposure levels clearly above the physiological levels.

4.230 As regards testosterone, the US other than referring to the 1999 JECFA assessment, does not put forward any specific argument. However, the JECFA assessment had been addressed by the SCVPH in 1999. As pointed out above with regard to progesterone, the US' reference to the epidemiological studies on the effects of the hormones on post-menopausal women, in the context of an assessment of testosterone, is equally erroneous. Furthermore, as regards the US' comparison between bulls and steers and which have different endogenous testosterone levels very much depends on the age at slaughter, the breed used, and the type of husbandry employed in rearing these animals. The US argument is therefore at best irrelevant in deciding the central issues of the present dispute.

4.231 As regards trenbolone, the US does not put forward any specific argument as to why the evidence assessed by the SCVPH would not be insufficient. As a matter of fact, the only assessment on trenbolone publicly available is that of JECFA 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.

4.232 As regards zeranol, the US does not put forward any specific argument as to why the evidence assessed by the SCVPH 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.

4.233 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. The US 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. Moreover, the US referred to a draft 2005 report from the UK CVP in support of its arguments. However, even this draft report confirms the insufficiency of the currently available evidence.

4.234 Contrary to what the US asserts, the EC's compliance measure has been adopted on the basis of available pertinent information. In this context, the European Communities would reject the US assumption that a risk has to be demonstrated in order to justify a measure adopted on the basis of Article 5.7 of the *SPS Agreement*. The whole point of evidence being "insufficient" is that it does not allow the clear demonstration of a risk. If a risk can be demonstrated, it means that there is sufficient evidence to carry out a proper risk assessment. In its reply to the Panel Question 68 the European

Communities explained the difference between the objective or rational relationship between sufficient scientific evidence and a measure within the meaning of Article 5.1, on the one hand, and insufficient evidence and a measure within the meaning of Article 5.7, on the other. Under Article 5.1, an objective or rational relationship is required between the evidence and the measure. Under Article 5.7 a scientifically established doubt must be sufficient. As explained for each of the five hormones, the available pertinent information while being inconclusive in terms of demonstrating a risk, nevertheless points to the possible occurrence of certain adverse effects, which invalidate or put into serious doubts previously held assumptions about the safety of these hormones by the defending parties and Codex/JECFA.

4.235 Furthermore, in contrast to the US, the European Communities does see itself under an obligation, under Article 5.7 of the *SPS Agreement*, to seek additional information. It has specifically laid down that obligation in Directive 2003/74/EC and the European Communities 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.

4.236 Finally, the European Communities has not violated its obligation to review the provisional measure within a reasonable period of time as argued by the US. First, it is erroneous for the US to apply a review requirement to a measure before that measure has even come into existence. That shortcoming becomes even more apparent as it raises the question how the US explains what it is the European Communities has actually done between 1998 and 2003 if not to review the measure in question. In the view of the European Communities a requirement to review a measure "within a reasonable period of time" can only apply after the provisional measure has come into effect. In the light of the time it took to review the original measure (1998-2002) it can hardly be argued that a reasonable period of time has actually already elapsed. Furthermore, the only new information that has come to the knowledge of the European Communities until now is the recent draft assessment of the UK Group. That draft report has already been forwarded to European Food Safety Authority (EFSA) for review. Equally, should the recent call for new scientific information yield any new evidence, such evidence would also be assessed by EFSA without any undue delay.

(b) Article 5.1 of the *SPS Agreement*

4.237 The European Communities has based the permanent prohibition of oestradiol-17β on an appropriate risk assessment. The European Communities has already pointed out in its reply to Question 24 of the Panel, the difference between a scientific risk assessment in the narrow sense clearly referred to here by the United States 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 of the scientific bodies. Furthermore, the SCVPH has explicitly based its assessment on the three elements of hazard identification, hazard characterization and exposure assessment recommended and applied by the Codex. A few qualifications, however, apply. First, risk assessment criteria as they have been developed by the dispute settlement bodies are clearly more relevant to the application of the *SPS Agreement* than those developed by international scientific bodies. This follows naturally from the fact that it is the former's duty and privilege to interpret the provisions of the *SPS Agreement*. Second, there is no Codex standard specifically on the risk assessment of effects of residues of veterinary drugs. There only exists a general standard on microbiological assessment. Third, Codex techniques or standards exclusively apply to risk assessments on food safety and not to other risk assessments such as those for animal health and environmental risks. This is of relevance here insofar as the SCVPH Opinions also discuss environmental risks of the hormonal substances in question and some of the 17 EC studies have generated for the first time pioneering results in these areas.

4.238 Regarding the various steps of the risk assessment, the US does not criticize the hazard identification by the SCVPH but its hazard characterization because no or no adequate dose response assessment would have been carried out. However, the US' equation of hazard characterization and dose-response assessment is clearly erroneous. As defined by Codex, hazard characterization refers to the possibility of either a *quantitative* or a *qualitative* evaluation. While a dose-response assessment is a quantitative evaluation, a qualitative evaluation may equally be done, in particular in the absence of available data on dose-response. That is confirmed by the last sentence of the definition which recognises that data may not be available on biological or physical agents. More generally, it is confirmed by the Appellate Body which stressed that a risk assessment within the meaning of Article 5.1 does not necessarily require a quantitative evaluation. Moreover, it should be further clarified that it is generally recognised that for substances which have genotoxic potential (as is the case with oestradiol-17β) a threshold cannot be identified. Therefore it cannot be said that there exists a level below which intakes from residue should be considered to be safe. Therefore the fact the doses used in growth promotion are low is not of relevance. Thus, the argument of the United States that there is no hazard characterization is incorrect.

4.239 Regarding the exposure assessment, the US argument concerning pathway/residue analysis, no risks of abuse and low bioavailability do not demonstrate that the Opinions of the SCVPH fail to complete an exposure assessment as defined by Codex. Moreover, what the US does also not explain is that its own responsible health authorities have, for the first time since 2002, declared that oestradiol-17β is proven to be a human carcinogen and it is now listed as such, since 2002, in the USA Annual Report on Carcinogens.

4.240 The European Communities' ban on oestradiol-17β is also based on a risk assessment. Contrary to what the United States asserts, the SCVPH's assessment supports the ban on oestradiol-17β, but more recent research as referred to in detail in the EC second written submission equally confirms that that measure is warranted.

(c) Article 3.3 of the *SPS Agreement*

4.241 The US argues that a violation of Article 3.3 exists because the ban would not be in conformity with Article 5.1 of the *SPS Agreement*. The European Communities does not contest that the ban on oestradiol-17β is not based on international standards. The only relevant standard is the Codex recommendation on MRLs for oestradiol-17β. The European Communities, however, has decided not to set MRLs as recommended by Codex, but instead to prohibit the use of oestradiol-17β for growth promotion purposes altogether. That decision is based on a comprehensive risk assessment which, as has been demonstrated above is in full conformity with Article 5.1 of the *SPS Agreement*.

H. SECOND WRITTEN SUBMISSION OF THE UNITED STATES

1. Introduction

4.242 The United States maintains the measures at issue in this dispute in accordance with express authority from the Dispute Settlement Body. At this point in this dispute, it is clear that the European Communities has not, and cannot, demonstrate that these measures breach US obligations under the DSU or the GATT 1994, nor has nor can the EC demonstrate that other so-called "measures" that it challenges in fact existed as of the time this Panel was established.

4.243 As the United States has already pointed out, the EC's arguments relating to its DSU claims underscore its inability to meet its burden in this dispute, that is, to demonstrate that it has satisfied the Article 22.8 condition of removing the WTO-inconsistencies of its measures or providing a solution to US nullification or impairment. Moreover, for the reasons already set forth in previous submissions and discussed further below, the EC's arguments that various DSU provisions can create obligations

"in conjunction with" each other cannot change the fact that whether a provision is read on its own or "in conjunction with" another provision does not alter the substance of the provision. Nor can unilateral declarations by a Member concerned create a "presumption of good faith."

4.244 The United States has not breached Article 23 of the DSU. The United States was authorized to suspend concessions by the DSB, and the EC's declaration of compliance did not cause this authorization to lapse, to be revoked or to be suspended. The EC's declaration did not mean that the United States could no longer apply the suspension of concessions without breaching its obligations under the DSU. Nor did the EC's declaration and development of a "new" measure create a scenario whereby US application of the suspension of concessions could be considered a "determination" as to the WTO-consistency or inconsistency of the amended ban.

4.245 Regarding the EC's purported demonstration of how it has come into compliance, the EC merely asserted in its first submission that it had come into compliance. Notwithstanding the EC's failure to even undertake the required demonstration, the United States responded in its first written submission by explaining in detail that the EC's import bans, despite DSB recommendations and rulings, continue not to be based on a risk assessment within the meaning of Article 5.1 of the *SPS Agreement*. Neither are they legitimate "provisional" bans within the meaning of Article 5.7 of the *SPS Agreement*. The materials put forward by the EC in its replies to questions from the Panel do little to change these conclusions. In fact, in several of its replies, the EC appears to have completely shifted its focus from theoretical risks posed by the six hormones themselves to a perceived "risk" of failure to satisfy good veterinary practices in administering the hormones to cattle in the United States.

2. Legal arguments

(a) The EC has failed to demonstrate a US breach of DSU Articles 21.5, 22.8 or 23

4.246 The EC has failed to demonstrate that the United States has breached its obligations under Article 21.5 of the DSU. In fact, the EC has failed to link US action or inaction to any obligation contained in Article 21.5's text whatsoever. Instead, it claims that the United States has breached Article 21.5 by acting in contravention of Article 23 of the DSU. The United States has not acted in breach of Article 23, and therefore, even under the EC's theory, the United States can not have breached any obligations under Article 21.5 of the DSU.

4.247 Rather than pointing the Panel to a particular obligation in Article 21.5 of the DSU that it alleges the United States breached, the EC instead persists in its argument that a violation of Article 21.5 can only be found "in conjunction with" or when that Article is "read together" with DSU Article 23. In support of this claim, the EC notes that "there is nothing unusual to cite various provisions to substantiate a claim. This follows actually the same approach the Panel took in the dispute *US - Certain Measures*."

4.248 The EC is simply wrong about the approach that the Panel took, however. When the Appellate Body examined the findings to which the EC is referring, the Appellate Body pointed out that "[o]ur reading of the Panel Report does not lead us to conclude that the Panel based its finding of the inconsistency of the 3 March Measure with Article 21.5 on its conclusion that the measure was inconsistent with Article 23.2(a) ... The Panel's *references to Article 23.2(a) cannot be construed as the basis upon which the Panel reached its conclusions under Article 21.5*."

4.249 As the United States has demonstrated, nowhere in Article 21.5 of the DSU is there an obligation for the United States to have sought recourse to an Article 21.5 compliance panel, and only such a panel, upon hearing the EC's declaration of compliance. Nor does Article 21.5 contain any time limitation or deadline by which a Member must initiate dispute settlement proceedings. Indeed,

the EC does not claim that such obligations can be found in the text of Article 21.5. Yet, it seeks a specific finding of a US breach of Article 21.5 just the same. Taking into account the Appellate Body's guidance in *India – Patent* and *US – Shrimp*, the EC's theory in this dispute (*i.e.*, a violation of Article 21.5 read "in conjunction with" Article 23) has no textual basis and must therefore be rejected. Any analysis of whether US actions have breached Article 21.5 of the DSU must be based on the text of that provision.

4.250 In addition to its attempt to impute obligations into the text of Article 21.5, the EC provides other non-textual arguments in support of its claim of a US Article 21.5 breach. Primary among these is the EC's reference to a presumption or principle of good faith. The EC considers that referring to such a presumption justifies imputing into Article 21.5 an unspecified and unwritten obligation that "[a] retaliating Member has at a minimum a *good faith obligation* to assess within a reasonable delay the compliance measure". As noted above, the key to interpretation of the DSU, and Members' obligations under its provisions, lies in the actual text of the provisions. The text of Article 21.5 does not contain a time limitation, let alone what would amount to a case-by-case-determined "reasonable time period". Neither does it contain an obligation that, in the post-suspension setting, the suspending Member initiate dispute settlement proceedings upon a declaration of compliance by the Member concerned. "Good faith" applies to implementing the obligations that are agreed upon by Members, evidenced in the text; "good faith" cannot serve to create new obligations that were never agreed by Members.

4.251 Similarly, the EC has failed to make a prima facie case of a US violation of Article 22.8 of the DSU. Rather than presenting any evidence of how it has satisfied the conditions of Article 22.8 (removal of WTO-inconsistent measure; provision of solution to nullification or impairment of benefits; mutually satisfactory solution), it posits its claim "in conjunction with" Article 23 and asserts that the "presumption of good faith" or compliance satisfies its burden of proof. Even were one to presume that the EC implemented its amended bans in good faith, this fact would not in turn demonstrate that the EC's bans actually satisfy the elements of Article 22.8, *e.g.*, the EC could be acting in good faith, but still be wrong about the WTO-consistency or compliance of its amended measure.

4.252 The United States notes that the EC's interpretation of Article 23, and specifically Article 23.2(a), is complicated by a lack of clarity regarding when, exactly, a determination on the part of the suspending Member would be inferred. Regardless of whether this fictional deadline is a "reasonable period" or immediate, the EC's interpretation establishing such a deadline is not sustainable. Not only would it beg litigation to determine on a case-by-case basis whether a Member has unreasonably delayed in making a determination, it would convert Article 23.2(a) from a prohibition on making determinations into an obligation to make them – ironically, a Member would in effect be required to make a determination upon learning of another Member's declaration of compliance, and to do so within some unspecified time frame.

4.253 Furthermore, as the United States has noted on several occasions, the United States was in the course of reviewing the EC's materials at the outset of this dispute. In light of this fact, it is difficult to comprehend how the United States could have made a "determination" as to the WTO-consistency of the EC's amended bans. A critical element of this US evaluation is the review of the studies and Opinions ostensibly underpinning the EC's bans. Specifically, the EC refers to a number of studies which it commissioned after the Appellate Body proceedings in the *EC – Hormones* dispute, referring to them as the "17 Studies". The EC invokes these studies throughout its 2000 Review and 2002 Opinion, and a review of their methodology and results are therefore critical to an analysis of the EC's measure. However, as noted at the first substantive meeting with the Panel, the United States has not had the opportunity to review all of these documents, and referred to this fact in explaining why it had not yet been able to reach a determination of the EC's Opinions or its bans. Indeed, the EC has only recently informed us of a number of studies – which it contends comprise the basis for its claim of

compliance with the DSB's recommendations and rulings – that were not referenced in the EC's response to the US request for information under Article 5.8 of the *SPS Agreement*, through which the United States sought all relevant scientific information on which the EC premised its bans.

4.254 Because the EC has failed to demonstrate a US breach of its obligations under the DSU, there can be no "in conjunction with" breach of the objectives set out in Article 3.7 of the DSU, even were such a claim possible.

4.255 Because the United States has not breached its obligations under the DSU and continues to suspend concessions pursuant to DSB authorization, there can be no US breach of Articles I or II of the GATT 1994. Any finding of a breach of these provisions would be premised on a finding that the United States did not have authorization to suspend concessions to the EC.

