

**EUROPEAN COMMUNITIES – MEASURES AFFECTING
THE APPROVAL AND MARKETING
OF BIOTECH PRODUCTS**

Reports of the Panel

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<i>Argentina – Textiles and Apparel</i>	Panel Report, <i>Argentina – Measures Affecting Imports of Footwear, Textiles, Apparel and Other Items</i> , WT/DS56/R, adopted 22 April 1998, as modified by Appellate Body Report, WT/DS56/AB/R, DSR 1998:III, 1033
<i>Australia – Salmon</i>	Appellate Body Report, <i>Australia – Measures Affecting Importation of Salmon</i> , WT/DS18/AB/R, adopted 6 November 1998, DSR 1998:VIII, 3327
<i>Australia – Salmon</i>	Panel Report, <i>Australia – Measures Affecting Importation of Salmon</i> , WT/DS18/R and Corr.1, adopted 6 November 1998, as modified by the Appellate Body Report, WT/DS18/AB/R, DSR 1998:VIII, 3407
<i>Brazil – Desiccated Coconut</i>	Appellate Body Report, <i>Brazil – Measures Affecting Desiccated Coconut</i> , WT/DS22/AB/R, adopted 20 March 1997, DSR 1997:I, 167
<i>Canada – Wheat Exports and Grain Imports</i>	Appellate Body Report, <i>Canada – Measures Relating to Exports of Wheat and Treatment of Imported Grain</i> , WT/DS276/AB/R, adopted 27 September 2004
<i>Canada – Wheat Exports and Grain Imports</i>	Panel Report, <i>Canada – Measures Relating to Exports of Wheat and Treatment of Imported Grain</i> , WT/DS276/R, adopted 27 September 2004, as upheld by the Appellate Body Report, WT/DS276/AB/R
<i>Chile – Alcoholic Beverages</i>	Appellate Body Report, <i>Chile – Taxes on Alcoholic Beverages</i> , WT/DS87/AB/R, WT/DS110/AB/R, adopted 12 January 2000, DSR 2000:I, 281
<i>Chile – Price Band System</i>	Appellate Body Report, <i>Chile – Price Band System and Safeguard Measures Relating to Certain Agricultural Products</i> , WT/DS207/AB/R, adopted 23 October 2002, DSR 2002:VIII, 3045
<i>Chile – Price Band System</i>	Panel Report, <i>Chile – Price Band System and Safeguard Measures Relating to Certain Agricultural Products</i> , WT/DS207/R, adopted 23 October 2002, as modified by Appellate Body Report, WT/DS207AB/R, DSR 2002:VIII, 3127
<i>Dominican Republic – Import and Sale of Cigarettes</i>	Appellate Body Report, <i>Dominican Republic – Measures Affecting the Importation and Internal Sale of Cigarettes</i> , WT/DS302/AB/R, adopted 19 May 2005
<i>Dominican Republic – Import and Sale of Cigarettes</i>	Panel Report, <i>Dominican Republic – Measures Affecting the Importation and Internal Sale of Cigarettes</i> , WT/DS302/R, adopted 19 May 2005, as modified by Appellate Body Report, WT/DS302/AB/R
<i>EC – Asbestos</i>	Appellate Body Report, <i>European Communities – Measures Affecting Asbestos and Asbestos-Containing Products</i> , WT/DS135/AB/R, adopted 5 April 2001, DSR 2001:VII, 3243
<i>EC – Asbestos</i>	Panel Report, <i>European Communities – Measures Affecting Asbestos and Asbestos-Containing Products</i> , WT/DS135/R and Add.1, adopted 5 April 2001, as modified by Appellate Body Report, WT/DS135/AB/R, DSR 2001:VIII, 3305
<i>EC – Bananas III</i>	Appellate Body Report, <i>European Communities – Regime for the Importation, Sale and Distribution of Bananas</i> , WT/DS27/AB/R, adopted 25 September 1997, DSR 1997:II, 591
<i>EC – Bed Linen</i>	Appellate Body Report, <i>European Communities – Anti-Dumping Duties on Imports of Cotton-Type Bed Linen from India</i> , WT/DS141/AB/R, adopted 12 March 2001, DSR 2001:V, 2049
<i>EC – Bed Linen</i>	Panel Report, <i>European Communities – Anti-Dumping Duties on Imports of Cotton-Type Bed Linen from India</i> , WT/DS141/R, adopted 12 March 2001, as modified by the Appellate Body Report, WT/DS141/AB/R, DSR 2001:VI, 2077
<i>EC – Chicken Cuts</i>	Appellate Body Report, <i>European Communities – Customs Classification of Frozen Boneless Chicken Cuts</i> , WT/DS269/AB/R, WT/DS286/AB/R, adopted 27 September 2005
<i>EC – Commercial Vessels</i>	Panel Report, <i>European Communities – Measures Affecting Trade in Commercial Vessels</i> , WT/DS301/R, adopted 20 June 2005
<i>EC – Computer Equipment</i>	Appellate Body Report, <i>European Communities – Customs Classification of Certain Computer Equipment</i> , WT/DS62/AB/R, WT/DS67/AB/R, WT/DS68/AB/R, adopted 22 June 1998, DSR 1998:V, 1851