(b) The EC has neither removed its WTO-inconsistent bans nor provided a solution to US nullification or impairment within the meaning of Article 22.8 of the DSU

4.256 A determination of whether or not the EC has complied with the DSB's recommendations and rulings in the *EC – Hormones* dispute is central to an analysis of whether or not it has satisfied the conditions of Article 22.8 by either removing its WTO-inconsistent measure or providing a solution to US nullification or impairment. The EC has failed to make its prima facie case of a US breach of Article 22.8 of the DSU because it has not demonstrated, other than by simple assertions that it deems its own measure to satisfy DSB recommendations and rulings, how its import bans are now WTO-consistent.

(i) The EC has failed to demonstrate that its import ban is a provisional measure within the meaning of SPS Article 5.7

4.257 Despite several opportunities to present evidence as to why its ban on five of the hormones (testosterone, progesterone, trenbolone acetate, zeranol and MGA) is a legitimate provisional measure, the EC fails to demonstrate how its ban on meat and meat products from cattle treated with these five hormones in fact satisfies the criteria of Article 5.7 of the *SPS Agreement*. Because the EC's ban fails to meet the requirements of Article 5.7, the EC is therefore not exempt from satisfying its obligations under Article 2.2 (measures not to be maintained without sufficient scientific evidence) and Article 5.1 (measures to be based on a risk assessment) of the *SPS Agreement*.

4.258 The simple fact regarding the five hormones at issue is that international standards and a significant body of scientific studies exist on the risks posed by each hormone. The Joint FAO/WHO Expert Committee on Food Additives ("JECFA") and several national regulatory bodies have determined that the scientific evidence regarding these hormones is adequate or sufficient to conduct a risk assessment. The EC alone alleges that this body of information is not "sufficient" to conduct a risk assessment, as required by Article 5.1 of the *SPS Agreement*, and the EC has only taken this position after firmly stating to the WTO several times that the information is sufficient and only after the WTO finding that the EC had breached its SPS obligations. In so doing, however, the EC does little more than assert that this is the case, failing to cite to any scientific evidence demonstrating risks to consumers from the five hormones when used for growth promotion purposes in meat according to good veterinary practices. Indeed, our review of the available materials comprising the 17 Studies has failed to uncover any new evidence of risk from the five provisionally banned hormones, further casting doubt on the EC's conclusion that evidence relating to these hormones is now somehow insufficient.

4.259 In the case of the five hormones "provisionally" banned by the EC, there is no "pertinent information" upon which the EC's import ban can be based because none of the information presented by the EC in its Opinions suggests that meat and meat products from cattle treated with the five

hormones for growth promotion purposes according to good veterinary practice pose a risk to consumers. The EC does not consider information pertaining to the specific risk in question (*i.e.*, that to consumers ingesting hormones in meat from cattle treated according to good veterinary practices), including relevant international standards for the five hormones and their underpinning studies, which indicates that hormone residues in such meat are safe. Instead, the EC restricts its consideration to general information or evidence on the hormones – evidence that was considered by Codex and JECFA in determining that the hormones do not pose a risk to consumers.

4.260 Finally, the EC has failed to demonstrate that it has reviewed its ban within a reasonable period of time. As noted by the Appellate Body, the "reasonable period of time" is not a fixed period, but rather reflects circumstances on a case-by-case basis. Furthermore, in determining whether a reasonable time has elapsed, one of the factors that should be taken into account is the "difficulty of obtaining the additional information necessary for the review and the characteristics of the provisional SPS measure." In the case of the five hormones banned by the EC, as noted above, there is already a substantial body of evidence available for completing a risk assessment, contradicting the suggestion that any "additional information" whatsoever might be required to review the amended ban. In addition, the "provisional" ban simply prolongs the original ban, marking over fifteen years that the import ban, the most trade-restrictive measure possible, has been in place. Taking into account the severity of the measure, and the ready availability of information on the five hormones, the EC has not reviewed its measure within a reasonable period of time within the meaning of Article 5.7.

(ii) The EC has failed to base its import ban on meat from cattle treated with oestradiol-17β for growth promotion purposes according to good veterinary practices on a risk assessment within the meaning of SPS Article 5.1

4.261 The EC has failed to base its import ban on meat from cattle treated with oestradiol-17β on a risk assessment within the meaning of SPS Article 5.1. Indeed, the EC's Opinions and underpinning studies fail to demonstrate a risk from residues in meat from cattle treated with oestradiol-17β for growth promotion purposes according to good veterinary practices. Instead, the studies on which the Opinions rely only succeed in demonstrating theoretical risks when the hormones are administered at doses or levels well-above those present in residues from hormone-treated meat; when good veterinary practices are not met; or in ways not germane to the relevant risk pathway.

4.262 The EC's assumption that oestradiol is genotoxic is essential to its overall conclusions regarding this hormone. Nevertheless, despite reaching the conclusion that oestradiol-17β is genotoxic in its Opinions, the EC does not in fact demonstrate through scientific evidence that this is the case. It fails to provide evidence demonstrating that oestradiol has carcinogenic effects other than through the receptor mediated, cell division stimulating activity of the hormone – in other words, at levels exerting a hormonal effect on consumers, and not at the exponentially smaller levels that would be found in meat residues. The fact that effects may be observed at exposure levels above the hormonal effect level or threshold is well established, and is one of the reasons that groups such as Codex set acceptable daily intakes ("ADIs") and maximum residue levels ("MRLs") at levels exponentially lower than this threshold.

4.263 The EC seeks support for its argument that oestradiol-17β is genotoxic in a JECFA conclusion that "oestradiol-17β has genotoxic potential", yet fails to cite to the rest of the relevant paragraph, in which JECFA notes, "[t]he Committee reviewed studies of the genotoxic potential of oestradiol-17β. Estradiol-17β *did not cause gene mutations in vitro*. In some other assays, sporadic but unconfirmed positive results were obtained." Furthermore, the EC's citation to the JECFA safety assessment ignores its ultimate conclusion, *i.e.*, that a maximum residue level for oestradiol-17β in meat need not be specified because there is a "wide margin of safety for consumption of residues in food when the drug is administered according to good practice in the use of veterinary drugs."

JECFA's conclusion corresponds to that of the EC's own Center for Veterinary Medicinal Products ("CVMP").

4.264 The EC's CVMP, upon review of the 1999 IARC monograph cited in the US Report on Carcinogens, as well as the scientific materials comprising the EC's 1999 Opinion, concluded that oestradiol-17β "belong[s] to the group of non-genotoxic carcinogens" and "exogenous exposure to hormones would need to be substantial (*i.e.*, in the order of post-menopausal therapy levels) before carcinogenic effects would be detectable in humans." These conclusions do not ignore the fact that, at physiological, hormonal-effect concentrations, there are carcinogenic risks from oestrogens. However, they do not support a theory that oestradiol-17β is either genotoxic, or will have carcinogenic effects, at concentrations present in meat from cattle treated with the hormone for growth promotion purposes according to good veterinary practices.

4.265 The severe limitations of the alleged "evidence" for genotoxicity of oestradiol-17β was also noted in the recent 2005 U.K. Report. In that Report, the Veterinary Products Committee ("VPC") concluded that only limited evidence was available to indicate that oestradiol-17β is capable of inducing gene mutations, and cautioned that even this "evidence" has been obtained using non-standard assays, some of which suffer from flawed experimental design.

4.266 The EC also asserts that the US argument that oestradiol-17β is generally inactive when given orally, while "well known", is "still controversial and not consensually accepted by the scientific community." To the contrary, oestradiol's low oral bioavailability has found international support in Codex and JECFA ("[i]n general, oestradiol-17β is inactive when given orally because it is inactivated in the gastrointestinal tract and liver"), as well as support within the EC from the CVMP, which noted that "the *bioavailability of 17β-oestradiol* esters after oral administration *is low (3% as unchanged oestradiol)*, but might be higher if estron, an oestrogenic metabolite, is included." The EC's assertion is also surprising in light of unpublished, EC-generated data which the EC only recently provided to the US which confirmed the internationally-accepted principle that bioavailability of oestradiol-17β is low in humans.

4.267 In an attempt to bolster its argument on the bioavailability of estradiol 17β, the EC cites to data it has developed on estrogen levels in young children. While it is unclear how this comparison relates in any way to a discussion on bioavailability, we can only assume that the EC makes this argument in an attempt to cast doubt on previously established standards for estradiol 17β and the other hormones at issue, *i.e.*, that the relevant standard setting groups were not taking into account populations identified as more sensitive than previously thought. The EC's argument fails for two fundamental reasons: (1) populations such as young children were indeed taken into account in establishing international standards and domestic requirements for the six hormones; and (2) the studies cited by the EC by which it attempts to cast such groups as even more susceptible than previously thought are flawed.

4.268 As to the first point, JECFA, in its safety assessment for the hormones, including oestradiol-17β, took into account data on most sensitive populations. The CVMP, in determining that oestradiol-17β is safe within certain concentrations also took into account data on prepubertal boys. As to the second point, the EC's own CVMP and the U.K. Group raised serious doubts relating to the methodology of the Klein assay, and determined that these concerns were sufficient to cast doubt on the conclusions drawn in the EC's Opinions.

4.269 The EC's Opinions also conclude that meat from cattle treated with oestrogens may accelerate the onset of puberty in children. The EC attempts to support this conclusion with a publication describing an outbreak of breast enlargement (gynecomastia) in school children in Milan in 1977. The study's authors state that oestrogenic contamination of meat served in the school canteen was the "suspected" cause of breast enlargement. However, the presence of oestrogen in meat consumed by

the students was never confirmed and a causal link between oestrogen in meat and gynecomastia was never demonstrated. Indeed, in a retrospective study conducted some twenty years later, the original study's author questions his own earlier conclusions and recognizes the likelihood that some other factor caused the early onset of puberty. The results of this unpublished, and previously unavailable study clearly demonstrate that the conclusion that hormones in meat are causative factors for early onset of puberty is unfounded.

4.270 In addition, the EC's Opinions ignore the scientific evidence relating to human *in vivo* DNA repair mechanisms, specifically that genotoxic effects of relevant residue levels of growth promoting hormones would not be expressed *in vivo* based in part on the existence of the efficient DNA repair mechanisms that exist in all mammalian cells. The efficacy of these repair mechanisms is exemplified in one of the unpublished reports recently provided by the EC. In this study, it was suggested that the lack of genotoxic effects of oestradiol-17β on human intestinal cells was due to a very efficient and rapid repair system. Despite these relevant findings, however, the EC's Opinions completely ignore the influence of endogenous DNA repair mechanisms, and instead attempt to implicate genotoxicity as a basis for the purported human health risk associated with oestradiol-17β residues in meat and meat products at any concentration.

(iii) The EC fails to demonstrate that there is a risk of failure of controls or failure to satisfy good veterinary practices

4.271 The EC's replies to the Panel's questions were enlightening regarding what, exactly, is the perceived "risk" against which the EC has imposed its import bans on US meat and meat products. From the outset, the United States has argued that the scientific evidence, and the EC's Opinions and 17 Studies, do not demonstrate a risk from the six growth promoting hormones when used for growth promotion purposes according to good veterinary practices. Our focus on this specific risk and exposure pathway seemed obvious because this is the legally permitted use of growth promoting hormones in the United States. This focus also seemed obvious since, if a WTO Member were concerned about a failure of controls, or a failure to satisfy good veterinary practices, there are countless less trade restrictive methods for mitigating against this perceived risk than an absolute ban on another Member's goods, and Article 5.6 of the *SPS Agreement* requires Members to ensure that their SPS measures are not more trade-restrictive than required. Furthermore, a logical extension of the EC's argument is that since the EC cannot be confident its own controls will never fail (indeed, as discussed below, there is evidence that these controls have failed), the EC should ban all EC meat and meat products. Nevertheless, the EC's replies consistently invoke the "risk" of a failure to satisfy good veterinary practices. Indeed, it is as a result of this additional perceived "risk" that the EC appears to discount the conclusions reached in previous JECFA risk assessments and set out in Codex standards as MRLs and ADIs.

4.272 In its replies to the Panel's questions, the EC frequently cites to the processes of "risk analysis" and "risk management", neither of which are explicitly referred to in the text of the *SPS Agreement*. This is not to say that concepts such as "risk management" and "risk analysis" find no expression in the *SPS Agreement* whatsoever. Rather, they may be found in, *e.g.*, Article 5.2 of the *SPS Agreement*. Whether or not the EC engaged in a proper evaluation of the factors set out in SPS Article 5.2 would inform a decision on whether or not they have indeed properly assessed the risk of failure to satisfy good veterinary practices within the meaning of Article 5.1 and Annex A of the *SPS Agreement*. As discussed below, the EC has not engaged in the necessary evaluation of these factors as required by Articles 5.1, 5.2 and Annex A of the *SPS Agreement*.

4.273 The United States has rigorous controls in place, which include the establishment of tolerances (maximum allowable levels) for hormone residues in food by the Food and Drug Administration, and USDA/Food Safety and Inspection Service ("FSIS") enforcement of these tolerances through (1) residue control programs; and (2) ante mortem, post mortem, and processing

inspection, to which all cattle entering the human food supply are subjected. This system provides extremely efficient safeguards against a hypothetical failure of controls in the United States, while at the same time being significantly less trade restrictive than an outright ban on US meat and meat products. A review of these relevant factors in its Opinions would have assisted the EC in making its ultimate determination of whether a ban on US meat and meat products is "not maintained without sufficient scientific evidence" and is not "significantly more trade restrictive than required to achieve the appropriate level of sanitary or phytosanitary protection" as required by the *SPS Agreement*.

4.274 Instead, the EC's Opinions focus on several hypothetical "failure of control" scenarios that ignore actual regulatory processes in the United States, and for which it presents no support. It asserts that these scenarios "clearly identify a risk for excessive exposure of consumers to residues from misplaced or off-label used implants and incorrect dose regimes." Yet, the EC fails to produce any evidence identifying a real risk of failure of controls or failure to satisfy good veterinary practices in the United States.

4.275 The EC's 1999 Opinion alleges that "from 6% to 30% of the original dose [of a hormone implant] remained in the ears from 65 to 150 days after implantation ... These data indicate that consumption of tissue from implantation sites would result in substantial exposure." This hypothetical assumes that ears containing implants will enter the human food chain, but provides no evidence in support of this scenario. Contrary to the EC's assumption, very clear instructions are provided on manufacturers' labels on all FDA-approved growth promoting implants, indicating that implants must be placed beneath the skin of the middle third of ears of cattle. Because ears are then discarded at slaughter, excess dietary exposure to hormone residues via consumption of implant sites does not occur. USDA inspectors confirm through ante- and post-mortem inspections that ears are discarded and that no hypothetical misplaced implants enter the human food chain. Therefore, the EC's conclusion that cattle ears containing hormone implants will enter the human food chain is unsupported by relevant scientific evidence and real world conditions.

4.276 The EC's Opinions also contemplate a scenario whereby growth promoting hormone implants are placed in parts of cattle other than the ear. In support of its claim that this is a realistic scenario, the EC asserts that "correct implantation can neither be guaranteed nor expected." However, the EC provides no evidence in support of this claim. In the real world, the likelihood that a US beef producer would intentionally misplace hormone implants in muscle is negligible given the economic and enforcement considerations at stake. First, the implants are specifically designed to achieve maximum effect when inserted into the animal's ear. There is therefore no economic benefit for injecting cattle in other parts of the body. Second, misplaced implants would ruin surrounding muscle tissue, thereby decreasing the value of the carcass. Third, discovery of any intramuscular (non-ear) implants at slaughter by a federal inspector would cause the entire carcass to be condemned, resulting in not only zero profit, but significant economic loss to the producer.