Short Title	Full Case Title and Citation
<i>EC – Hormones</i>	Appellate Body Report, <i>EC Measures Concerning Meat and Meat Products (Hormones)</i> , WT/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998, DSR 1998:I, 135
<i>EC – Hormones (Canada)</i>	Panel Report, <i>EC Measures Concerning Meat and Meat Products (Hormones) – Complaint by Canada</i> , WT/DS48/R/CAN, adopted 13 February 1998, as modified by the Appellate Body Report, WT/DS26/AB/R, WT/DS48/AB/R, DSR 1998:II, 235
<i>EC – Hormones (US)</i>	Panel Report, <i>EC Measures Concerning Meat and Meat Products (Hormones) – Complaint by the United States</i> , WT/DS26/R/USA, adopted 13 February 1998, as modified by the Appellate Body Report, WT/DS26/AB/R, WT/DS48/AB/R, DSR 1998:III, 699
<i>EC – Sardines</i>	Appellate Body Report, <i>European Communities – Trade Description of Sardines</i> , WT/DS231/AB/R, adopted 23 October 2002
<i>EC – Tariff Preferences</i>	Appellate Body Report, <i>European Communities – Conditions for the Granting of Tariff Preferences to Developing Countries</i> , WT/DS246/AB/R, adopted 20 April 2004
<i>Guatemala – Cement I</i>	Appellate Body Report, <i>Guatemala – Anti-Dumping Investigation Regarding Portland Cement from Mexico</i> , WT/DS60/AB/R, adopted 25 November 1998, DSR 1998:IX, 3767
<i>India – Autos</i>	Panel Report, <i>India – Measures Affecting the Automotive Sector</i> , WT/DS146/R, WT/DS175/R and Corr.1, adopted 5 April 2002
<i>India – Patents (US)</i>	Appellate Body Report, <i>India – Patent Protection for Pharmaceutical and Agricultural Chemical Products</i> , WT/DS50/AB/R, adopted 16 January 1998, DSR 1998:I, 9
<i>Indonesia – Autos</i>	Panel Report, <i>Indonesia – Certain Measures Affecting the Automobile Industry</i> , WT/DS54/R, WT/DS55/R, WT/DS59/R, WT/DS64/R and Corr.1, 2, 3, and 4, adopted 23 July 1998, DSR 1998:VI, 2201
<i>Japan – Agricultural Products II</i>	Appellate Body Report, <i>Japan – Measures Affecting Agricultural Products</i> , WT/DS76/AB/R, adopted 19 March 1999, DSR 1999:I, 277
<i>Japan – Agricultural Products II</i>	Panel Report, <i>Japan – Measures Affecting Agricultural Products</i> , WT/DS76/R, adopted 19 March 1999, as modified by the Appellate Body Report, WT/DS76/AB/R, DSR 1999:I, 315
<i>Japan – Alcoholic Beverages II</i>	Appellate Body Report, <i>Japan – Taxes on Alcoholic Beverages</i> , WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, adopted 1 November 1996, DSR 1996:I, 97
<i>Japan – Apples</i>	Appellate Body Report, <i>Japan – Measures Affecting the Importation of Apples</i> , WT/DS245/AB/R, adopted 10 December 2003, DSR 2003:IX, 4391
<i>Japan – Apples</i>	Panel Report, <i>Japan – Measures Affecting the Importation of Apples</i> , WT/DS245/R, adopted 10 December 2003, as upheld by the Appellate Body Report, WT/DS245/AB/R, DSR 2003:IX, 4481
<i>Japan – Semi-Conductors</i>	GATT Panel Report, <i>Japan – Trade in Semi-Conductors</i> , adopted 4 May 1988, BISD 35S/116
<i>Korea – Dairy</i>	Appellate Body Report, <i>Korea – Definitive Safeguard Measure on Imports of Certain Dairy Products</i> , WT/DS98/AB/R, adopted 12 January 2000, DSR 2000:I, 3
<i>Korea – Dairy</i>	Panel Report, <i>Korea – Definitive Safeguard Measure on Imports of Certain Dairy Products</i> , WT/DS98/R and Corr.1, adopted 12 January 2000, as modified by Appellate Body Report, WT/DS98/AB/R, DSR 2000:I, 49.
<i>Mexico – Corn Syrup</i>	Panel Report, <i>Mexico – Anti-Dumping Investigation of High Fructose Corn Syrup (HFCS) from the United States</i> , WT/DS132/R and Corr.1, adopted 24 February 2000, DSR 2000:III, 1345
<i>Mexico – Corn Syrup (Article 21.5 – US)</i>	Appellate Body Report, <i>Mexico – Anti-Dumping Investigation of High Fructose Corn Syrup (HFCS) from the United States – Recourse to Article 21.5 of the DSU by the United States</i> , WT/DS132/AB/RW, adopted 21 November 2001, DSR 2001:XIII, 6675

Short Title	Full Case Title and Citation
<i>Thailand – H-Beams</i>	Appellate Body Report, <i>Thailand – Anti-Dumping Duties on Angles, Shapes and Sections of Iron or Non-Alloy Steel and H-Beams from Poland</i> , WT/DS122/AB/R, adopted 5 April 2001, DSR 2001:VII, 2701
<i>US – Carbon Steel</i>	Appellate Body Report, <i>United States – Countervailing Duties on Certain Corrosion-Resistant Carbon Steel Flat Products from Germany</i> , WT/DS213/AB/R and Corr.1, adopted 19 December 2002
<i>US – Carbon Steel</i>	Panel Report, <i>United States – Countervailing Duties on Certain Corrosion-Resistant Carbon Steel Flat Products from Germany</i> , WT/DS213/R and Corr.1, adopted 19 December 2002, as modified by the Appellate Body Report, WT/DS213/AB/R
<i>US – Certain EC Products</i>	Appellate Body Report, <i>United States – Import Measures on Certain Products from the European Communities</i> , WT/DS165/AB/R, adopted 10 January 2001, DSR 2001:I, 373
<i>US – Certain EC Products</i>	Panel Report, <i>United States – Import Measures on Certain Products from the European Communities</i> , WT/DS165/R and Add.1, adopted 10 January 2001, as modified by Appellate Body Report, WT/DS165/AB/R, DSR 2001:II, 413
<i>US – Corrosion-Resistant Steel Sunset Review</i>	Appellate Body Report, <i>United States – Sunset Review of Anti-Dumping Duties on Corrosion-Resistant Carbon Steel Flat Products from Japan</i> , WT/DS244/AB/R, adopted 9 January 2004
<i>US – Corrosion-Resistant Steel Sunset Review</i>	Panel Report, <i>United States – Sunset Review of Anti-Dumping Duties on Corrosion-Resistant Carbon Steel Flat Products from Japan</i> , WT/DS244/R, adopted 9 January 2004, as modified by the Appellate Body Report, WT/DS244/AB/R
<i>US – Cotton Yarn</i>	Appellate Body Report, <i>United States – Transitional Safeguard Measure on Combed Cotton Yarn from Pakistan</i> , WT/DS192/AB/R, adopted 5 November 2001, DSR 2001:XII, 6027
<i>US – Export Restraints</i>	Panel Report, <i>United States – Measures Treating Exports Restraints as Subsidies</i> , WT/DS194/R and Corr.2, adopted 23 August 2001, DSR 2001:XI, 5767
<i>US – FSC</i>	Appellate Body Report, <i>United States – Tax Treatment for "Foreign Sales Corporations"</i> , WT/DS108/AB/R, adopted 20 March 2000, DSR 2000:III, 1619
<i>US – FSC (Article 21.5 – EC)</i>	Appellate Body Report, <i>United States – Tax Treatment for "Foreign Sales Corporations" – Recourse to Article 21.5 of the DSU by the European Communities</i> , WT/DS108/AB/RW, adopted 29 January 2002
<i>US – Gambling</i>	Appellate Body Report, <i>United States – Measures Affecting the Cross-Border Supply of Gambling and Betting Services</i> , WT/DS285/AB/R, adopted 20 April 2005
<i>US – Gasoline</i>	Appellate Body Report, <i>United States – Standards for Reformulated and Conventional Gasoline</i> , WT/DS2/AB/R, adopted 20 May 1996, DSR 1996:I, 3
<i>US – Gasoline</i>	Panel Report, <i>United States – Standards for Reformulated and Conventional Gasoline</i> , WT/DS2/R, adopted 20 May 1996, as modified by Appellate Body Report, WT/DS2/AB/R, DSR 1996:I, 29
<i>US – Lamb</i>	Appellate Body Report, <i>United States – Safeguard Measures on Imports of Fresh, Chilled or Frozen Lamb Meat from New Zealand and Australia</i> , WT/DS177/AB/R, WT/DS178/AB/R, adopted 16 May 2001, DSR 2001:IX, 4051
<i>US – Offset Act (Byrd Amendment)</i>	Appellate Body Report, <i>United States – Continued Dumping and Subsidy Offset Act of 2000</i> , WT/DS217/AB/R, WT/DS234/AB/R, adopted 27 January 2003
<i>US – Section 211 Appropriations Act</i>	Appellate Body Report, <i>United States – Section 211 Omnibus Appropriations Act of 1998</i> , WT/DS176/AB/R, adopted 1 February 2002, DSR 2002:II, 589
<i>US – Shrimp</i>	Appellate Body Report, <i>United States – Import Prohibition of Certain Shrimp and Shrimp Products</i> , WT/DS58/AB/R, adopted 6 November 1998, DSR 1998:VII, 2755
<i>US – Steel Plate</i>	Panel Report, <i>United States – Anti-Dumping and Countervailing Measures on Steel Plate from India</i> , WT/DS206/R and Corr.1, adopted 29 July 2002