4.277 In another portion of the failure of controls discussion, the EC's Opinions allege that overdosing cattle with hormone implants is commonplace in the United States. The EC fails to provide evidence to support its conclusion that off-label use actually occurs in the United States. The EC Opinion cites to one publication from which it extrapolates its conclusion that off-label use of hormones occurs, but it appears to misinterpret the data and information provided in that document. Furthermore, there is no economic incentive for the off-label implant use alleged by the EC; to the contrary, such use would have negative economic effects on cattle producers. Therefore, the Opinions' conclusion that off-label use of hormone implants occurs in cattle for export to the EC in the United States is unsupported by available scientific evidence and real world conditions. Indeed, the conclusion that multiple implanting poses a hypothetical health risk to consumers appears to ignore the findings of some of the very laboratory studies commissioned by the EC ostensibly in support of its claim that multiple implanting actually occurs and poses a risk to consumers in the real

world. Accordingly, the EC fails to take into account available scientific evidence related to this "risk" within the meaning of SPS Article 5.2.

4.278 The EC's Opinions also cite to the existence of "black market" drugs, other non-authorized pharmaceutical formulations, or hormone "cocktails" as contributing to the risk of a failure of controls. However, the EC again provides no evidence of such a black market actually existing in the United States. Indeed, the analysis set out in the EC's Opinions ignores available evidence relating to black markets, as well as relevant processes and production methods and relevant inspection, sampling and testing methods as they exist in the United States. Available materials focusing on the black market use of growth promoting hormones only discuss evidence of such a market for their use within the EC (and thus would indicate that the EC, under its own approach in this dispute, should ban the sale of EC meat and meat products). EC inspection missions appear to confirm this fact. The presence of this market emphasizes that a total ban is not necessarily the most effective (and certainly not the least trade restrictive) means of preventing a theoretical failure of good veterinary practices. The *Hormones* panel reiterated this concern, noting that "the banning of a substance does not necessarily offer better protection of human health than other means of regulating its use."

3. Conclusion

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

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

4.280 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.

4.281 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.

4.282 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.

4.283 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.

4.284 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.

4.285 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).

4.286 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. Second, that the evidence put forward by the EC allegedly does not support the ban.

4.287 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.

4.288 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."

4.289 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.

4.290 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.

4.291 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).

4.292 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." Dr. Cogliano answered your question of whether this disagreement is arbitrary or unreasonable by stating "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."

4.293 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."

4.294 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).

4.295 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 17 β. 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.

4.296 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 became 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

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

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.

4.297 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" 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.

4.298 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.

4.299 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.

4.300 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.

---

[21] Ibid.

[22] Appellate Body Report,*EC – Hormones* at para. 245.

[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, *EC – Hormones*, para. 175.

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. Chairman, members of the Panel, would you 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?

4.301 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.

4.302 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*.

4.303 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 THE UNITED STATES ON EXPERTS OPINIONS DURING THE SECOND SUBSTANTIVE MEETING

4.304 The United States has repeatedly argued throughout these proceedings that the European Communities' ("EC") permanent ban on oestradiol-17β ("estradiol") is not based on a risk assessment within the meaning of Article 5.1 of the *Agreement on the Application of Sanitary and Phytosanitary Measures* ("*SPS Agreement*"). We have also argued that the EC's provisional bans on progesterone, testosterone, zeranol, trenbolone acetate ("TBA"), and melengestrol acetate ("MGA") do not satisfy the necessary conditions for a provisional measure within the meaning of Article 5.7 of the *SPS Agreement*. Indeed, the very conclusions underpinning the EC's decision-making are unsupported by the scientific evidence relating to these hormones. The experts' written responses and oral testimony support these US arguments.

4.305 At the outset of this meeting, it is essential to recall the purpose of last week's meetings and today's discussions. The World Trade Organization ("WTO") and this Panel are not being called upon to conduct a risk assessment for the EC. You have not been requested to provide or complete a *de novo* review of the numerous scientific materials relating to the six hormones at issue. The pertinent analysis, as discussed a moment ago, is what the EC has done. Not what the EC could have done, or may still do. Not what this Panel can do for the EC. To conduct an analysis of what the EC

has actually done, we may ask much less complex questions such as: has the EC presented scientific evidence of a risk from these hormones when consumed as residues in meat and assessed this risk in the proper fashion?

4.306 As I will highlight this morning, the experts' responses confirm that the EC has not based its ban on meat from cattle treated with oestradiol for growth promotion purposes on a risk assessment. It has not satisfied the four necessary steps for a risk assessment, and several of the conclusions set out in the EC's Opinions are not supported by scientific evidence. A measure banning meat from cattle treated with oestradiol cannot be "sufficiently warranted" or "reasonably supported" by this absence of a risk or assessment of the risk.

4.307 Likewise, the experts' responses confirm that there is sufficient scientific evidence to complete a risk assessment for each of the five "provisionally banned" hormones and that the EC has not based its provisional bans on available pertinent information. In other words, the EC's measures and "risk assessment" do not satisfy its obligations under the *SPS Agreement*.

4.308 I think that a brief discussion of the term zero risk provides a good starting point for today's discussions. It is an important principle and one to which the EC referred several times in the meeting with the experts. Indeed, the EC at several points asked the experts whether they could ensure that there was "zero risk" of a certain event occurring. The EC used this same tactic in its written comments on the experts' answers. For example, it demanded that Dr. Boobis "provide the necessary assurance" to the EC that residues in meat will never be shown to pose a risk to consumers. (*See*, *e.g.*, EC Comments on Question 20).

4.309 The analysis must refocus on the question of whether the EC has provided any evidence of a risk. The relevant discussion is one of whether the EC, in support of its ban, has adduced sufficient evidence to demonstrate a risk from meat from cattle treated with oestradiol for growth promotion purposes. Included in this discussion is an analysis of whether the EC has provided scientific evidence that oestradiol is genotoxic, mutagenic or carcinogenic (at levels found in residues in meat from treated cattle). Whether a scientist refuses to commit to a stance that there will never be a risk from meat treated with oestradiol at some point in the future is not pertinent to this analysis because it is not scientific evidence of a risk. It is simply theoretical uncertainty and cannot be the basis for a risk assessment or an SPS measure.

4.310 Regarding what, exactly, makes up a risk assessment, the experts and international organizations reiterated the four steps of risk assessment. In addition, the Codex representative stressed that a risk assessment must be based on all available data.

4.311 As to whether and when a risk assessment must satisfy each of the four steps, there was clear agreement among Drs. Boobis and Boisseau and JECFA that an evaluation of the human food safety of a drug should include all four steps of risk assessment. JECFA noted that a hazard identification does not qualify as a risk assessment and that the assessment should continue through each of the four steps unless there is "clear cut" evidence, both *in vitro* and *in vivo*, of genotoxicity. Dr. Boobis commented that the only instance in which such an assessment would stop at the hazard identification stage would be if the compound were identified as a DNA-reactive mutagen. Dr. Boisseau confirmed Dr. Boobis' opinion.

4.312 Recalling that, as we learned last week, genotoxicity and mutagenicity are not synonymous. Genotoxic substances damage DNA but the damage may be repaired. If the damage results in a mutation and the cell divides, then the substance is a "mutagen." As will be discussed in a moment, the experts did not identify any scientific evidence in the EC's Opinions that confirms, *in vivo*, the effects of oestradiol at levels below those causing a hormonal response, let alone any evidence that effects at that level are those of a DNA-reactive mutagen.

4.313 There are four steps for a risk assessment that have been clearly defined by the experts and the original *Hormones* panel. And the EC accepts that these four steps are required. As just mentioned, a risk assessment for oestradiol may not stop at the first step of hazard identification unless there is *in vivo*-confirmed evidence that oestradiol is either a genotoxin or a DNA-reactive mutagen. The EC has failed to present any evidence that oestradiol is genotoxic at levels below those eliciting a hormonal response, nor has it provided evidence that oestradiol is mutagenic at relevant levels *in vivo*. The EC was therefore not justified in failing to complete the three remaining steps.

4.314 The experts confirmed that the EC did not complete the remaining steps. Dr. Boobis noted, and Dr. Boisseau agreed, that the EC's Opinions are focused on the first step of risk assessment, hazard identification. As noted by JECFA, a hazard identification does not equal a risk assessment. An assessor must finish all four steps. Although he did not speak on this subject in last week's meetings, Dr. Guttenplan has described the EC materials as deserving at best a "mixed rating" in terms of the four steps of risk assessment(Question 14). He noted particular deficiencies in the hazard characterization and risk characterization sections (Questions 13 and 14).

4.315 Another avenue for finding that the EC has not completed a risk assessment for oestradiol is by determining that the conclusions set out in its assessment are not supported by scientific evidence. For example, the experts agree that the EC has not presented any scientific evidence that oestradiol is genotoxic *in vitro* or *in vivo* at physiological levels. The normal action of oestradiol on a cell is mediated through the oestrogen receptor. The genotoxic effects, which are abnormal, are not mediated through the estrogen receptor but instead involve direct damage to DNA. To date, concentrations of oestradiol required to cause genotoxic effects have been well above those required to elicit normal physiological effects.

4.316 As noted by Dr. Boobis, positive *in vitro* tests require positive *in vivo* confirmation, as toxicity is not always expressed *in vivo*. For Dr. Boobis, *in vivo* confirmation is critical because, among other things, it takes into account DNA repair mechanisms. He commented that he was "not persuaded" that oestradiol is genotoxic at levels below the normal hormonal concentrations present *in vivo*. In other words, that the genotoxicity has a threshold that requires overwhelming the DNA repair mechanisms – an event that will only occur at concentrations well beyond physiological levels.

4.317 The experts could not identify any studies providing evidence of the *in vivo* confirmation of genotoxicity of oestradiol at levels below those required to elicit a hormonal response. When put on the spot at last week's meetings with a new study produced by the EC in a last minute attempt to provide evidence of *in vivo* effects, Dr. Boobis quickly dismissed the study as irrelevant. The study's authors had treated the subject rats with so much oestradiol that the sheer level of the dose itself killed fifty percent of them, precluding any interpretation of oestradiol-specific effects.

4.318 Another example of an unsupported conclusion in the EC's Opinions is that oestradiol residues in meat from treated cattle are carcinogenic. The EC has failed to present any scientific evidence that oestradiol will have carcinogenic effects at levels found in residues in meat from treated cattle. Their failure to provide any evidence makes abundant sense. We consume oestradiol residues from numerous sources every day at levels much greater than those found in meat residues, whether from cattle treated for growth promotion or not. Milk, butter, eggs and, as noted by Dr. Boobis, a great number of phytoestrogens in plant products are all sources of oestrogen in our diets.

4.319 The EC has failed to support either of these major conclusions on genotoxicity or carcinogenicity with scientific evidence. The *SPS Agreement* does not permit the EC to do so. An assessment that fails to adduce scientific evidence in support of its underlying conclusions is not a risk assessment, as appropriate to the circumstances, under SPS Article 5.1.

4.320 There is a similarly uncomplicated analysis by which it can be determined that the EC's "provisional bans" do not satisfy the requirements of SPS Article 5.7. The first of Article 5.7's requirements for a provisional ban is that the evidence be insufficient to conduct a risk assessment. None of the experts believes that this is the case for testosterone, progesterone, zeranol, TBA or MGA.

4.321 Because the experts have confirmed that the evidence for each of the five hormones is sufficient to complete a risk assessment, discussion of the "provisional" bans may stop here in light of the cumulative nature of Article 5.7's requirements. The EC's ban is not a provisional measure for purposes of the *SPS Agreement*.

4.322 The second of Article 5.7's requirements is that a provisional measure be maintained on the basis of available pertinent information. The EC's "provisional" bans do not satisfy this requirement because there is no available pertinent information indicating that any of the five hormones poses a risk to consumers when used as a growth promoter in cattle.

4.323 The views of the experts are evidence of a lack of available pertinent information indicating that the five hormones pose a risk when consumed as residues in meat. Indeed, all available pertinent information indicates that consumption of these residues is safe. The EC has therefore not based its "provisional" bans on available pertinent information within the meaning of SPS Article 5.7.

4.324 In light of the experts' responses, it is clear that the EC has neither based its permanent ban on oestradiol on a risk assessment nor developed legitimate provisional bans. An analysis of these points would not entail the type of *de novo* review to which I alluded earlier. As noted, none of us are equipped for such a review and the *SPS Agreement* does not require or condone such a review.

4.325 While the Panel's analysis need not extend to this issue, I will now take a moment to discuss the EC's arguments relating to pre-pubertal children. The EC claims that oestradiol residues in meat from treated cattle pose a risk to this sub-population. However, the EC fails to provide scientific evidence of this risk.

4.326 In particular, the EC relies on an assay that, to date, remains unvalidated; the EC has failed to produce any scientific evidence demonstrating that JECFA's ADIs do not sufficiently protect children; and the EC has failed to complete the necessary steps of a risk assessment for this population.

4.327 This does not mean that the doubts and theoretical uncertainty on circulating oestradiol levels in pre-pubertal children identified in last week's meetings are unimportant. They are important. Indeed, JECFA reaffirmed that ensuring the safety of children is a "basic principle" of risk assessment and a fundamental focus of its work. As such, it is a safe guess that JECFA would be interested in any new evidence relating to this sub-population. As we have learned from the JECFA and Codex representatives, however, the EC has not shared any information with them. If the EC believes that the information it possesses has been properly validated and that the evidence is sound, then every Codex member around the world would benefit from its conclusions. The EC is not alone in its desire to protect the health of pre-pubertal children and other sensitive sub-populations.

4.328 Finally, we come to the issue of misuse of growth promoting hormones in the United States. I have left this subject for last because, quite frankly, it is unclear what role misuse plays in the EC's Opinions and arguments. The EC apparently considers potential misuse to be a risk, but has failed to provide any evidence or argument as to how it has actually assessed this risk. It provides no evaluation of the actual system of controls in place in the United States. We have described these controls at length in our previous submissions to the Panel. Dr. De Brabander claimed to have examined the US system of controls when he opined that the US system is nothing but "audits and paper work." However, he provided no analysis of the actual US system. Neither did the EC. In fact,

when asked in last week's meetings whether he was familiar with the US and Canadian meat safety systems, Dr. De Brabander noted that he was not a meat inspector and was not qualified to make judgments on these systems.

4.329 Even if one were to assume the unrealistic and hypothetical misuse scenarios developed by the EC, the EC has failed to present convincing evidence that misuse leads to violative residue levels.

4.330 Finally, the EC fails to assess the risk of misuse. While the experts did not have a chance to turn to this point last week, the necessary evidence of the EC's failure may be found in their written responses. (*See, e.g.,* the responses of Drs. Boobis and Boisseau to Question 48).

4.331 When you take a step back from the EC's Opinions, it becomes more and more clear that they are flawed in larger ways than the EC would like us to see or focus on. In light of its line of questioning to the experts last week, the EC apparently hopes to make this dispute one about getting lost in the weeds of several scientific dead-ends. The spectres of misuse, risks to sensitive populations and the unwillingness of the experts to commit to a position that there will never be evidence of a risk from any of these hormones in the future are examples of these scientifically unfounded pitfalls. We could go on *ad nauseam* in a debate as to whether science in these areas is evolving. As we know from our discussions with the experts last week, science is continually evolving. This evolution cannot be equated with evidence of a risk, however. We are not scientists, and an attempt to thrust ourselves into the debates on these issues would be nothing more than a misguided *de novo* review of the science by us, laypersons.