Short Title	Full Case Title and Citation
<i>US – Steel Safeguards</i>	Panel Reports, <i>United States – Definitive Safeguard Measures on Imports of Certain Steel Products</i> , WT/DS248, WT/DS249, WT/DS251, WT/DS252, WT/DS253, WT/DS254, WT/DS258, WT/DS259, adopted 10 December 2003, as modified by Appellate Body Report, WT/DS248AB/R, WT/DS249AB/R, WT/DS251AB/R, WT/DS252AB/R, WT/DS253AB/R, WT/DS254AB/R, WT/DS258AB/R, WT/DS259AB/R, DSR 2003:VIII, 3271
<i>US – Upland Cotton</i>	Appellate Body Report, <i>United States – Subsidies on Upland Cotton</i> , WT/DS267/AB/R, adopted 21 March 2005
<i>US – Wool Shirts and Blouses</i>	Appellate Body Report, <i>United States – Measure Affecting Imports of Woven Wool Shirts and Blouses from India</i> , WT/DS33/AB/R and Corr.1, adopted 23 May 1997, DSR 1997:I, 323

LIST OF ABBREVIATIONS

ARMG	Antibiotic resistance marker genes
At.	Attachment
Bt	<i>Bacillus thuringiensis</i>
CA	Competent authority
CBD	Convention on Biological Diversity
Commission	European Commission
Council	European Council of Ministers
DNA	Deoxyribonucleic acid
DSB	Dispute Settlement Body
DSU	Understanding on Rules and Procedures Governing the Settlement of Disputes
EC	European Communities
ECJ	European Court of Justice
EFSA	European Food Safety Authority
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
GATT 1994	<i>General Agreement on Tariffs and Trade 1994</i>
GM	Genetically modified
GMHT	Genetically modified and herbicide tolerant
GMOs	Genetically modified organisms
IPPC	<i>International Plant Protection Convention</i>
ISPM	International Standard for Phytosanitary Measures
LMOs	Living modified organisms

OECD	Organisation for Economic Cooperation and Development
OIE	World Organization for Animal Health
SCF	EC Scientific Committee on Food
SCP	EC Scientific Committee on Plants
SNIF	Summary Notification Information Form
SPS	Sanitary and phytosanitary
<i>SPS Agreement</i>	<i>Agreement on the Application of Sanitary and Phytosanitary Measures</i>
<i>TBT Agreement</i>	<i>Agreement on Technical Barriers to Trade</i>
UNEP	United Nations Environmental Programme
US	United States of America
WHO	World Health Organisation

SHORT AND FULL TITLES OF PRODUCTS

Short title of product (in alphabetical order)	Full Title of Product and EC Exhibit number
COTTON	
Bt-531 cotton	<u>Monsanto Bt cotton (531)</u> C/ES/96//02 (EC chronology 65)
BXN cotton	<u>Stoneville BXN cotton (10215, 10222, 10224)</u> C/ES/99/01 (EC chronology 73)
RR-1445 cotton	<u>Monsanto Roundup Ready cotton (RRC1445)</u> C/ES/97/01 (EC chronology 66)
MAIZE	
Bt-11 maize (EC-69)	<u>Syngenta glufosinate tolerant and Bt resistant (Bt-11) maize</u> C/F/96/05-10 (EC chronology 69)
Bt-11 maize (EC-80)	<u>Syngenta Bt-11 maize</u> C/ES/98/02 (EC chronology 80)
Bt-11 maize (EC-163)	<u>Bt-11 maize</u> C/GB/96/M4/1 (EC chronology 163)
Bt-11 sweet maize (food)	<u>Syngenta Bt-11 sweet maize</u> (EC chronology 92)
Bt-176 maize	<u>Bt 176 maize (Ciba Geigy, now Syngenta Seeds)</u> C/F/94/11-03 (EC chronology 158)
Bt-1507 maize (EC-74)	<u>Pioneer/Dow AgroSciences Bt maize Cry1F (1507)</u> C/NL/00/10 (EC chronology 74)
Bt-1507 maize (EC-75)	<u>Pioneer/Dow AgroSciences Bt maize Cry1F (1507)</u> C/ES/01/01 (EC chronology 75)
Bt-1507 maize (food)	<u>Pioneer/Dow AgroSciences Bt maize Cry1F (1507)</u> (EC chronology 95)
GA21 maize (EC-78)	<u>Monsanto Roundup Ready maize(GA21)</u> C/ES/98/01 (EC Chronology 78)
GA21 maize (EC-85)	<u>Monsanto Roundup Ready maize(GA21)</u> C/GB/97/M3/2 (EC Chronology 85)
GA21 maize (food)	<u>Monsanto Roundup Ready maize(GA21)</u> (EC Chronology 91)
MON809 maize	<u>Pioneer Bt maize (MON809)</u> C/F/95/12-01/B (EC chronology 83)
MON809 maize (food)	<u>Monsanto 809 maize</u> C/F/95/12-01/B (EC chronology 157)
MON810 maize	<u>Monsanto 810 maize</u> C/F/95/12-02 (EC chronology 159)

Short title of product (in alphabetical order)	Full Title of Product and EC Exhibit number
MON810 x GA21 maize	<u>Monsanto MaisGard & Roundup Ready (MON810 & GA21) maize (stack)</u> C/ES/99/02 (EC chronology 82)
MON810 x GA21 maize (food)	<u>Monsanto MaisGard & Roundup Ready (MON810 & GA21) maize (stack)</u> (EC Chronology 94)
NK603 maize	<u>Monsanto Roundup Ready maize (NK603)</u> C/ES/00/01 (EC Chronology 76)
NK603 maize (food)	<u>Monsanto Roundup Ready maize (NK603)</u> (EC Chronology 96)
T14 maize	<u>Agrevo maize T14 maize</u> C/F/96/06/12 (EC Chronology 156)
T25 maize	<u>T25 maize (AgrEvo, then Aventis Cropscience)</u> C/F/95/12-07 (EC chronology 160)
T25 x MON810 maize	<u>Pioneer Liberty Link and Bt (T25 and MON810) maize</u> C/NL/98/08 (EC chronology 86)
T25 x MON810 maize (food)	<u>Pioneer Liberty Link and Bt (T25 and MON810) maize</u> (EC chronology 101)
OILSEED RAPE	
Falcon oilseed rape	<u>Bayer oilseed rape (Falcon GS40/90)</u> C/DE/96/05 (EC Chronology 62)
Liberator oilseed rape	<u>Bayer winter oilseed rape(Liberator pHoe6/Ac)</u> C/D/98/06 (EC Chronology 68)
LL oilseed rape	<u>Bayer Liberty Link oilseed rape (T45 & Topas 19/2)</u> C/GB/99/M5/2 (EC chronology 72)
MS1/RF1 oilseed rape (EC-89)	<u>Bayer oilseed rape (MS1/RF1)</u> C/F/95/01A (EC chronology 89)
MS1/RF1 oilseed rape (EC-161)	<u>Bayer oilseed rape (MS1/RF1)</u> C/UK/94/M1/1 (EC chronology 161)
MS1/RF2 oilseed rape	<u>Bayer oilseed rape (MS1/RF2)</u> C/F/95/01B (EC chronology 90)
MS8/RF3 oilseed rape	<u>Bayer hybrid oilseed rape (MS8/RF3)</u> C/BE/96/01 (EC Chronology 63)
RR oilseed rape (EC-70)	<u>Monsanto Roundup Ready oilseed rape(GT73)</u> C/NL/98/11 (EC Chronology 70)
RR oilseed rape (EC-79)	<u>Monsanto Roundup Ready oilseed rape(GT73)</u> C/F/9506/011 (EC Chronology 79)

Short title of product (in alphabetical order)	Full Title of Product and EC Exhibit number
Topas oilseed rape	<u>Oilseed Rape Topas 19/2 (AgrEvo)</u> C/UK/95/M5/1 (EC chronology 162)
SOYBEANS	
High-oleic soybeans	<u>Pioneer/Dupont high-oleic soybeans (260-05)</u> C/NL/98/09 (EC chronology 87)
High-oleic soybeans (food)	<u>Pioneer/Dupont high-oleic soybeans (260-05)</u> (EC chronology 99)
LL soybeans (EC-71)	<u>Bayer Liberty Link soybeans (A2704-12 and A5547-127)</u> C/BE/98/01 (EC chronology 71)
LL soybeans (EC-81)	<u>Bayer Liberty Link soybeans (A2704-12 and A5547-127)</u> C/PT/99/01 (EC chronology 81)
LL soybeans (food)	<u>Bayer Liberty Link soybeans (A2704-12 and A5547-127)</u> (EC chronology 93)
MON soybeans	<u>Monsanto herbicide-resistant soybeans</u> C/UK/94/M3/1
OTHER	
BXN tobacco	<u>SEITA Tobacco tolerant to bromoxynil</u> C/F/93/08-02
RR fodder beet	<u>Trifolium/Monsanto/Danisco Roundup Ready fodder beet (A5/15)</u> C/DK/97/01 (EC chronology 64)
RR sugar beet	<u>Monsanto/Syngenta Roundup Ready sugar beet (77)</u> C/BE/99/01 (EC chronology 88)
RR sugar beet (food)	<u>Monsanto/Syngenta Roundup Ready sugar beet (77)</u> (EC chronology 102)
Transgenic green-hearted chicory	<u>Bejo-Zaden Green hearted chicory</u> C/NL/96/05 (EC chronology 110)
Transgenic green-hearted chicory (food)	<u>Bejo-Zaden Transgenic Green hearted chicory</u> (EC chronology 98)
Transgenic potato	<u>Amylogene starch potato</u> C/SE/96/3501 (EC chronology 67)
Transgenic red-hearted chicory	<u>Bejo Zaden red-hearted chicory (RM3-3, RM3-4, RM3-6)</u> C/NL/94/25 (breeding activities) C/NL/94/25/A(food/feed) (EC chronology 77)
Transgenic red-hearted chicory (food)	<u>Bejo Zaden red-hearted chicory (RM3-3, RM3-4, RM3-6)</u> (EC chronology 97)
Transgenic tomato	<u>Zeneca extended shelf life tomato (TGT7-F)</u> C/ES/96/01 (EC chronology 84)

Short title of product (in alphabetical order)	Full Title of Product and EC Exhibit number
Transgenic tomato (food)	<u>Zeneca extended shelf life tomato (TGT7-F)</u> (EC chronology 100)

I. INTRODUCTION

A. COMPLAINT OF THE UNITED STATES

1.1 On 13 May 2003, the United States requested consultations with the European Communities pursuant to Article 4 of the *Understanding on Rules and Procedures Governing the Settlement of Disputes* ("DSU"), Article 11 of the *Agreement on the Application of Sanitary and Phytosanitary Measures* ("*SPS Agreement*"), Article 19 of the *Agreement on Agriculture*, Article 14 of the *Agreement on Technical Barriers to Trade* ("*TBT Agreement*") and Article XXII of the *General Agreement on Tariffs and Trade 1994* ("GATT 1994") with regard to certain measures taken by the European Communities and its member States affecting products of biotechnology ("biotech products").¹

1.2 On 19 June 2003, the United States and the European Communities held the requested consultations, but failed to reach a mutually satisfactory resolution of the matter.

1.3 On 7 August 2003, the United States requested the establishment of a panel to examine the matter.²

B. COMPLAINT OF CANADA

1.4 On 13 May 2003, Canada requested consultations with the European Communities pursuant to Article 4 of the DSU, Article XXII of the GATT 1994, Article 11 of the *SPS Agreement*, Article 19 of the *Agreement on Agriculture*, and Article 14 of the *TBT Agreement*, concerning measures affecting the approval and marketing of products that contain, consist of, or are produced from, genetically modified organisms.³

1.5 On 25 June 2003, Canada and the European Communities held the requested consultations, but failed to reach a mutually satisfactory resolution of the matter.

1.6 On 7 August 2003, Canada requested the establishment of a panel to examine the matter.⁴

C. COMPLAINT OF ARGENTINA

1.7 On 14 May 2003, Argentina requested consultations with the European Communities pursuant to Article 4 of the DSU, Article 11.1 of the *SPS Agreement*, Article 19 of the *Agreement on Agriculture*, Article 14.1 of the *TBT Agreement*, and Article XXII.1 of the GATT 1994 with regard to certain measures taken by the European Communities and their member States which affect products of biotechnology.⁵

1.8 On 19 June 2003, Argentina and the European Communities held the requested consultations, but failed to reach a mutually satisfactory resolution of the matter.

1.9 On 7 August 2003, Argentina requested the establishment of a panel to examine the matter.⁶

¹ WT/DS291/1.

² WT/DS291/23.

³ WT/DS292/1.

⁴ WT/DS292/17.

⁵ WT/DS293/1.

⁶ WT/DS293/17.