4.332 If we follow the paths laid out by the EC, we will lose sight of the larger problems of the EC's Opinions and the fundamental obligations and requirements against which they are to be measured – those set out in the *SPS Agreement*. When we view the EC's measures in this context – in which we have the necessary knowledge and can perform the necessary analysis – it is clear that there are several avenues by which we can conclude that the EC has not based its permanent ban on oestradiol on a risk assessment within the meaning of SPS Article 5.1, nor has it implemented a provisional ban on the other five hormones within the meaning of SPS Article 5.7. I have discussed these avenues and the appropriate conclusions that can be reached for each based on the scientific record in this dispute this morning.

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

1. Introduction

4.333 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*

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

4.335 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.

4.336 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.

4.337 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. Chairman, 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?

4.338 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:

4.339 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.

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

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

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

4.343 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);

4.344 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.

4.345 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).

4.346 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.

4.347 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, work and die.

4.348 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.

4.349 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.

4.350 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).

4.351 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.

4.352 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*

4.353 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.

4.354 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 of the *SPS Agreement* as a basis for the claims of US and Canada in this case.

4. Article 5.7 of the *SPS Agreement*

4.355 Similarly, the fact that JECFA could carry out risk assessments on the 5 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 paragraph 35 of its statement yesterday morning).

4.356 The United States 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*

4.357 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 of the *SPS Agreement* is relevant to this case because 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*

4.358 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

4.359 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 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.

4.360 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. The Panel has 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.

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

4.361 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.

4.362 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 respondents 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 responding parties have argued yesterday this is not a theoretical risk. No, the risk is real, however minimal it may be.

4.363 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 a 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.

4.364 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.

4.365 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.

4.366 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

4.367 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' and Canada's purpose but it is not objective.

4.368 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.

4.369 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.

4.370 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 's 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.

4.371 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.

4.372 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.

4.373 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 oestradiol 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.

4.374 Another example is the US' 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.

4.375 A third and last example is Canada's statement today 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.

4.376 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 oestradiol 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.

4.377 There is a bottom line which 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

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

4.379 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.

4.380 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.

4.381 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.

4.382 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.

4.383 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 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 of the EC compliance measure with the WTO obligations. 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.

4.384 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.

4.385 Let me explain this aspect in more detail.

4.386 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.

4.387 However, following the extensive discussion of the scientific issues, it is clear that this approach by the United States and Canada is no 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.

4.388 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.

4.389 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' and Canada's unilateral determination of the alleged inconsistency of the EC' compliance measure.

4.390 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.

4.391 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.

4.392 Let me also recall, that while the United States in its view struggled to come up with a "determination" as early as 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

4.393 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 THE UNITED STATES ON LEGAL ISSUES DURING THE SECOND SUBSTANTIVE MEETING

1. Oral statement

4.394 The United States considers that last week's meeting with the scientific experts reinforced a fundamental point – that the European Communities ("EC") has failed to demonstrate that the conditions of Article 22.8 of the WTO's *Understanding on Rules and Procedures Governing the*

Settlement of Disputes (the "DSU") for ending the Dispute Settlement Body ("DSB") - authorized suspension of concessions in the *Hormones* dispute have been met. To prevail on its claim that the United States has breached Article 22.8, the EC must demonstrate that it has either removed its WTO-inconsistent measures or provided a solution to the nullification or impairment suffered by the United States as a result of its ongoing bans on US meat and meat products. The EC has done neither.

4.395 The EC could have satisfied its burden by demonstrating that its "amended" ban brought it into conformity with its obligations under the WTO *Agreement on the Application of Sanitary and Phytosanitary Measures* ("*SPS Agreement*"). But it did not. The experts have provided valuable scientific and technical advice that confirms this fact. Their written and verbal responses demonstrate that the EC has failed to complete a risk assessment for oestradiol or base its ban on a risk assessment within the meaning of SPS Article 5.1.

4.396 Similarly, the experts' responses confirm that the EC has not imposed provisional bans within the meaning of SPS Article 5.7. Before discussing the EC's failure to bring its measures into conformity with the *SPS Agreement* and DSB recommendations and rulings, and thereby satisfy the conditions of DSU Article 22.8, however, I would like to briefly touch on the other DSU claims raised by the EC in the course of these proceedings.

4.397 The Panel will recall that the EC initially alleged that the United States was breaching its WTO obligations by failing to meet the requirements of several provisions of the DSU – namely Articles 21.5, 22.8, 3.7 and several provisions of Article 23 read "in conjunction" with each other. The United States has demonstrated that the EC's DSU claims are merely a reflection of how the EC would like to see the DSU rewritten rather than based in the actual text of the DSU as written and agreed to by WTO Members. As noted by the Appellate Body, "[d]etermining what the rules and procedures of the DSU ought to be is not our responsibility nor the responsibility of panels; it is clearly the responsibility solely of the Members of the WTO."

4.398 The EC alleges that its "provisional bans" on meat and meat products from cattle treated with the five other hormones (testosterone; progesterone; zeranol; trenbolone acetate; and melengestrol acetate) satisfy its obligations under SPS Article 5.7 and thereby bring it into conformity with the DSB recommendations and rulings that it must base its measures for these hormones on a risk assessment, as appropriate to the circumstances, within the meaning of Article 5.1 of the *SPS Agreement*.

4.399 Article 5.7 is a qualified exemption from Article 2.2 of the *SPS Agreement* which stipulates, among other things, that Members shall not maintain sanitary measures without sufficient scientific evidence "except as provided for in paragraph 7 of Article 5". In light of the fact that "Article 5.1 may be viewed as a specific application of the basic obligations contained in Article 2.2" and that "Articles 2.2 and 5.1 should constantly be read together," it is clear that Article 5.7 is also a temporary exception from a Member's obligation to base its measure on a risk assessment within the meaning of Article 5.1. In order to qualify for this exception, however, the EC must demonstrate that it has satisfied the four cumulative conditions of Article 5.7.

4.400 The experts' written and oral comments confirm that the EC has failed to do so and thereby failed to demonstrate that it has brought its measures into conformity with DSB recommendations and rulings. As a result, the EC has not removed the WTO-inconsistencies of its measures or provided a solution of the nullification or impairment suffered by the United States within the meaning of DSU Article 22.8.

4.401 For example, the EC's bans on the other five hormones are not imposed in a situation where relevant scientific information relating to the hormones is insufficient within the meaning of SPS Article 5.7. As demonstrated by the United States and confirmed by the written and oral responses of

the experts, there is more than sufficient scientific evidence to permit "performance of an adequate assessment of risks as required under Article 5.1" for the five hormones.

4.402 In addition, the EC's bans on the other five hormones are not based on available pertinent information within the meaning of SPS Article 5.7. Its bans cannot be based on available pertinent information, because none of that information suggests that meat and meat products from cattle treated with the five hormones for growth promotion purposes according to good veterinary practices pose a risk to consumers.

4.403 The EC alleges that its permanent ban on meat and meat products from cattle treated with oestradiol for growth promotion purposes is based on a risk assessment within the meaning of Article 5.1 of the *SPS Agreement*. In these proceedings we have examined what, exactly, constitutes a risk assessment for Article 5.1 purposes from several angles and have confirmed a few basic concepts regarding the necessary components of a risk assessment for oestradiol. A risk assessment must identify adverse effects from the consumption of meat from cattle treated with oestradiol and evaluate the potential occurrence of such effects, and it must engage in four fundamental steps: hazard identification; hazard characterization; exposure assessment; and risk characterization.

4.404 Rather than concluding that the EC's Opinions constitute a complete risk assessment, the experts' responses indicate that the EC has failed to progress beyond the first step of risk assessment, hazard identification. As noted by the United States, this stage of risk assessment addresses the simple question of what can possibly go wrong, not the likelihood of something going wrong.

4.405 The EC has also failed to base its permanent ban on meat and meat products from cattle treated with oestradiol for growth promotion purposes on a risk assessment, as appropriate to the circumstances, within the meaning of SPS Article 5.1. In order for the EC's measure to be "based" on a risk assessment, its assessment (the Opinions) must sufficiently warrant or reasonably support its measure, a ban on meat and meat products from cattle treated with oestradiol for growth promotion purposes. Yet, the EC's Opinions and their underlying studies simply identify theoretical risks from oestradiol generally rather than the specific risk ostensibly addressed by the EC's measure.

4.406 The materials relied on by the EC focus on potential adverse effects from exposure to oestradiol or estrogens generally rather than providing evidence of the specific risk from residues in meat from cattle treated with oestradiol for growth promotion purposes. In its most recent set of exhibits, the EC has failed yet again to provide evidence of the specific risk allegedly posed by residues in meat from treated cattle.

4.407 While the sort of scientific evidence of a general risk presented by the EC, of which the US *Report on Carcinogens* it has referred to is a good example, may be handy for completing the hazard identification (first) component of a risk assessment, it is not evidence of the specific risk against which the EC purports to mitigate with its bans.

4.408 A measure banning the import of meat treated with oestradiol for growth promotion purposes cannot be premised on the EC's failure to produce evidence of a risk from this product. This failure represents the very type of theoretical uncertainty that is "not the kind of risk which, under Article 5.1, is to be assessed." As a result, the EC's Opinions fail to sufficiently warrant or reasonably support its measure.

4.409 This point is highlighted by the fact that so many of the studies relied on by the EC in its Opinions do not actually support the conclusions it has drawn from them. For instance, as discussed yesterday morning, the EC's Opinions reach conclusions on the genotoxicity, carcinogenicity and mutagenicity of oestradiol that simply are unsupported by scientific evidence. The experts have confirmed this point. The experts looked at the materials put forward by the EC in its attempt to

produce evidence of the specific risk, yet have disagreed with the fundamental conclusions the EC draws from those materials. For example, the experts agreed that the scientific evidence did not support the conclusion that residue levels found in meat would be carcinogenic.

4.410 This is why, in yesterday's meeting, the United States made the point in the discussion of Appellate Body guidance from the original *Hormones* dispute that the Appellate Body's language on appropriate levels of protection was not necessarily relevant to the debate at hand. The point the United States made is that if there is no evidence of a risk from meat treated with oestradiol for growth promotion purposes, it does not matter what level of protection the EC has set for itself. Its level of protection could be zero risk, no additional risk, negligible risk, or some risk – if the product in question is safe, all of these levels of protection are satisfied and there is no need to parse distinctions between them. Despite this fact, if the Panel wishes to delve deeper into this Appellate Body discussion, the United States would note that the Appellate Body provided additional guidance on the matter of appropriate levels of protection and existence of distinctions in those levels in its Report in the *Australia – Salmon* dispute beginning at page 42.

4.411 For these reasons, those set out in the US submissions, and in light of the responses of the Panel's scientific experts, the EC has failed to conduct a risk assessment for oestradiol and has failed to base its permanent import ban on meat and meat products from cattle treated with oestradiol for growth promotion purposes on a risk assessment, as appropriate to the circumstances, within the meaning of Article 5.1 of the *SPS Agreement*.

4.412 Finally, by failing to base its permanent ban on meat from cattle treated with oestradiol on a risk assessment within the meaning of SPS Article 5.1 or to satisfy the conditions of SPS Article 5.7 for its provisional bans on meat from cattle treated with the other five hormones, the EC has not brought its measures into conformity with its obligations under SPS Article 3.3. As a consequence, the EC has again failed to satisfy the conditions of DSU Article 22.8 because it has not removed the WTO-inconsistencies of its measure.

4.413 The EC's measures are not based on international standards, and must therefore be premised on a "scientific justification" or maintained "as a consequence of the level of ... protection [the EC] determined to be appropriate in accordance with the relevant provisions of [Article 5 of the *SPS Agreement*]."[25] Because the EC's measures are neither based on a risk assessment nor satisfy the necessary conditions for a provisional ban as required by Article 5 of the *SPS Agreement*, they fail to satisfy its obligations under SPS Article 3.3.

4.414 In conclusion, the EC has failed to base its permanent ban on oestradiol on a risk assessment within the meaning of Article 5.1 of the *SPS Agreement* or to satisfy the conditions of SPS Article 5.7 with its provisional ban on the other five hormones. As a consequence, the EC also fails to satisfy its obligations under Article 3.3 of the *SPS Agreement*. The experts' responses and comments provide the necessary scientific underpinning for these conclusions, as well as the corresponding conclusion that the EC has not satisfied the conditions of DSU Article 22.8, the conditions by which the United States would have been obligated to cease to apply the suspension of concessions in the *Hormones* dispute to the EC.

4.415 For all the reasons discussed above and in its various submissions to the Panel, as well as the arguments raised by Canada in these proceedings, the United States respectfully requests the Panel to reject the EC's claims in their entirety.

[25] SPS Article 3.3.

2. Concluding statement by the United States

4.416 The United Stated considers that we have had a very productive debate over the last week-and-a-half. In the course of our discussions, which included meetings with the panel of scientific experts, a few central issues have come to light.

4.417 First, as I noted yesterday, the task at hand is not one of conducting a risk assessment for the European Communities. It is not one of conducting a review for the EC of the numerous materials it has put forward since completion of its Opinions. Rather, the relevant analysis is one of what the EC has actually accomplished in its Opinions.

4.418 Second, the Panel has consulted scientific experts to sift through the EC's Opinions and related materials in an attempt to determine whether any of these materials actually addressed the specific risk at issue in these proceedings – that from oestradiol residues in meat from animals treated with growth promoting hormones. The experts also looked at information put forward by the EC in support of its provisional bans on the other five hormones. The experts noted, as discussed in the US statement yesterday, that the EC had not completed the necessary steps of a risk assessment for oestradiol. Nor had the EC presented evidence that oestradiol residues in meat from treated cattle are carcinogenic. The United States described how these major conclusions factor into an analysis of the EC's permanent ban on oestradiol. They demonstrate that it is not based on risk assessment for purposes of SPS Article 5.1.

4.419 As to the other five hormones, the experts indicated that there was sufficient scientific evidence to conduct a risk assessment for each one and that the scientific evidence did not demonstrate a risk at levels found in residues in meat from treated cattle. This means that the EC failed to demonstrate that scientific evidence was insufficient to conduct a risk assessment for these hormones or that it had based its ban on available pertinent information. Therefore, the EC's bans do not satisfy the conditions of Article 5.7 of the *SPS Agreement*.

4.420 Third, the EC has claimed a US breach of Article 22.8 of the DSU. To demonstrate this breach, it must show that it has removed the WTO-inconsistencies of its measures or provided a solution to the nullification or impairment of benefits suffered by the United States. These conditions could theoretically be met if the EC's measures satisfy its obligations under the *SPS Agreement*. However, they do not. The experts' comments inform this analysis.

4.421 Fourth, and finally, the EC's various other DSU claims reflect the EC's hopes for how the DSU should be rewritten rather than finding a basis in the text of the DSU as it currently reads. Through a string of provisions read "in conjunction" with each other, it seeks very specific findings of specific provisions of the DSU. As the Appellate Body cautioned, "[d]etermining what the rules and procedures of the DSU ought to be is not our responsibility nor the responsibility of panels; it is clearly the responsibility solely of the Member of the WTO. Disregarding this guidance, the EC seeks to insert new obligations into the text of the DSU through the vehicle of dispute settlement. It may not do this. The EC, like the rest of the Membership of the WTO, is left with the text of the DSU as it reads today, and the EC has failed to demonstrate any US violation of the specific provisions of that text.

4.422 In closing, I would like to thank you for the professional manner in which you have conducted these proceedings. Thank you very much.