D. ESTABLISHMENT AND COMPOSITION OF THE PANEL

1.10 At its meeting of 29 August 2003, the Dispute Settlement Body established a single panel pursuant to the requests of the United States in document WT/DS291/23, Canada in document WT/DS292/17 and Argentina in document WT/DS293/17, in accordance with Articles 6 and 9 of the DSU.

1.11 At that meeting, the Parties to the dispute also agreed that the Panel should have standard terms of reference. The terms of reference are, therefore, the following⁷:

"To examine, in the light of the relevant provisions of the covered agreements cited by the United States in document WT/DS291/23, Canada in document WT/DS292/17 and Argentina in document WT/DS293/17, the matter referred to the DSB by the United States, Canada and Argentina in those documents, and to make such findings as will assist the DSB in making the recommendations or in giving the rulings provided for in those agreements."

1.12 On 23 February 2004, the United States, Canada and Argentina requested the Director-General to determine the composition of the Panel, pursuant to paragraph 7 of Article 8 of the DSU. On 4 March 2004, the Director-General composed the Panel as follows⁸:

Chairperson: Mr Christian Häberli

Members: Mr Mohan Kumar
Professor Akio Shimizu

1.13 Argentina (in respect of the United States' and Canada's complaints), Australia, Brazil, Canada (in respect of the United States' and Argentina's complaints), Chile, China, Colombia, El Salvador, Honduras, Mexico, New Zealand, Norway, Paraguay, Peru, Chinese Taipei, Thailand, Uruguay and the United States (in respect of Canada's and Argentina's complaints) have reserved their rights to participate in the Panel proceedings as Third Parties.

1.14 On 8 March 2004 the Panel received a preliminary written submission from the European Communities requesting the Panel to make an early ruling to the effect that the requests for the establishment of a panel made respectively, by the United States, Canada and Argentina fail to comply with the requirements of Article 6.2 of the DSU.

1.15 The Panel requested the United States, Canada and Argentina to provide a preliminary written submission in response to the European Communities' preliminary submission. On 24 March 2003, the Panel received preliminary written submissions from the United States, Canada and Argentina.

1.16 On 8 April 2004, the Panel issued a "Preliminary Ruling by the Panel on the Consistency of the Complaining Parties' Panel Requests with Article 6.2 of the DSU" finding that the complaining parties' requests for the establishment of a panel of 7 August 2004 (documents WT/DS291/23, WT/DS292/17 and WT/DS293/17) met the requirements of Article 6.2 of the DSU.

⁷ WT/DSB/M/155.

⁸ WT/DS291/24, WT/DS292/18 and WT/DS293/18.

E. PANEL PROCEEDINGS

1.17 The Panel met with the Parties on 2-4 June 2004 for the first substantive meeting. It met with the Third Parties in a special session on 3 June 2004. The Panel in this case also sought the advice of scientific and technical experts and met with them in the presence of the Parties on 17-18 February 2005. The Panel held the second substantive meeting with the Parties on 21-22 February 2005.

1.18 On 7 February 2006, the Panel issued its interim reports to the Parties. On 17 March and 19 April 2006, the Panel received comments from the Parties on the interim reports. None of the Parties requested an interim review meeting. On 10 May 2006, the Panel issued its final reports to the Parties.

II. FACTUAL ASPECTS

2.1 This dispute concerns two distinct matters: (1) the operation and application by the European Communities of its regime for approval of biotech products; and (2) certain measures adopted and maintained by EC member States prohibiting or restricting the marketing of biotech products.

2.2 "Biotech products" in this dispute refers to plant cultivars that have been developed through recombinant deoxyribonucleic acid ("recombinant DNA") technology.

2.3 The European Communities' regime for approval of biotech products consists of two primary legal instruments: EC Directive 2001/18 (hereinafter "Directive 2001/18")⁹ (and its predecessor, EC Directive 90/220 (hereinafter "Directive 90/220")¹⁰) governing "the deliberate release into the environment of genetically modified organisms" and EC Regulation 258/97 (hereinafter "Regulation 258/97")¹¹ regulating "novel foods and novel food ingredients".

2.4 The objective of the EC regime is to protect human health and the environment. To achieve these objectives, the applicable legislation requires the European Communities to conduct a case-by-case evaluation of the potential risks biotech products might pose to human health and the environment. On the basis of that evaluation, the marketing of a particular biotech product is either approved or not. The relevant legal instruments outline the administrative procedure to be conducted in the event a company seeks to obtain approval to place a biotech product on the market and the standards by which an application for approval is evaluated.

2.5 The measures maintained by EC member States are linked to the EC regime for approval of biotech products. The above-noted EC legislation – Directive 2001/18 (and its predecessor, Directive 90/220) governing "the deliberate release into the environment of genetically modified organisms" and Regulation 258/97 regulating "novel foods and novel food ingredients" – under certain conditions permits EC member States to adopt "safeguard" measures in respect of biotech products that have obtained approval for EC-wide marketing. More particularly, individual EC member States may provisionally restrict or prohibit the use and/or sale of an approved biotech product in their own territory if these member States have detailed grounds for considering, based on new or additional information or scientific knowledge, that the particular product poses a risk to human health or the environment. In cases where a member State adopts a "safeguard" measure, it must inform other EC member States and the Commission of the action it has taken and a decision on

⁹ Directive 2001/18/EC, O.J. 17.4.2001 L106/1.

¹⁰ Directive 90/220/EEC, O.J. 8.5.1990 L117/15, preamble, as amended by Directive 94/15/EC, O.J. 22.4.1994 L103, and Directive 97/35/EC, O.J. 27.6.1997 L169.

¹¹ Regulation (EC) No. 258/97, O.J. 14.2.1997 L043/1.

the member State "safeguard" measure must then be taken at Community level within a prescribed time period.

III. COMPLAINING PARTIES' REQUESTS FOR FINDINGS AND RECOMMENDATIONS

3.1 Below is a summary of the complaining parties' requests for findings and recommendations as set out in their requests for the establishment of a panel.

A. UNITED STATES

3.2 The United States, in its request for establishment of a panel¹², requests the Panel to find that the measures at issue are inconsistent with:

- (a) Articles 2.2, 2.3, 5.1, 5.2, 5.5, 5.6, 7 and 8, and Annexes B(1), B(2), B(5), C(1)(a), C(1)(b), and C(1)(e) of the *SPS Agreement*;
- (b) Articles I:1, III:4, X:1, and XI:1 of the GATT 1994;
- (c) Article 4.2 of *Agreement on Agriculture*; and
- (d) Articles 2.1, 2.2, 2.8, 2.9, 2.11, 2.12, 5.1.1, 5.1.2, 5.2.1, 5.2.2, 5.6 and 5.8 of the *TBT Agreement*.

3.3 The United States also requests the Panel to find that the measures at issue nullify or impair benefits accruing to the United States directly or indirectly under the cited agreements.

B. CANADA

3.4 Canada, in its request for establishment of a panel¹³, requests the Panel to find that the measures at issue are inconsistent with:

- (a) Articles 2.2, 2.3, 5.1, 5.2, 5.5, 5.6, 7, 8, and paragraphs 1, 2 and 5 of Annex B, and paragraphs 1(a), 1(b), 1(c), and 1(e) of Annex C of the *SPS Agreement*;
- (b) Articles 2.1, 2.2, 2.8, 2.9, 2.11, 2.12, 5.1, 5.2.1, 5.2.2, 5.2.3, 5.6 and 5.8 of the *TBT Agreement*;
- (c) Articles I:1, III:4, X:1 and XI:1 of the GATT 1994;
- (d) Article 4.2 of the *Agreement on Agriculture*.

3.5 Canada also requests the Panel to find that that the measures at issue nullify or impair benefits accruing to Canada directly or indirectly under the cited agreements. Canada further requests the Panel to find that the measures at issue nullify and impair benefits accruing to Canada in the sense of Article XXIII:1(b) of the GATT 1994.

¹² WT/DS291/23.

¹³ WT/DS292/17.

C. ARGENTINA

3.6 Argentina, in its request for establishment of a panel¹⁴, requests the Panel to find that the measures at issue are inconsistent with:

- (a) Articles 2.2, 2.3, 5.1, 5.2, 5.5, 5.6, 7, 8 and 10.1 and Annexes B(1) and (5) and C(1)(a), (b), (c), (d) and (e) of the *SPS Agreement*;
- (b) Article 4.2 of the *Agreement on Agriculture*;
- (c) Articles I.1, III.4, X.1, X.3(a) and XI.1 of the GATT 1994;
- (d) Articles 2.1, 2.2, 2.8, 2.9, 2.11, 5.1, 5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.6, 5.8 and 12 of the *TBT Agreement*.

3.7 Argentina also requests the Panel to find that the measures at issue nullify or impair the benefits accruing to Argentina under cited agreements.

IV. ARGUMENTS OF THE PARTIES

4.1 The arguments of the parties are set out in their written and oral submissions to the Panel and in their answers to questions. The parties' arguments as presented in their submissions are summarized in this Section.¹⁵

A. PRELIMINARY WRITTEN SUBMISSION OF THE EUROPEAN COMMUNITIES

1. Introduction

4.2 The European Communities submits that the requests for the establishment of a panel (hereinafter "Requests") made respectively by the United States¹⁶, Canada¹⁷ and Argentina¹⁸ fail to comply with the requirements of Article 6.2 of the DSU.

4.3 The Requests in the present case neither identify the specific measures at issue nor do they provide a brief summary of the legal basis of the complaint sufficient to present the problem clearly. These are two requirements provided by Article 6.2 of the DSU which form the basis for the panel's term of reference under Article 7.1 of the DSU (*US – Carbon Steel* para. 125). The purposes of these two requirements are: to define the scope of the dispute and to serve the due process objective by notifying the parties and third parties of the nature of the complainant's case (*ibidem*, para. 126).

4.4 Given the deficiencies pointed out above, neither can the Panel's jurisdiction be clearly defined, nor is the European Communities able to properly prepare its defence. Taking into consideration that these are two fundamental requirements in dispute settlement proceedings, it is of the utmost importance that the issues raised by the Requests are clarified at the earliest juncture possible. The European Communities, therefore, respectfully requests the Panel to issue a preliminary ruling on Article 6.2 in these proceedings.

¹⁴ WT/DS293/17.

¹⁵ The summaries of the parties' arguments below are based on the executive summaries submitted by the parties where the parties made available such summaries to the Panel.

¹⁶ WT/DS291/23.

¹⁷ WT/DS292/17.

¹⁸ WT/DS293/17.

2. The Panel requests fail to identify the "specific measure at issue"

4.5 The Requests do not comply with Article 6.2 in that they fail to identify the specific measure at issue. As the Panel in *Canada – Wheat Exports and Grain Imports* has stated, a panel request "must establish the identity of the precise measures at issue."¹⁹ The Panel has underlined the importance of the "specificity" requirement by pointing to the difference in wording between Article 6.2 and Article 4.4 of the DSU.

4.6 Whether the actual terms used in a panel request are sufficiently precise to "identify the measure at issue" under Article 6.2, according to the Appellate Body depends upon whether they satisfy the purposes of the requirements of that provision (jurisdiction and due process) and must be determined on a case by case basis.²⁰

4.7 Applying these principles, the Panel, in the above case *Canada – Wheat Exports and Grain Imports*, has provided two further indications on how to assess "specificity" putting a particular emphasis on the safeguarding of due process rights.²¹

4.8 First, the panel held that, while it is not necessarily required for a request to explicitly specify measures of general application by name, date of adoption etc., "sufficient information must be provided in the request for establishment of a panel itself that effectively identifies the precise measures at issue."²² Sufficiency of the information depends, on whether it serves the purposes of Article 6.2 (in particular due process objective) and on specific circumstances of each case (*ibidem*, para. 20).

4.9 Second, the Panel had made it clear that it considered due process to require that the complaining party fully assumed the burden of identifying the specific measures under challenge namely by bearing the risk of any lack of precision in the panel request (para. 25).

(a) The "measures" as described in the Requests

4.10 The Requests refer to a "moratorium" (United States, Canada) or "*de facto* moratorium" (Argentina) which the European Communities allegedly has applied (United States, Argentina) or maintained (Canada) since October 1998.²³ They then each list the "measures at issue", describing in ways similar to each other, two distinct measures, namely, on the one hand the suspension by the European Communities of approval of biotech products and on the other, the failure by the European Communities to consider for approval applications for the biotech products.²⁴

¹⁹ Panel Report, *Canada – Wheat Exports and Grain Imports*, Preliminary Ruling, para. 14.

²⁰ See also Panel Report, *Canada – Wheat Exports and Grain Imports*, Preliminary Ruling, para. 17.

²¹ The Panel concluded on a violation of the specificity requirement in Article 6.2. It found that the identification of the measure at issue had created "significant uncertainty" regarding the identity of the precise measure at issue thus "impairing the defendant's ability to begin preparing its defence in a meaningful way". See, *ibidem*, para. 28.

²² Panel Report, *Canada – Wheat Exports and Grain Imports*, Preliminary Ruling, para. 19.

²³ The following arguments on the identification of the measure under Article 6.2 of the DSU are without prejudice to any substantive debate on the nature of measures under specific provisions of the relevant applicable agreements.

²⁴ WT/DS291/23, page 1; WT/DS292/17, page 1; WT/DS293/17, page 1.

- (b) Speaking of two distinct measures, suspension and failure to act, without describing them, the requests fail to identify the specific measure at issue

4.11 Although it is clear that the Requests do not attack the European Communities' legislation on genetically modified products as such, but only its application, it is not clear, in what respect the latter is being challenged. All three Requests have in common that they make an explicit distinction between, on the one hand, an alleged "suspension" of the approval process and, on the other hand, an alleged "failure" to act. These are presented as separate measures. None of the Requests, however, contains any explanation or description of what the "suspension" is *as opposed to* the "failure" to proceed in the approval process.