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.[26]

2. Opening Panel meetings for public observation

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.[27]

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.[28]

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 authorised 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.[29]

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.[30]

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 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

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

the complainant and undermines the presumption that Members act in good faith in taking action to comply with DSB recommendations and rulings.[31]

5.7 Australia further submits that this position is consistent with Appellate Body findings on the presumption of good faith in *Chile – Alcoholic Beverages*,[32] 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.[33] Australia also noted observations on good faith made by the Appellate Body in *US – Hot- Rolled Steel*[34]and *US – Line Pipe*.[35]

5.8 Australia thus points out that the fact that a complainant may have been granted temporary authorisation 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.[36]

5.9 Australia posits that the DSU is explicit on the following points, which provide context for the interpretation of Article 21.5:[37]

- 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 authorised 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.[38] 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 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

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

been nullified or impaired or that the attainment of any objective of the covered agreements has been impeded.[39]

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.[40]

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.[41]

2. Opening Panel meetings for public observation

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 public observation. 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.[42]

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.[43]

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.[44]

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

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

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.[45]

5.17 Brazil considers that 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.[46]

5.18 Brazil submits that only in the case of a multilateral determination confirming that the EC has fully complied could there be grounds for consideration of whether the United States is in breach of Articles 23, 21.5, 3.7 and 22.8 of the DSU and Articles I:1 and II of the GATT 1994, as claimed.[47]

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.[48]

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).[49]

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 referred to by the European Communities regarding the *US – Upland Cotton* dispute[50], and *Softwood Lumber*[51] 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. 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.[52]

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

[45] Third party submission of Brazil, paras. 5 and 6.
[46] Third party submission of Brazil, para. 8.
[47] Third party submission of Brazil, para. 9.
[48] Third party submission of Brazil, para. 20.
[49] Replies by Brazil to questions from the European Communities, question 3.
[50] *US –Upland Cotton*, WT/DS267/22.
[51] *US – Softwood Lumber VI*, WT/DS277/11.
[52] Third party submission of Brazil, paras. 22-24.

be revoked by a multilateral determination of compliance not by a unilateral declaration of implementation or a presumption of compliance.[53]

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.[54]

5.24 Brazil also argues that the European Communities professes that no Member shall be 'judged' except through multilateral judicial proceedings.[55] 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)*.[56]

5.25 Brazil argues that Article 21.5 of the DSU does not specify which Member is to initiate an 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.[57]

C. CANADA

1. Introduction

5.26 Canada submits that for the reasons set out in its first written submission in *Canada – Continued Suspension of Obligations in the EC – Hormones Dispute* (WT/DS321)[58], the continued suspension by the United States of concessions to the European Communities is fully consistent with the obligations of the United States under the Marrakesh Agreement Establishing the World Trade Organization. Consequently, Canada agrees with the United States that the claims of the European Communities have no basis in the DSU or GATT 1994.[59]

2. Opening Panel meetings for public observation

5.27 Canada submits that its views on this matter have been expressed in the relevant portion of the Panel's Report (Section IV.B.2) in *Canada – Continued Suspension of Obligations in the EC – Hormones Dispute* (WT/DS321). The arguments that Canada expressed in that dispute as the defendant equally apply to the present case as Canada's third party arguments.[60]

---

[53] Replies by Brazil to Panel questions, question 3.
[54] Third party submission of Brazil, paras. 10 and 11.
[55] See EC's first written submission, para. 1.
[56] Third party submission of Brazil, paras. 13 and 14.
[57] Replies by Brazil to Panel questions, questions 2 and 5.
[58] WT/DS321/06.
[59] Letter of 19 August 2005 to the Panel explaining Canada's third party submission.
[60] Letter of 30 June 2005 from Canada to the Panel.

D. CHINA

1. Introduction

5.28 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.[61]

2. Opening Panel meetings for public observation

5.29 China did not provide a reply on the potential legal constraint that would exclude the Panel from opening the Panel meeting for public observation. China however preferred the Panel to 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.[62]

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

5.30 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:[63]

(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.

5.31 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.[64]

5.32 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.[65]

5.33 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.[66]

---

[61] Third party submission of China, paras. 1 and 2.
[62] Replies by China to Panel questions concerning open hearings, questions 1 and 2.
[63] Third party submission of China, para. 6.
[64] Third party submission of China, paras. 7 and 8.
[65] Replies by China to Panel questions, question 7.
[66] Third party submission of China, para. 9.

5.34 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 the United States, 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.[67]

5.35 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 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.[68]

5.36 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.[69]

4. Article 21.5 of the DSU and burden of proof

5.37 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.[70]

5.38 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*[71] and *Canada – Aircraft (Article 21.5 – Brazil)*[72] 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

[67] Third party submission of China, para. 10.
[68] Third party submission of China, paras. 11 and 12.
[69] Replies by China to Panel questions, question 3.
[70] Third party submission of China, para. 15.
[71] Third party submission of China, para. 17.
[72] Third party submission of China, para. 18.

fulfilled the procedure obligation under the DSU, and should not be required to bear the burden of proof.[73]

5.39 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* [74], 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*[75] 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 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.[76]

5.40 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.[77]

5.41 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 onto the shoulders of the European Communities to establish compliance, which is against the nature and logic of the Article 21.5 proceeding.[78]

5.42 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 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 United States as an original complaining party should bear the burden to institute the Article 21.5 proceeding.[79]

5.43 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

---

[73] Third party submission of China, paras. 19 and 20.

[74] See Appellate Body Report, *Japan – Alcoholic Beverages II* (WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R) p. 13

[75] *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.

[76] Third party submission of China, paras. 21-24.

[77] Third party submission of China, para. 25.

[78] Third party submission of China, para. 26.

[79] Third party submission of China, paras. 27 and 28.

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.[80]

5.44 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.[81]

5.45 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 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.[82]

5. Article 23.2 of the DSU

5.46 China argues that to establish a violation of Article 23.2 (a), the Panel shall firstly assess whether the act of "determination" is made "in such cases", where a Member seeks the redress of a WTO violation.[83]

5.47 China analyses the different interpretations of the term "seek the redress of violation" in *US – Section 301 Trade Act,*[84] in *US – Certain EC Products*"[85] and in *European Communities – Measures Affecting Trade in Commercial Vessels,*[86] 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.[87]

5.48 China argues that after the European Communities provided notice of the Directive to the DSB in October 2003, the original complaining party raised doubt on the WTO consistency of this European Communities' implementation measure. Since then it 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.[88]

---

[80] Third party submission of China, para. 29.
[81] Third party submission of China, para. 31.
[82] Third party submission of China, para. 32.
[83] Third party submission of China, para. 35.
[84] See Panel Report, *US – Section 301 Trade Act*, para. 7.50, footnote 657.
[85] See Panel Report, *US – Certain EC Products,* paras. 6.22 and 6.23.
[86] See Panel Report, *EC – Commercial Vessels,* WT/DS301/R, para. 7.196
[87] Third party submission of China, paras. 36-39.
[88] Third party submission of China, para. 41.

5.49 With respect to the meaning of the term "determination", China refers to the panel in *US – Section 301 Trade Act*[89] 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 that it made such a determination.[90]

5.50 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; (2) sufficiency of information related to the compliance measure; and (3) the ability of the original complaining party to evaluate such new measure.[91]

E. INDIA

1. Introduction

5.51 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.[92]

2. Opening Panel meetings for public observation

5.52 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,[93] and its deliberations have to remain confidential[94] as provided in the DSU.[95]

5.53 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.[96]

5.54 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

[89] See Panel Report, *US – Section 301 Trade Act*, para. 7.50, footnote 657.
[90] Third party submission of China, paras. 41 and 42.
[91] Replies by China to Panel questions, question 1.
[92] Oral statement by India, para. 3.
[93] Paragraph 2 of the Working Procedures in Appendix 3 of the DSU
[94] Paragraph 3 of the Working Procedures in Appendix 3 of the DSU
[95] Replies by India to Panel questions concerning open hearings, question 1.
[96] Oral statement of India, para. 5.

flexibilities so as to ensure high-quality panel reports.[97] 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)*[98] *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.[99]

5.55 India argues that Article VII of the Rules of Conduct[100] requires each 'covered person' to maintain the confidentiality of dispute settlement deliberations and proceedings at all times. India questions how the Panel is going to ensure that these requirements are met after opening the proceedings to the public for observation.[101]

5.56 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.[102]

5.57 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.[103]

5.58 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.[104]

F. MEXICO

1. Introduction

5.59 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

[97] Article 12.2, DSU

[98] *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products – Complaint by the United States,* Panel Report, WT/DS50/R.

[99] Oral statement of India, para. 6.

[100] 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).

[101] Oral statement of India, para. 7.

[102] Oral statement of India, para. 8.

[103] Oral statement of India, para. 9.

[104] Replies by India to Panel questions concerning open hearings, question 2.

not only the letter of the DSU, but also the objectives of security, predictability and prompt settlement of the dispute.[105]

2. Opening Panel meetings for public observation

5.60 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, 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.[106]

5.61 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 will in all likelihood end up complicating the preparation of working procedures of future panels.[107]

5.62 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 to the public.[108] Mexico suggests that third party sessions follow the established WTO practice of being in closed session.[109]

3. Whether the DSB authorization remains in effect

5.63 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.[110]

5.64 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.[111]

5.65 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.[112]

---

[105] Replies by Mexico to Panel questions concerning open hearings, question 1, paras. 2, 3 and 9.
[106] Oral statement of Mexico, para. 2; Replies by Mexico to Panel questions, paras. 9 and 3.
[107] Oral statement of Mexico, para. 3.
[108] Replies by Mexico to Panel questions concerning open hearings, question 1, para. 7.
[109] Replies by Mexico to Panel questions concerning open hearings, question 2.
[110] Oral statement of Mexico, para. 5.
[111] Oral statement of Mexico, para. 4.
[112] Replies by Mexico to questions from the European Communities, question 4.

4. Article 21.5 of the DSU

5.66 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.[113]

G. NEW ZEALAND

1. Introduction

5.67 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 been commenced under Article 21.5. In New Zealand's view, the Panel's terms of reference[114] are sufficiently broad to encompass this question and in doing so, the Panel should focus on actual compliance and not presumed compliance.[115]

2. Opening Panel meetings for public observation

5.68 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.[116]

3. Whether the DSB authorization remains in effect

5.69 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 authorisation of suspension of concessions remains valid.[117]

---

[113] Oral statement of Mexico, para. 6.

[114] 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).

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

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

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

5.70 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.[118] 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 authorisation from the DSB to impose a retaliatory suspension of concessions.[119]

5.71 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 authorisation 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 given way to the actual compliance of the suspension of concessions which has been duly authorised by the DSB.[120]

4. Articles 21.5, 22.8 and 23 of the DSU

5.72 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.[121]

5.73 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 authorisation under Article 22.6, which has never been revoked.[122]

5.74 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 of the DSU.[123]

---

[118] 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.

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

[120] Third party submission of New Zealand, para. 2.12.

[121] Third party submission of New Zealand, para 2.14.

[122] Third party submission of New Zealand, paras. 2.14-2.16.

[123] Third party submission of New Zealand, para. 2.17.

5.75 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.[124]

5.76 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 authorisation and the absence of any agreement that the original respondent has brought its measures into compliance.[125]

5.77 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.[126]

5.78 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.[127]

5.79 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.[128]

5. Burden of proof

5.80 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*[129], 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 EC does not argue (b), and (c) is clearly not the case, but it instead relies on (a).[130]

5.81 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

[124] Third party submission of New Zealand, para. 2.18.
[125] Replies by New Zealand to questions from the European Communities, questions 4 and 5.
[126] Replies by New Zealand to questions from the European Communities, question 6.
[127] Replies by New Zealand to Panel questions, question 2.
[128] Replies by New Zealand to Panel questions, question 5.
[129] *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.
[130] Third party submission of New Zealand, paras. 2.21-2.22.

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.[131]

6. Article 5.7 of the *SPS Agreement*

5.82 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.[132] 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*[133], the European Communities must demonstrate that: (a) its measure was imposed in a situation where '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."[134]

5.83 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."[135] 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".[136] 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:[137]

> " '[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*."[138]

5.84 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

---

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

[132] 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.

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

[134] Third party submission of New Zealand, paras. 2.28 and 2.29.

[135] Appellate Body Report on *Japan – Agricultural Products II*, para. 89. Emphasis original.

[136] First written submission of the European Communities, para. 145.

[137] Third party submission of New Zealand, paras. 2.30-2.32.

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

European Communities previously maintained was based on sufficient scientific evidence to be definitive, is now held out as a merely 'provisional' measure.[139]

5.85 New Zealand submits that on the other hand, the respondent in its first written submissions shows that a considerable body of relevant scientific evidence exists as to the use of hormones for growth promotion purposes.[140] New Zealand argues that the United States points out that the hormones at issue have been "intensively studied over the last twenty-five years"[141] 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)".[142] 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.[143]

5.86 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 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.[144]

5.87 According to New Zealand, by contrast, the United States claims that a large body of 'available pertinent information'[145] indicates that proper use of the hormones in question poses no risk to consumers.[146]

5.88 New Zealand submits that under the third prong 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]."[147] 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.[148]

5.89 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

[139] Third party submission of New Zealand, para. 2.34.
[140] See US's first written submission, paras. 55-91.
[141] US's first written submission, para. 122.
[142] US's first written submission, para. 123.
[143] Third party submission of New Zealand, para. 2.35.
[144] Third party submission of New Zealand, para. 2.36.
[145] See US's first written submission at paras. 127-128.
[146] Third party submission of New Zealand, para. 2.37.
[147] EC's first written submission, para. 145.
[148] Third party submission of New Zealand, para. 2.38.

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 submission.[149]

7. Article 5.1 of the *SPS Agreement*

5.90 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[150] 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.[151]

5.91 New Zealand further argues that the panel in the *Japan – Apples* case summarized 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 took into account 'risk assessment techniques developed by the relevant international organizations'.[152] New Zealand posits that the panel in that case added that these two factors would "pervade the entire assessment of the risk".[153]

5.92 New Zealand stresses that while the European Communities claims to have conducted "a comprehensive risk assessment" since the Appellate Body decision in 1998[154], 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.[155] 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.[156]

5.93 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[157] 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.[158]

5.94 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

[149] Third party submission of New Zealand, paras. 2.38 and 2.39.
[150] Appellate Body Report on *EC – Hormones*, para. 187.
[151] Third party submission of New Zealand, paras. 2.42-2.44.
[152] Panel Report on *Japan – Apples*, para. 8.236.
[153] Panel Report on *Japan – Apples*, para. 8.237.
[154] EC's first written submission, para. 142.
[155] EC's first written submission, para. 142.
[156] Third party submission of New Zealand, para. 2.48.
[157] EC's first written submission, para. 144.
[158] Third party submission of New Zealand, para. 2.49.