4.12 It is, in particular, the reference to an alleged "suspension" that remains entirely in the dark. One meaning of "suspension" is "the *action* of suspending something."²⁵ The complaining parties may have such an "action" in mind, as might be inferred from the fact that the US request speaks of the European Communities "blocking" the approval process.²⁶ If this is the case, however, the action is not described anywhere. Is there supposed to be a decision or some other kind of normative or executive act, by which the European Communities has proceeded to "suspend"? If so, according to the above standards, the Requests would at least need to contain sufficient information to allow – both the Panel and the defendant – to effectively identify these acts.

4.13 "Suspension", on the other hand, according to the Oxford Dictionary may also mean "the *condition* of being suspended".²⁷ The word, then, would describe a state of being, a situation of "nothing happening". If that is what the complaining parties have in mind, it would seem impossible, however, to distinguish this "measure" from the alleged inaction, which is that of failing to consider/grant approvals. Listing them as two distinct measures would not make sense any longer.

4.14 From the above it can be seen that the Requests create considerable uncertainty which *de facto* shifts the burden of identifying the specific measure under challenge onto the European Communities. If it wants to properly prepare its defence, the European Communities has no choice but to second-guess what the complaining parties might have meant with "suspension" as opposed to "failure to act" taking the risk of being presented with an entirely different reading at a later stage in the proceedings. This situation is irreconcilable with the minimum standards of due process as exemplified by the WTO case law and fails to comply with the requirement in Article 6.2 to identify the specific measures at issue.

3. The Panel requests do not provide a brief summary of the legal basis of the complaint sufficient to present the problem clearly

4.15 The Requests' lack of sufficient specificity in the identification of the measures at issue is coupled with the absence of a brief summary of the legal basis of the complaint sufficient to present the problem clearly, as required by Article 6.2 of the DSU.

4.16 According to the constant jurisprudence of the Appellate Body, this second requirement in Article 6.2 entails that the claims "must all be specified sufficiently in the request for the establishment of a panel in order to allow the defending party and any third parties to know the legal

²⁵ *The New Shorter Oxford English Dictionary*, L. Brown (ed.) (Clarendon Press, 1993), Vol. 2, p. 3162.

²⁶ WT/DS291/23, page 1.

²⁷ *Ibidem*.

basis of the complaint".²⁸ This allows the defending party to "know what case it has to answer and what violations have been alleged so that it can begin preparing its defence" in a meaningful way, and allows it an opportunity to effectively respond to the complaint.²⁹ Furthermore, the panel needs to know what claims are raised by the complaining parties to exercise correctly its jurisdiction since it cannot address claims that have not been made.³⁰

4.17 The significance of this requirement can be better appreciated with regard to the context of Article 6.2 of the DSU. In particular, the European Communities (following the Panel in *Canada – Wheat Exports and Grain Imports*) notes again the difference in the language between Article 4.4 and Article 6.2 of the DSU, that "must be given meaning" (para. 15). The word "indication" used in the former, means "something that indicates or suggests and thus conveys the idea of briefness and allusion. The word "summary" used by the latter however, comes from the Latin word "*summa*" and covers the idea of something "containing all the main points of a matter; dispensing with unnecessary detail. Thus, whilst it is sufficient that a request for consultations mentions the provisions invoked in order to "suggest" what the case could be about, a request for the establishment of a panel must be detailed enough to cover "all the main points of a matter".

4.18 In the present case, all three requests limit the illustration of the legal basis to long lists of provisions of the GATT 1994, the *SPS Agreement*, the *TBT Agreement* and the *Agreement on Agriculture*³¹, without any link being made between the challenged measures and the facts of the case. In other words, the Requests do not make at all clear which obligations are alleged to be violated and which measures are in violation of which obligations. This has impaired the European Communities' ability to understand what the claims in the present case are and, thus, to start preparing its defence in any meaningful way.

(a) The mere listing of provisions is not sufficient in this case

4.19 It is true that the Appellate Body has recognized in *EC – Bananas III* that it may be sufficient for a complaining party "to list the provisions of the specific agreements alleged to have been violated without setting out detailed arguments as to which specific aspects of the measures at issue relate to which specific provisions of those agreements".³² However, it has added that the question as to whether the mere listing meets the standard of Article 6.2 of the DSU must be examined on case-by-case basis, taking into account if the ability of the respondent to defend itself was prejudiced by the fact that the panel request simply lists the provisions (Appellate Body Report, *Korea – Dairy*, para. 127).

4.20 In the same case, the Appellate Body stated that in *EC – Bananas III* it did not purport that a mere listing of the provisions could always suffice to comply with Article 6.2 of the DSU without regard to the particular circumstances of the case (*ibidem*, para. 123). In particular, such a listing will not satisfy the standard of Article 6.2 if the provisions listed establish not single but multiple obligations (*ibidem*, para. 124).

²⁸ Appellate Body Report, *EC – Bananas III*, para. 143.

²⁹ Appellate Body Report, *Thailand – H-Beams*, para. 88. See also, more recently, Panel Report, *Canada – Wheat Exports and Grain Imports*, Preliminary Ruling, para. 29.

³⁰ Appellate Body Report, *EC – Hormones*, para. 156.

³¹ WT/DS291/23, page 2; WT/DS292/17, page 2; WT/DS293/17, page 2.

³² Appellate Body Report, *EC – Bananas III*, para. 141.

4.21 The Requests indicate as legal basis thirty-eight provisions, several of which contain multiple (distinct or parallel) obligations (i.e. Articles 2.2, 2.3, 5.5, 7, 8, and Annex B(5), C(1)(b), of the *SPS Agreement*; Articles 2.9, 5.2.2, 5.6 and 12 of the *TBT Agreement*).

4.22 Added to the provisions which contain a single obligation, the European Communities is faced with alleged violation of thirty-eight different provisions, which altogether contain more than sixty distinct obligations. Furthermore, several of those provisions are either mutually exclusive – such as those contained in the *SPS* and in the *TBT Agreements*³³ – or subordinated – such as those of the GATT 1994 in relation to the ones contained in the other agreements.³⁴ The panel requests do not explain even remotely how the claims would be articulated, for instance, whether all provisions and obligations apply simultaneously to different aspects of the measures, or whether some provisions are listed only subsidiarily. In front of such an uncoordinated array of provisions and obligations, the European Communities has not been able to understand even remotely which are the claims the complaining parties intend to pursue.

(b) No link is made between the provisions listed and the facts of the case

4.23 The fact that the complaining parties have only merely listed the provisions they allege as violated, several of which contain multiple obligations, is made worse by the fact that they have also failed to make any link whatsoever between these provisions and the facts of the case. Where a panel request covers several separate measures, as is the case in the present dispute, it should indicate which provisions may be relevant for the examination of each measure, possibly describing the substantive aspects or the effects of the measures which are allegedly in breach of those provisions. The panel requests do not provide the slightest explanation in that regard. Thus, the European Communities is completely in the dark also about which provisions would have been violated by which measures, in other words about what claims are pursued.