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;[159] (b) evaluates the potential or possibility of occurrence of such adverse effects;[160] (c) is 'as appropriate to the circumstances';[161] (d) takes into account risk assessment techniques developed by the relevant international organisations;[162] and (e) takes into account the available scientific evidence as matters specified in Article 5.2 of the *SPS Agreement*.[163]

5.95 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.[164]

5.96 New Zealand contends that in contrast, the United States outlines some of the scientific evidence that exists on the use of growth-promoting hormones,[165] and evokes long-standing practice on the proper assessment of risks related to veterinary drug residues.[166] According to New Zealand, this casts doubt on both the process and the substance of the European Communities' risk assessment.[167]

5.97 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*,[168] and states that the term 'based on' required a certain objective relationship between the risk assessment and the measure in question.[169]

5.98 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.[170]

---

[159] *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.
[160] *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.
[161] *SPS Agreement*, Article 5.1.
[162] *SPS Agreement*, Article 5.1.
[163] Third party submission of New Zealand, para. 2.51.
[164] Third party submission of New Zealand, para. 2.52.
[165] See, for example, US's first written submission, paras. 55–91.
[166] US's first written submission, para. 136.
[167] Third party submission of New Zealand, para. 2.53.
[168] Appellate Body Report on *EC – Hormones*, para. 193.
[169] Third party submission of New Zealand, para. 2.55.
[170] Third party submission of New Zealand, para. 2.58.

H. NORWAY

1. Opening Panel meetings for observation by the public

5.99 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.[171]

2. Whether the DSB authorization remains in effect

5.100 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.[172]

5.101 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.[173]

5.102 Norway contends that the common concept in all 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.[174]

5.103 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.[175]

5.104 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.[176]

5.105 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

[171] Replies by Norway to Panel questions concerning open hearings, questions 1 and 2.
[172] Replies by Norway to questions from the European Communities, questions 3, 4 and 5, para. 2.
[173] Replies by Norway to questions from the European Communities, questions 3, 4 and 5, para. 3.
[174] Replies by Norway to questions from the European Communities, questions 3, 4 and 5, paras. 4 and 5.
[175] Replies by Norway to questions from the European Communities, questions 3, 4 and 5, para. 6.
[176] Replies by Norway to questions from the European Communities, questions 3, 4 and 5, para. 7.

adopted rulings and recommendations, then the obligation to refer a "compliance dispute" to a panel according to Article 21.5 is incumbent upon them.[177]

3. Article 21.5 of the DSU

5.106 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.[178]

5.107 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.[179]

5.108 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 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.[180]

5.109 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)*.[181] 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.[182] 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[183], and that the United States had submitted a request for retaliation that led to arbitration.[184] Norway submits that the panel in that

[177] Replies by Norway to Panel questions, question 5 para. 10.
[178] Replies by Norway to questions from the European Communities, questions 3, 4 and 5, para. 8.
[179] Replies by Norway to Panel questions, question 5, paras. 11 and 12.
[180] Joint reply by Norway to question 2 from the Panel and question 6 from the European Communities, para. 13.
[181] *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.
[182] Joint reply by Norway to question 2 from the Panel and question 6 from the European Communities, para. 14.
[183] *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.
[184] *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.

particular case could thus justify not making any recommendations or rulings by pointing to these other proceedings.[185]

5.110 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.[186]

5.111 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.[187]

5.112 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 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.[188] 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.[189]

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

1. Introduction

5.113 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 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.[190]

---

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

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

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

[188] Joint reply by Norway to question 2 from the Panel and question 6 from the European Communities, para. 18.

[189] Joint reply by Norway to question 2 from the Panel and question 6 from the European Communities, paras. 17 and 19.

[190] Third party submission of Chinese Taipei, para. 1.

2. Opening Panel meetings for public observation

5.114 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.[191]

5.115 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.[192]

5.116 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.[193]

5.117 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.[194]

5.118 Chinese Taipei is of the opinion that the third party sessions be in closed session.[195]

3. Whether the DSB authorization remains in effect

5.119 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.[196]

5.120 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

[191] Replies by Chinese Taipei to Panel questions concerning open hearings, question 1, paras. 1 and 2.
[192] Replies by Chinese Taipei to Panel questions concerning open hearings, question 1, paras. 4 and 5.
[193] Replies by Chinese Taipei to Panel questions concerning open hearings, question 1, para. 3.
[194] Replies by Chinese Taipei to Panel questions concerning open hearings, question 1, paras. 6 and 7.
[195] Replies by Chinese Taipei to Panel questions concerning open hearings, question 2, para. 12.
[196] Replies by Chinese Taipei to questions from the European Communities, question 1.

measure, the *status quo* would be considered as maintaining the existing balance of rights and obligations among WTO Members.[197]

5.121 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.[198]

5.122 Chinese Taipei rejects the view that the lack of action for any period of time on the part of the United States and Canada constitutes an expression of the US and Canada's determination. According to Chinese Taipei, the existence of the determination by the United States and Canada cannot depend on such an indeterminate criteria as the length of time it takes for the United States and Canada to take action under Article 21.5 of the DSU. Therefore, in its view, Article 22.8 of the DSU allows the United States and Canada to continue its suspension of concessions until one of the three conditions therein have been met.[199]

4. Article 21.5 of the DSU

5.123 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 the absence of the initiation by the United States of an Article 21.5 compliance panel, the European Communities' implementing measure must be presumed to be consistent with WTO rules and the continuation of the suspension of concessions by the United States would amount to a unilateral determination of a violation of WTO rules[200], 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.[201]

5.124 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 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.[202]

5.125 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. According to Chinese Taipei, 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.

---

[197] Replies by Chinese Taipei to questions from the European Communities, question 4.
[198] Replies by Chinese Taipei to questions from the European Communities, question 5.
[199] Replies by Chinese Taipei to Panel questions, question 1.
[200] EC's first written submission para. 61.
[201] Oral statement of Chinese Taipei, para. 2.
[202] Oral statement of Chinese Taipei, para. 3.

5.126 Chinese Taipei 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. In its view, 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.[203]

5. The relationship between DSU Article 22.8 and Article 23

5.127 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.[204]

5.128 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.[205] 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.[206]

5.129 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.[207]

5.130 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.[208]

5.131 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

[203] Oral statement of Chinese Taipei, para. 4.
[204] Third party submission of Chinese Taipei, paras. 2 and 7.
[205] EC's first written submission para. 87.
[206] Third party submission of Chinese Taipei, paras. 2-4.
[207] Third party submission of Chinese Taipei, para. 5.
[208] Third party submission of Chinese Taipei, para. 6.

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.[209]

5.132 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.[210]

5.133 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.[211]

5.134 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 a 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.[212]

5.135 Chinese Taipei thus argues that the suspension of concessions by the United States 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 the United States does not violate the existing provisions of the DSU.[213]

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 the United States separately requested an interim review by the Panel of certain aspects of the interim report issued to the Parties on 31 July 2007.[214] 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

[209] Third party submission of Chinese Taipei, para. 7.
[210] Third party submission of Chinese Taipei, para. 8.
[211] Third party submission of Chinese Taipei, para. 9.
[212] Third party submission of Chinese Taipei, para. 10.
[213] Third party submission of Chinese Taipei, para. 11.
[214] Letters of the parties dated 28 September 2007.

a request by the European Communities for the Panel to hold an additional meeting with the parties. Furthermore, the Panel notes that the United States 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.[215] These comments are discussed, where relevant, together with the requests 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 number of the comments 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;

(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 where 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 two instances, however, the Panel partly rejected the modifications requested by the European Communities and deems it appropriate to provide its reasons in this section.

6.8 The first 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

[215] Letters of the parties dated 19 October 2007.

comments of the third parties on logistical matters have been reported in the descriptive part. Thus, the European Communities requested 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.[216] 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 solutions finally selected, more particularly the broadcast of the hearings into a separate room through closed-circuit television, were adopted in accordance with the positions expressed by the parties.

6.12 The second instance where a request for modification of the descriptive part was at least partly rejected by the Panel relates to paragraph 4.234. In its second written submission to the Panel, the European Communities stated that, "[u]nder Article 5.1 of the *SPS Agreement*, a convincing link is required between the evidence and the measure. Under Article 5.7 a mere doubt must be sufficient."[217] In its comments on the descriptive part of the report and in its comments of 19 October 2007[218] in response to a request by the United States for review of a precise aspect of the interim report[219], the European Communities requested us to replace the term "convincing link" with "rational relationship", and to replace "mere doubt" with "reasonable doubt". We recall that in its reply to question 9 of the Panel, after the second substantive meeting, the European Communities had clarified that what it meant by "mere doubt" was "doubt that has been scientifically established". In light of that request, we replaced "mere" with "scientifically established". The Panel also notes that the EC reply to question 68 of the questions of the Panel after the first substantive meeting qualified the relationship addressed by Article 5.1 of the *SPS Agreement* as an "objective or rational relationship". As a result, the Panel replaced the term "convincing link" with "objective or rational relationship."

[216] 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 of the remit of this Panel.

[217] See EC's second written submission, para. 181, and second executive summary, para. 29 (emphasis added).

[218] EC's comments of 19 October 2007, para. 24.

[219] US's written request of 28 September 2007, p. 9.

C. PARTIES' COMMENTS REGARDING THE FINDINGS OF THE PANEL

1. Preliminary remarks

6.13 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."[220] (emphasis added)

6.14 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.

6.15 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 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.

6.16 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.

6.17 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*[221] 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

[220] EC's written request of 28 September 2007, para. 5.
[221] Panel Report on *Australia – Salmon*, para. 7.3.

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."

6.18 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 on 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

6.19 The European Communities considers the Panel's reference to Article 17.10 of the DSU in paragraph 7.50 of the interim report 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 the United States. 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.

6.20 The European Communities considers that the description of IARC contained in paragraph 7.78 footnote 378 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, as also pointed out by the United States in its comments on comments of 19 October 2007[222], 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.

6.21 The European Communities argues that the second sentence of paragraph 7.85 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 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 7.85 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.

6.22 The European Communities further requests us to redraft the fourth sentence of paragraph 7.85 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

[222] Para. 3.

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 notes that JECFA is the body that provides the independent scientific advice on which the work of Codex is based and Codex is expressly recognized by the *SPS Agreement* as having responsibilities for the establishment of "international standards, guidelines and recommendations". The Panel also recalls the role given to international standards, guidelines and recommendations by Article 3.1 and 3.2 of the *SPS Agreement*. It is therefore consistent with this role for the Panel to rely on experts who contributed in the preparation and drafting of JECFA's risk assessments of the substances at issue.

6.23 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 recalls that they have been selected by the FAO and WHO as part of the JECFA selection process. The selection procedure has been described in JECFA's reply to question 14 to JECFA.[223] The Panel fails to understand why the JECFA selection would not be evidence of the international reputation of the scientists at issue.[224] 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 not having carried out experiments with the substances at issue and does not see any need for further substantial elaboration. The Panel notes that the United States, in its comments of 19 October 2007, considered that any new objection on the experts by the European Communities would be untimely. The Panel has nevertheless deemed it necessary to make some clarifications, in response to the EC request, to paragraph 7.85.

6.24 The European Communities requests that we modify the first sentence of paragraph 7.87 to better reflect the content of its letter of 28 March 2006. We consider that the letter largely reiterated points which the Panel already addressed in paragraph 7.85 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 addressed by the Panel in paragraph 7.87. 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.

6.25 Having reviewed the EC comments on paragraph 7.89 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.

6.26 The European Communities argues that the statements in paragraph 7.123 and footnote 396 are not accurate as some of the subsequent evidence did expand and confirm the scientific basis of

[223] Annex E-2, pp. 115-116.

[224] See also Dr. Boobis, Annex G, para. 511; Dr. Tritscher, Annex G, para. 515; Dr. Wennberg, Annex G, para. 517.

Directive 2003/74/EC. The European Communities refers to the replies of Dr. Guttenplan and Dr. Sippell. The Panel also notes the US comments of 19 October 2007 on this request for review from the European Communities. In paragraph 7.123 and footnote 396, 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.[225] The statements of Dr. Guttenplan referred to by the European Communities[226] 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[227], 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 7.123 and footnote 396.

6.27 The European Communities also argues with respect to paragraph 7.124 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.[228] The Panel, having regard to the comments of the United States of 19 October 2007, 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.

6.28 The European Communities also considers with respect to paragraph 7.133 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 in its replies to the Panel questions posed after the 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.

6.29 The European Communities also alleges, with respect to paragraphs 7.135 *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,

[225] Annex C, pp. 5-7.
[226] Annex G, paras. 709 and 713.
[227] Annex D, para. 319.
[228] See EC's letter to the Panel dated 29 May 2006.

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[229], 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.

6.30 The European Communities also seems to request, with respect to paragraph 7.148 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"[230] or "defactual threshold" instead of "de facto threshold"[231]). 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 the United States

6.31 With respect to the discussion of the procedural question of the opening of the Panel meetings with parties and experts for public observation, the United States 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.

6.32 The United States also requests that we modify paragraphs 7.151 and 2.7. We see no reason not to adjust the description of the measure since it is actually the absence of recourse to the DSU by the United States which seems to be at the origin of the EC complaint. However, under the circumstances, we also deem in necessary to specify that the issue stems from the fact that the United States maintained the measure after the notification of Directive 2003/74/EC to the DSB and we modified paragraphs 2.7 and 7.151 accordingly.

6.33 The United States contests the conclusion of the Panel in paragraphs 7.162-7.164 that the European Communities narrowed the terms of reference of the Panel through the approach it followed in its first written submission. For the United States, 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.

[229] See US letter dated 14 February 2007.
[230] Annex G, para. 422.
[231] Annex G, para. 707.

6.34 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."[232]

6.35 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[233], 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*[234]:

> "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."

6.36 The Panel also quotes the Appellate Body in *US – Carbon Steel*.[235] It seems to be accepted that complainants can clarify their claims throughout the proceedings. In this instance however, it appears that the United States 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.

6.37 Panels are free to address claims in the order that they deem appropriate.[236] 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.[237] Regarding the second question, the reply might be less clear and depend on the type of "clarification" made by the complainant. In this case, the clarification had serious consequences on how the Panel could address the claims listed in the terms of reference. It was not 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 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 paragraphs 7.162-7.164.

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

6.38 The European Communities disagrees with the interpretation the Panel makes, in paragraphs 7.174 *et seq*., as well as in paragraph 7.272 of the EC claims as set out in its first written

---

[232] Appellate Body Report on *EC – Bananas III*, paras. 141-143; Appellate Body Report on *US – Lead and Bismuth II*, paras. 72 and 73.
[233] See para. 7.176.
[234] Panel Report on *EC – Tubes and Pipes Fittings*, para. 7.10.
[235] See para. 7.161.
[236] Appellate Body Report in *Canada – Wheat Exports and Grain Imports*, para. 126.
[237] See, e.g., Appellate Body Report on *EC – Selected Customs Matters*, para. 308.

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 the US 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.[238]

6.39 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 Articles 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.

6.40 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 7.181. The Panel notes that it has clearly explained in paragraphs 7.277-7.278 why it believes that this claim was premised on compliance with the DSB recommendations and rulings in the *EC – Hormones* case.

6.41 Consequently, the Panel will not delete the section of its report considering the allegedly non-existent EC claim under Article 22.8 of the DSU.

6.42 The Panel, however, deems it appropriate to clarify paragraph 7.181, and to make the modification suggested by the United States in its comments of 19 October 2007 with respect to paragraph 7.359 in order to make clear that it is not reviewing the EC claim of violation of Article 22.8 in isolation.

---

[238] See, for instance:
- EC's first written submission, para. 73: "Under Article 23.1 of the DSU, the United States 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 "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. 122: "For these reasons, the United States, 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 reply to questions of the United States after the first substantive meeting, para. 8: "More specifically, the European Communities considers that the continued application of sanctions despite the unchallenged EC compliance measure is in violation of Articles 23.1 and 22.8 read together."
- EC's second written submission, para. 217.

6.43 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 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 the United States must remove its suspension of concessions, whereas the United States requests that we note that, once our findings are adopted by the DSB, recourse to dispute settlement in accordance with the rules and procedures of the DSU for the purpose of Article 23.2(a) read together with Articles 21.5 and 23.1 of the DSU will have been achieved in respect of this matter.

6.44 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 the United States. The Panel notes, however, that their proposed suggestions or concluding remarks are divergent. The Panel wishes to recall its conclusion in paragraph 7.251. 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 United States 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 the United States

6.45 The United States requests the Panel to harmonize the lists of means of dispute settlement which appear in paragraphs 7.247 and 7.350. While the Panel sees no reason not to expressly refer to panel proceedings in paragraph 7.247**,** it notes that paragraph 7.247 uses the word "including" before listing means of dispute settlement. Its list is, thus, not exhaustive. The Panel also believes that this would be more necessary for the sake of completeness than for the sake of consistency. Indeed, the two lists relate to different matters. In paragraph 7.247, the Panel listed the means of dispute settlement available *to the United States* to comply with the requirements of Article 23.2(a) of the DSU to have "recourse to dispute settlement in accordance with the rules and procedures of [the DSU". Comparatively, paragraph 7.350, addresses the means available *to the European Communities* to obtain the termination of the suspension of concessions or other obligations. The addition of recourse to a "normal" panel in paragraph 7.247 should not be taken to imply that the United States would satisfy its obligation under Article 23.2(a) if any party to the dispute such as, for instance, the European Communities had recourse to dispute settlement. The Panel reads Article 23.2(a) and 23.1 as requiring that the dispute settlement procedure be initiated by the United States. Having also regard to the EC comments of 19 October 2007[239], the Panel does not deem it necessary to modify paragraph 7.247.

6.46 The Panel also accepted the US request to harmonize certain terms of paragraph 7.270 with the terms of paragraph 7.251.

6.47 In its comments on paragraphs 7.308 through 7.359, the United States argues that, whereas it is the case that a complaining party in WTO dispute settlement bears the burden of proof to make out a prima facie case of the WTO-inconsistency of the defending Member's measure, that concept does

[239] Paras. 14-16.

not equate to, nor does it imply that, there exists a presumption that the responding Member is in good faith compliance with its WTO obligations. The United States argues that questions of good faith or bad faith do not form a basis for a presumption of consistency or inconsistency.

6.48 The Panel agrees with the United States that good faith in the performance of treaties and the question of consistency are ultimately to be distinguished in the panel proceedings. A finding of violation of a Member's obligations will ultimately be based on an objective assessment of the conformity of the measure at issue. However, the Panel considers that, whereas a party to a dispute may ultimately be found in breach of its obligation irrespective of whether it is acting in good faith or not, good faith remains the premise on which the presumption of compliance is based. In other words, it is because a Member is supposed to comply with its obligations in good faith that it can be presumed to be in conformity with its obligations and that it is for the complaining Member in a dispute to make a prima facie case of violation.

6.49 The United States argues, on the contrary, that the burden of proof is testament solely to the fact that there is no presumption of bad faith that attaches to measures taken by a WTO Member. The Panel disagrees. The Panel note that the United States does not cite to any report in support of its position. Comparatively, the Panel notes that the Appellate Body, in *EC – Sardines*, stated that:

> "We must assume that Members of the WTO will abide by their treaty obligations in good faith, as required by the principle of *pacta sunt servanda* articulated in Article 26 of the *Vienna Convention*. And, always in dispute settlement, every Member of the WTO must assume the good faith of every other Member."[240]

6.50 In that context, the Panel fails to see why burden of proof should be based on an absence of presumption of bad faith.

6.51 Likewise, the Panel does not understand why good faith should not form the basis for a presumption of consistency because it is ultimately irrelevant for purposes of finding whether a measure is consistent or not with the WTO. Since WTO Members are to be assumed to abide by their treaty obligations in good faith, it is normal that, until a prima facie case has been made by the complaining Member, the responding Member enjoy this presumption of compliance in good faith. Whereas this presumption goes to the substance or the "merits" of the measures at issue, it does not affect the ultimate finding of the Panel, which will be ultimately based on an objective assessment of the matter, including all the relevant evidence submitted by the parties. For these reasons, the Panel sees no reason to modify its findings in paragraphs 7.308 through 7.359.

6.52 The United States also requests that we modify paragraph 7.360. According to the United States**,** the fact that the Panel's terms of reference do not include provisions of the *SPS Agreement* does not necessarily mean that the conformity of the EC Directive 2003/74/EC with the *SPS Agreement* lies outside the Panel's mandate. The United States refers to the Appellate Body report in *Argentina – Footwear (EC)*[241] to conclude that the Panel would not exceed its terms of reference by examining provisions not cited in the Panel request and would comply with its obligations under Article 11 of the DSU.

6.53 The European Communities, in its comments of 19 October 2007[242], disagrees with the comments of the United States to the extent that, unlike in the case referred to by the United States 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

---

[240] Appellate Body Report in *EC – Sardines*, para. 278.
[241] Appellate Body Report on *Argentina – Footwear (EC),* paras. 74-75.
[242] Para. 21.

considers that if the US 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.

6.54 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 agrees with the United States 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 paragraph 7.377. The Panel also believes that its approach is consistent with the scope of a panel mandate as confirmed by the Appellate Body.

6.55 The United States also requests that we modify the second sentence of paragraph 7.366 to take into account the terms of Article 7.2 of the DSU which provides that "Panels shall address the relevant provisions of any covered agreement cited *by the parties to the dispute*" (emphasis added). The Panel agrees with the United States that provisions invoked by the responding party, for instance, as affirmative defence must be addressed by a panel. The Panel notes, however, that the "matter" before it is defined by the request for establishment of the Panel. The matter before this Panel is whether the United States' measure has breached, *inter alia*, Article 22.8 of the DSU, not whether EC Directive 2003/74/EC complies with the *SPS Agreement*. As a result, the US references to provisions of the *SPS Agreement* are not claims. The Panel may address them, however, as part of its findings on Article 22.8 of the DSU. The Panel has nevertheless clarified paragraphs 7.366 and 7.367.

6.56 Finally, the United States requests a modification to paragraph 8.2 and the addition of concluding observations. 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.

6.57 Regarding the addition of concluding observations, we do not agree with the United States that, "once [our findings are] adopted by the Dispute Settlement Body, recourse to dispute settlement in accordance with the rules and procedures of the DSU for the purpose of Article 23.2(a) read together with Articles 21.5 and 23.1 of the DSU will have been achieved in respect of this matter." For reasons explained in this report, the Panel does not believe that recourse by the European Communities to dispute settlement exempts the United States from its obligations under Article 23.1 and 23.2(a) of the DSU. The Panel has 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

6.58 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.

6.59 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 oestradiol-17β 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.

6.60 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*[243], as well as with the presumption of compliance under Article 3.2 of the *SPS Agreement*.

[243] Appellate Body Report on *Japan - Apples*, para. 179.

6.61 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.[244] 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 and that relevant scientific evidence was insufficient for the other five hormones.

6.62 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.[245] 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.[246] 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:

---

[244] Paras. 7.643-7.647.

[245] 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, 5.2, 5.7 and 3.3 of the *SPS Agreement*, and of the presumption of conformity with the *SPS Agreement*.

[246] 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.

> "[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."[247]

6.63 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.[248]

6.64 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.

6.65 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 7.380-7.386 and 7.412-7.427 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.

6.66 The European Communities argues that the statement originally found in paragraph 7.371 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[249] 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:[250]

> "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."

6.67 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

---

[247] See Annex G, para. 346.
[248] See, e.g., Dr. Guttenplan, Annex D, para. 145.
[249] EC's replies to Panel questions after the first substantive meeting, Annex B, para. 274.
[250] EC's replies to Panel questions after the first substantive meeting, Annex B, para. 275.

"New experts will have to be consulted".[251] 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 7.371 was modified accordingly.

6.68 The European Communities suggests that the Panel contradicted itself in paragraph 7.377 of the interim report 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 7.133, 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 7.133, 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 7.374.

6.69 The European Communities argues that, in paragraphs 7.376-7.377, 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 7.377, 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.

6.70 The European Communities states that paragraph 7.404 and footnote 516 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

[251] 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.

such factual corrections were made. Thus, the Panel sees no reason to correct paragraph 7.404 and footnote 516.

6.71 With respect to paragraph 7.410**,** the European Communities argues that the statement of the Panel is unsupported and is an error of law. We do not share the European Communities' opinion. First, the Panel did not base its decision to include Article 5.2 of the *SPS Agreement* in its review of the conformity of Directive 2003/74/EC exclusively on the comment of the European Communities quoted in paragraph 7.409. In paragraph 7.404, the Panel mentioned that it would "consider all allegations and arguments raised by each party". Since the United States had alleged a violation of Article 5.2, the Panel could look at it irrespective of the EC position on this matter. In paragraph 7.410, the Panel simply notes the absence of objection of the European Communities. It was, therefore, not deemed necessary to modify paragraph 7.410.

6.72 The European Communities argues, with respect to paragraph 7.420, 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 7.71 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*.[252] 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.[253] The Panel explained its approach in detail in paragraph 7.420 and thus does not believe that it engaged into "picking and 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 7.420.

6.73 The European Communities considers that, in paragraphs 7.423-7.427, 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 7.427. 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 7.427: (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.

---

[252] Appellate Body Report on *EC – Asbestos*, para. 161.
[253] See para. 7.74.

6.74 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[254], 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 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

6.75 The European Communities argues that the use of the term "measure" in paragraphs 7.443 and 7.518 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."[255] 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."[256] The Panel believes that judging or appraising something, in this case the SCVPH Opinions, against a certain standard or rule, in this case Articles 5.1 (including an examination of Article 5.2) 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

[254] The Panel did not use the quotation from Dr. Wennberg in paragraph 7.426 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."

[255] EC's comments on interim report, para. 50.
[256] *Shorter Oxford English Dictionary*, 5th edition (1993), p.1730.

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.

6.76 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 7.443. 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 (including an examination of Article 5.2) 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"

6.77 The European Communities argues that the discussion by the Panel of risk assessment techniques in paragraphs 7.446 to 7.469 is irrelevant and unnecessary given that no relevant international risk assessment techniques for veterinary drug residues have been agreed upon.[257]

6.78 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*.

6.79 The Panel notes in paragraph 7.449 that no specific techniques or guidelines had 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.

6.80 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.[258]

6.81 The Panel is surprised by this comment, because it states in paragraph 7.467:

> "[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

[257] EC's comments on interim report, para. 51.
[258] EC's comments on interim report, para. 51.

> measure is based is not in conformity with the requirements of Article 5.1.'"[259]

6.82 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 7.467 and added paragraph 7.468.

6.83 The European Communities also takes issue with paragraph 7.455. 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. However, the European Communities maintains that the risk assessment criteria as developed by the WTO dispute settlement bodies are clearly more relevant to the application of the *SPS Agreement.*"

6.84 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.

6.85 The arguments summarized in this paragraph are contained in paragraph 192 of the European Communities' second written submission.

6.86 Paragraph 192 of the European Communities' second written submission states:

> "[A]ll parties to this dispute agree on the relevance of the risk assessment techniques developed by Codex recently. Indeed, Article 5.1 itself points to the relevance of risk assessment techniques developed by relevant international organisations. Furthermore, the SCVHP has explicitly based its assessment on the three elements of risk identification, risk characterization and exposure assessment recommended and applied by the Codex.[260] A few qualifications, however, apply. First, risk assessment criteria as they have been developed by the dispute settlement bodies are clearly more relevant to the application of the *SPS Agreement* than those developed by

---

[259] Panel Report on *Japan – Apples*, para. 8.241.

[260] In response to a question from the Panel, the European Communities clarified the following: "As regards the statement in para. 192 of its Rebuttal Submission, the European Communities is grateful to the Panel for pointing out the error and oversight. The error is double because: first, the steps of a risk assessment as defined by Codex are four (not three) and, second, the terminology used in para. 192 to describe the first three of them is not correct either (see following para. 193 where the proper terminology is used for the first three steps). The words used in para. 192 is an isolated oversight and does not reflect the position which the European Communities has expressed in so many other places in its written submissions and the oral hearing. Indeed, with its reply of 3 October 2005 to Written Question No. 24 from the Panel, in particular paragraphs 140-143, the European Communities has properly described the four steps of a risk assessment and the reasons for which it thinks it has complied with them in this case. See also paragraphs 145-152 of its reply of 3 October to Written Question No. 25 from the Panel. Moreover, a careful examination of the 1999 Opinion shows beyond doubt that the European Communities has completed the four steps, albeit it made a qualitative exposure assessment for the reasons explained therein." (EC's replies to Panel questions after the second substantive meeting, question 8, para. 34, Annex C-1)

> international scientific bodies. This follows naturally from the fact that it is the former's duty and privilege to interpret the provisions of the *SPS Agreement*."

6.87 The Panel believes that the sentiment of the European Communities' argument is adequately summarized in paragraph 7.455 and will not alter the paragraph.

6.88 As to the European Communities' argument that paragraph 7.455 is misleading because the European Communities has followed the four steps of risk assessment as defined by Codex, the Panel notes that it does not discuss in any way in paragraph 7.455 whether the European Communities' has complied with the four steps. In addition, the Panel notes in paragraph 7.458 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 ..."

6.89 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 7.469, the Panel finds that it has.

6.90 The European Communities asks the Panel to more fully summarize its arguments in paragraphs 7.502 and 7.503.[261] The Panel has, therefore, modified those paragraphs.

(iv) Assessment of the scientific arguments

6.91 The European Communities, argues that paragraphs 7.504 through 7.573 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.[262] The Panel notes that the content of paragraphs 7.504 through 7.573 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.

6.92 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.

6.93 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 7.464. The Panel also changed the first sentence of paragraph 7.467.

6.94 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

[261] EC's comments on interim report, para. 52.
[262] EC's comments on interim report, para. 53.

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 7.497.

6.95 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 7.529.

6.96 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[263] as paragraph 7.559.

6.97 The European Communities argues that paragraphs 7.518 and 7.519 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*.[264] 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 7.517.

6.98 The Panel based its reasoning in paragraphs 7.518 and 7.519 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.[265] The Panel describes the latter as 'non-scientific' and as pertaining to 'risk management' rather than to 'risk assessment'.[266] 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."

6.99 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

---

[263] 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]").

[264] EC's comments on interim report, para. 55.

[265] (*footnote original*) US Panel Report, para. 8.94; Canada Panel Report, para. 8.97.

[266] (*footnote original*) US Panel Report, para. 8.95; Canada Panel Report, para. 8.98.

stated that the term "risk management" is not to be found in Article 5 or any other provision of the *SPS Agreement.* The Panel, therefore, finds no basis for the European Communities' assertion that the Appellate Body "confirmed that a risk assessment within the meaning of Article 5.1 includes a risk management stage which is the responsibility of the regulator to carry out and not of the scientific bodies."[267]

6.100 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'.[268] To the extent that the Panel intended to refer to a process characterized by systematic, disciplined and objective enquiry and analysis, that is, a mode of studying and sorting out facts and opinions, the Panel's statement is unexceptionable.[269] 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."[270]

6.101 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.

6.102 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*

---

[267] EC's second written submission, para. 191.

[268] (*footnote original*) US Panel Report, para. 8.107; Canada Panel Report, para. 8.110.

[269] (*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.

[270] Appellate Body Report on *EC – Hormones*, para. 187.

includes "weighing policy alternatives in light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures."[271] 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*.

6.103 To avoid any confusion or misunderstanding the Panel modified paragraphs 7.518 through 7.521.

6.104 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 7.522.

6.105 The European Communities takes issue with the reliance of the Panel on certain statements by the experts in paragraphs 7.522 to 7.528 and cites to various other statements by the same experts which it claims stand for the opposite proposition.[272] 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.[273] 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. It also considered the comments of the United States of 19 October 2007.

6.106 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.[274]

6.107 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 7.523, the Panel amended the paragraph to better reflect Dr. Guttenplan's complete response to the question.

6.108 Additionally, to more fully reflect Dr. Guttenplan's written answer to question 52 of the Panel, the Panel modified paragraph 7.528.

6.109 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.

6.110 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

[271] EC's reply to question 24 of the Panel after the first substantive meeting, Annex B-1, para. 137.
[272] EC's comments on interim report, para. 56.
[273] Appellate Body Report on *EC – Hormones*, para. 138; see also section VII.C.3.(d)(iii) of this report.
[274] EC's comments on interim report, para. 56.

effects."[275] Paragraph 393 of Annex G refers generally to the issue of conducting risk assessments of genotoxic substances with no threshold.[276] The Panel believes it has dealt with these issues in the amendments mentioned above.

6.111 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.

6.112 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.

6.113 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.

6.114 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.[277] 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.[278] In any event, in both those paragraphs Dr. Cogliano provides general background information on what is meant by a linear dose response curve.

6.115 Dr. Cogliano, in paragraph 871 of Annex G[279], 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

[275] Transcript of the Panel meeting with the experts, Annex G, para. 366.
[276] Transcript of the Panel meeting with the experts, Annex G, para. 393.
[277] EC's comments on interim report, paras. 56-58.
[278] 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.
[279] Paragraph 870 is the Chairman giving the floor to Dr. Cogliano.

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.

6.116 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 7.465, 7.466 and 7.530.

6.117 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.[280] 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 *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*.

6.118 The Panel does not take a position on the science or on how to evaluate data when a particular substance exhibits no threshold.[281] 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.

6.119 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 7.535 quotations from the 1999 SCVPH Opinion on this issue directly, and a new paragraph 7.536.

6.120 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 7.534 and 7.535.

[280] EC's comments on interim report, paras. 57-64.

[281] 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.

6.121 The European Communities also refers to a statement by Dr. Boobis at paragraph 725 of Annex G.[282] 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."[283]

6.122 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.[284]

6.123 The European Communities argues that in paragraphs 7.557 to 7.566 the Panel relies solely on the responses of Drs. Boobis and Boisseau and does not reflect the opinions of the other experts.[285]

6.124 The Panel notes that the relevant section is from paragraphs 7.552 to 7.572 and that the Panel cites Dr. Cogliano and Dr. Guttenplan in paragraph 7.568, and Dr. Guttenplan again in paragraph 7.569. 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.

6.125 The European Communities argues that the Panel is in error in paragraph 7.570 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.[286] 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 7.570, 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 7.570.

6.126 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 7.533.

---

[282] Paragraph 725 is an interjection by Canada. See transcript of the Panel meeting with the experts, Annex G, para. 725.

[283] Transcript of the Panel meeting with the experts, Annex G, paras. 723 and 729.

[284] 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?"

[285] EC's comments on interim report, footnote 11.

[286] EC's comments on interim report, footnote 11.

6.127 The European Communities argues with respect to paragraph 7.572 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.

6.128 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.

6.129 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 in paragraphs 7.552-7.572, the section to which paragraph 7.572 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 assessment, toxicology, studies of carcinogens, and biochemistry.[287] The Panel regrets if it caused any confusion by using the phrase "most convincing" and accordingly clarified paragraph 7.572.

6.130 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 7.538 in order to provide additional explanation.

(v) Comments on the Panel analysis regarding the other five hormonal substances

6.131 The European Communities argues that paragraph 7.605 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.[288] 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 7.605 thus applies equally to both statements.

6.132 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

[287] Transcript of the Panel meeting with the experts, Annex G, paras. 54-72.
[288] *Inter alia* in paras. 137, 143, 149, 153, 176 and 183.

what respect this statement affects its finding in paragraph 7.605. As recalled by the Panel in its findings[289], 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[290] 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*.

6.133 Having also regard to the comments of the United States of 19 October 2007, the Panel did not deem it necessary to delete or modify paragraph 7.605.

6.134 The European Communities makes a general reference to its second written submission and takes issue with the assessment of the Panel in paragraphs 7.649 to 7.721 by stating that the Panel did 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.

6.135 The European Communities finds the Panel reference to a risk assessment "in substance" in paragraph 7.628 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.[291] 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.

6.136 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.

[289] See paras. 7.443-7.444.
[290] Annex G, para. 871.
[291] Panel Report on *Japan – Apples (Article 21.5 – US)*, para. 8.136.

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"[292] 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 7.628 in order to clarify what it meant.

6.137 Regarding paragraphs 7.630 to 7.637, 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.[293]

6.138 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 7.637. 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 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.

6.139 The European Communities argues, with respect to paragraph 7.644**,** 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

[292] Appellate Body Report on *EC – Hormones*, para. 190.
[293] Annex G, para. 348.

the Panel has said, is that such an analysis is required by Article 5.1 and Annex A(4) of the *SPS Agreement*.

6.140 With respect to the Panel's reference to the concept of "critical mass" in paragraph 7.648, 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*.

6.141 The Panel used the term "critical mass" in full knowledge of its meaning.[294] It used it in the sense of a situation where evidence becomes quantitatively and qualitatively sufficient to call into question the fundamental precepts of previous knowledge and evidence. The Panel does not mean that there must be sufficient evidence to perform a new risk assessment. Otherwise, Article 5.7 of the *SPS Agreement* would become meaningless. It used the term "critical mass" very much in its common scientific usage, i.e. the new scientific information and evidence must be such that they are *at the origin* of a change in the understanding of a scientific issue. We do not see in what respect this approach by the Panel, which applies to the specific situation in this case (i.e. one where a party alleges that previously sufficient scientific evidence has become insufficient) would be contrary to the findings of the Appellate Body in *EC – Hormones.*

6.142 The United States suggests in its counter-comments[295] that the Panel consider using the term "weight of evidence" to explain its use of the "critical mass" criterion in conducting its analysis and reaching its conclusions. The United States adds that the weight of evidence approach is standard in science. Weight of evidence is explained by the experts primarily in paragraphs 487, 489, 493, 501 of Annex G. At the experts' hearing, Dr. Boobis defined weight of evidence as:

> "[T]he evaluation of the available information about a particular toxicological endpoint taking into account factors such as the adequacy and number of available studies and the consistency of results across studies. It is not an issue of seeking to weigh one person's opinion against another." (para. 487)

and:

> "This is not a question of what people think and minority opinions, it is a question of looking at the data ... There is an element of interpretation of the quality of the study, I accept, but that is why you have experts on the evaluation committee." (para. 501)

6.143 From the above it may be concluded that weight of evidence is in the first instance concerned with the quality of studies. "Badly done" studies are excluded so that the evaluation is based only on studies that are "well done" i.e. studies carefully carried out using validated methods. In a second stage, an assessor taking a weight of the evidence approach looks at the number of studies and the consistency of results across studies. If one follows Dr. Boobis, in particular his comment in paragraph 501 of the transcript (Annex G), the weight of the evidence approach may contradict the views of the Appellate Body in paragraph 194 of its report in *EC – Hormones* because it would favour the "mainstream" scientific opinion, whereas the Appellate Body accepted that an SPS measure may be based on a "divergent opinion coming from qualified and respected sources" and still be in compliance with the substantive obligations of the *SPS Agreement*. This is why we do not wish to replace the terms "critical mass" used in our report with "weight of evidence". In our view, a "critical

[294] 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.

[295] At para. 28.

mass" of scientific evidence and information could be small and may include situations where the weight of the evidence has not shifted away from the existing prevailing knowledge, but where the new knowledge is qualitatively and quantitatively sufficient to create a situation where a Member can legitimately decide that the pre-existing scientific evidence is no longer sufficient to complete a risk assessment within the meaning of Article 5.1 and Annex A(4) of the *SPS Agreement*.

6.144 The European Communities takes issue with paragraph 7.662. 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.

6.145 The Panel first recalls that, as a general principle, panels are free to structure the order of their analysis as they see fit.[296] The Panel does not deny that the EC Opinions addressed each hormone individually. However, as explained in paragraphs 7.660 to 7.662, 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 paragraph 7.652 to 7.663 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.

6.146 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 7.722 to 7.830 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.[297]

6.147 The European Communities contests the conclusions of the Panel in paragraph 7.665, footnote 792 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 7.665, 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 792.

---

[296] Appellate Body Report on *Canada – Wheat Exports and Grain Imports*, para. 126.
[297] EC's comments on Sections VII.C.3(f)(vii), (viii), (ix), (x), (xi).

6.148 With respect to paragraphs 7.667 to 7.670, 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.[298] 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 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.

6.149 The European Communities requests that we clarify the first sentence in paragraph 7.670. 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[299] 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.

6.150 With respect to the EC comment on the second sentence of paragraph 7.670, 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.[300] 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.

6.151 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."[301]

6.152 In its comments regarding paragraphs 7.672-7.675 the European Communities considers that the Panel's approach to the issue of dose response is flawed and circular.

6.153 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"[302] 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

[298] Annex G, para. 561 *et seq*.
[299] See para. 7.668 quoting Dr. Sippell. See, also, Dr. Sippell's statement in Annex G, para. 588.
[300] Annex G, para. 572.
[301] 1999 Opinion, section 3.2, p. 30.
[302] See EC reply to question 26 of the first series of questions of the Panel, para. 153, Annex B; see also EC's second written submission, paras. 196-200.

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.

6.154 The European Communities argues that, in paragraph 7.677, 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 conclusions can be applied to hormones other than oestrogens. The European Communities considers that this assertion by the Panel is without foundation.

6.155 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[303] and in its second written submission.[304] 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".[305] 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.

6.156 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.

6.157 With respect to paragraphs 7.685 to 7.700, 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 7.567 *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.

[303] Annex B-1, paras. 155-159.
[304] Paras. 133-176.
[305] EC reply to question 28 of the questions of the Panel after the first substantive meeting, Annex B-1, para. 158.

6.158 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 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.[306] 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.

6.159 The European Communities also takes issue with the Panel's discussion on the immunological effect of the five hormones in paragraphs 7.701 to 7.708. 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.

6.160 Regarding the first issue, the Panel notes that all three experts who answered question 59[307] 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.

6.161 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 7.704, 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 7.706-7.707.

6.162 Regarding paragraphs 7.709 to 7.721, 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.

6.163 Regarding Dr. Sippell's statement in paragraph 7.714, the Panel has further discussed the points raised by the experts on this matter in paragraphs 7.715 through 7.721.

---

[306] In this respect, the Panel inserted a footnote in para. 7.648 to address the EC argument on standard of proof.

[307] Annex D, paras. 443-448.

6.164 With respect to paragraphs 7.700 to 7.713 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 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.[308] Indeed, the question of misuse or abuse in the administration of hormones is relevant to the extent that it can lead to higher concentrations of hormone residues in meat and meat products than would occur if good veterinary practices were applied. As stated by the 1999 Opinion, it is an aspect of exposure assessment. In this case, the Panel found that the European Communities had not evaluated specifically the possibility that the adverse effect 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.

6.165 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.

6.166 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 7.603.

6.167 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.

6.168 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.[309] 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.

6.169 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*,

[308] It is nonetheless discussed in para. 7.483, in relation to Article 5.2 of the *SPS Agreement*.
[309] Statement of Dr. Tritcher, Annex G, para. 463.

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.

6.170 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 7.799, this would have amounted to a complete risk assessment in the sense of Article 5.1 of the *SPS Agreement*. The 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 7.799.

6.171 As regards the alleged application of a similar standard in paragraphs 7.803-7.804, 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 7.637, 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.

6.172 In paragraph 7.812, 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 7.813 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 7.814 to 7.817.

6.173 Finally, the European Communities requests the Panel to clarify the meaning and extent of its conclusion in paragraph 7.837. 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.

6.174 Thus, the problems identified by the Panel are not related to the 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 6.112 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 the United States

6.175 The United States observes that the EC Opinions to which the Panel refers in the first sentence of paragraph 7.482 address bioavailability and susceptibility of sensitive populations, but not *in vivo* repair mechanisms. The United States refers the Panel to paragraph 46 of its second written submission, where it noted that the Opinions ignore the scientific evidence relating to human *in vivo* DNA repair mechanisms. Therefore, the United States requests that the Panel strike the phrase "and *in vivo* repair mechanisms" from the first sentence of paragraph 7.482.[310]

6.176 The Panel has reviewed paragraph 46 of the US second written submission as well as the Opinions themselves and has found that the United States is correct that the SCVPH Opinions do not mention the phrase "*in vivo* repair mechanisms". However, as also noted by the European Communities in its comments of 19 October 2007, they do contain reviews of data on DNA adducts and DNA damage and the Panel maintains its conclusion that the European Communities did not ignore the scientific evidence with respect to the effects of oestradiol-17β on DNA. Therefore, the Panel clarified paragraph 7.482 accordingly.

6.177 The United States also suggests that the Panel change the phrase "general risk" in paragraph 7.537 as it may be confusing to the reader, because the Panel has carefully defined "risk", but has not defined "general risk".[311] The European Communities, in its comments of 19 October

[310] US's comments on interim report, p. 7.
[311] US's comments on interim report, p. 8.

2007[312], 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".[313]

6.178 The United States' point about avoiding confusion in terminology is well taken. The Panel accordingly modified paragraph 7.537. However, the Panel will not use the term "identified the hazard" as this too has very specific meanings as set forth in the Codex Procedural Manual and cited in paragraph 7.448. Instead, it will modify paragraph 7.537 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."

6.179 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.

6.180 When necessary, the Panel also made a number of minor editorial or typographical corrections suggested by the United States. However, the Panel refrained from making the changes suggested in two instances. With respect to the correction suggested in paragraph 4.234, the Panel refers to paragraph 6.12 above. With respect to another correction suggested by the United States but opposed by the European Communities (in paragraph 7.566), the Panel decided not to modify the existing sentence to the extent that it paraphrased a statement of Dr. Boobis. The European Communities objected to any change by arguing that it did not know what Dr. Boobis had actually said since it did not have access to the tape recording of the hearing with the experts. The Panel notes, however, that the statement at issue comes from the written reply of Dr. Boobis to question 22 of the Panel, Annex D, paragraph 202.

VII. FINDINGS

A. PROCEDURAL ISSUES

1. Opening of the Panel meetings with the parties and experts for public observation

(a) Introduction

7.1 On 13 June 2005, at the first organizational meeting of the Panel, the parties jointly requested that the Panel's substantive meetings with parties be open for public observation. Through written questions, the Panel requested the parties to specify the legal basis in the DSU for such a request. Parties replied on 20 June 2005. On 30 June 2005, the Panel posed additional questions to the parties on the logistical implications of a hearing that was open to the public. The parties replied on 7 July 2005. The Panel held a second organizational meeting with the parties to discuss this issue on 8 July 2005.[314]

[312] Para. 23.
[313] Appellate Body Report on *EC – Hormones*, para. 200.
[314] The parties agreed to hold joint panel meetings in this case and that against Canada (WT/DS321) and to harmonize the Panels' timetables.