4.24 Even assuming, in fact, that the complaining parties intend to allege a violation of each of the thirty-eight provisions and of the over sixty obligations listed and that the measures at issue were clear – which is not the case –, in order to prepare its defence the European Communities would still have to assess each of the measures indicated against each of the obligations alleged to have been violated. This would result in the preparation of arguments of defence in case of US request for well over three thousands³⁵ hypotheses of different claims.

4.25 In order to facilitate the task of the Panel in assessing what is the acceptable standard of precision for requests under Article 6.2 of the DSU, the European Communities points at some recent cases³⁶, where the United States, Canada and Argentina were also complaining parties. In all of them both measures and claims are clearly and precisely specified.

4. Article 6.2 issues must be decided as early as possible in the proceedings

4.26 Taking into consideration the double purpose of the requirements of Article 6.2 of the DSU, that is defining jurisdiction of the panel and guaranteeing due process, it is evident in the case law that

³³ See Article 1.5 of the *TBT Agreement* and Article 1.4 of the *SPS Agreement*.

³⁴ See the General interpretative note to Annex 1A of the Marrakech Agreement Establishing the WTO.

³⁵ Forty-one applications plus nine safeguard measures applied by the member States of the European Communities equals a number of fifty measures at issue. These must then be multiplied by at least sixty obligations alleged to have been violated. The result is over three thousand!

³⁶ WT/DS295/2 of 22 September 2003; WT/DS277/2 of 4 April 2003; WT/DS268/2 of 4 April 2003

it is of the outmost importance that issues arising in regard of these requirements are decided as early as possible.

(a) The Panel has to be able to establish the limits of its jurisdiction

4.27 If a claim is not properly before a panel, it is established practice that the panel declines to examine it.³⁷ As the Appellate Body has made clear in several instances, "[t]he vesting of jurisdiction in a panel is a fundamental prerequisite for lawful panel proceedings" (Appellate Body, *Mexico – Corn Syrup*, para. 36).

4.28 Where the request for the establishment of a panel lacks precision, the panel lacks authority to proceed. It is therefore necessary that, before proceeding, it first establishes where the limits of its jurisdiction are.

4.29 If, as in the case at issue, the Panel Requests are not amended, the scope of the claims which are in front of the Panel will remain entirely unclear. Before proceeding, the Panel must know which of the three thousands hypotheses of claims are the ones actually referred to it.

(b) The European Communities has been unable to start preparing its defence in any meaningful way

4.30 Equally, safeguarding the due process rights of the defendant and possible third parties must be of central concern to the dispute settlement organs. The defendant in order to prepare its defence should know what violations have been alleged and what case it has to answer. The same holds true for member States that want to participate in the proceedings as third parties.³⁸

4.31 Where a request for the establishment of a panel lacks precision, neither the defendant nor third parties can adequately prepare their arguments. A violation of this due process requirement constitutes a fundamental flaw in the proceedings, which must not proceed before the flaw has been remedied.

4.32 In the present case, the lack of specificity of the identification of the measures at issue, coupled with the mere listing of an elevated number of provisions and the absence of co-relation between the two, has so far prevented the European Communities from starting preparing its defence in any meaningful way. The European Communities still – to date – does not know the claims that the complaining parties intend to bring before the Panel. Taking into consideration the very strict deadlines, the European Communities cannot be expected to wait for the first written submission of the complaining parties to start preparing its defence in a case as sensitive and as important as the current one.

(c) The Panel must scrutinize the request to ensure its compliance with Article 6.2

4.33 Because of the fundamental nature of the above requirements in Article 6.2 of the DSU, each Panel must be satisfied that its conditions are fulfilled before assuming jurisdiction over a case. This

³⁷ See, most recently, Panel Report, *US – Carbon Steel*, paras. 8.11-8.12.

³⁸ Appellate Body Report, *Thailand – H-Beams*, para. 88.

should be done very carefully especially because of the DSB practice consisting of the automatic approval of the requests.³⁹

4.34 Panels should deal with such issues, the Appellate Body has ruled, "even if the parties to the dispute remain silent on those issues", "if necessary, on their own motion, in order to satisfy themselves that they have authority to proceed".⁴⁰ *A fortiori* in the present case, where the European Communities as the defending party is submitting such claims to its attention, the Panel must scrutinize the Requests to ensure their compliance with Article 6.2 of the DSU.

(d) The Panel must scrutinize the request as early as possible in panel proceedings

4.35 In *EC – Bananas III*, the Appellate Body has also clarified that the claims, which are to be set out in the Panel request, must be distinguished from the subsequent arguments of the parties in support of such claims. Thus, the former must be specified sufficiently in the request of the panel and the latter cannot be used to "cure" a faulty request (para. 143).

4.36 For this reason the Panel must scrutinize the request to ensure its compliance with Article 6.2 as early as possible in panel proceedings in order to avoid causing prejudice or unfairness to any party or third party.⁴¹ That is also why the European Communities is submitting these issues to the Panel at the earliest possible juncture in time, i.e. immediately after its composition.⁴²

5. Request for preliminary ruling

4.37 For the reasons set out above, the European Communities respectfully requests that the Panel issue a preliminary ruling to the effect that the Requests do not meet the requirements of Article 6.2 of the DSU.

4.38 Since the procedural rules are designed to promote the fair, prompt and effective resolution of trade disputes⁴³ and in order to ensure a speedy resolution of the present dispute, the European Communities would consider it appropriate for the Panel to suggest to the complaining parties to introduce new panel requests in full compliance with Article 6.2 of the DSU to be judged by the same panel. The European Communities would like to note that such a course of action has recently been taken by a panel in another dispute.⁴⁴

B. PRELIMINARY WRITTEN SUBMISSION OF THE UNITED STATES

1. Introduction

4.39 The European Communities offers no basis for its request for a preliminary ruling ("EC Request") that the US panel request in this dispute fails to meet the requirements of Article 6.2 of the DSU. To the contrary, as required by Article 6.2, the US panel request properly "identif[ies] the

³⁹ Appellate Body Report, *US – Carbon Steel*, para. 126, recalling Appellate Body Report, *EC – Bananas III*, para. 142.

⁴⁰ Appellate Body Report, *Mexico – Corn Syrup (Article 21.5 – US)*, para. 36.

⁴¹ Appellate Body Report, *EC – Bananas III*, para. 144.

⁴² Appellate Body Report, *Thailand – H Beams*, para. 95.

⁴³ Appellate Body Report, *US – FSC*, para. 166.

⁴⁴ Panel Report, *Canada – Wheat Exports and Grain Imports*, Preliminary Ruling, para. 65. In this case, the United States indeed introduced a new Panel request (WT/DS276/9), after which the Panel originally established continued to exercise its jurisdiction.

specific measures at issue and provide[s] a brief summary of the legal basis of the complaint sufficient to present the problem clearly."

2. The requirements of Article 6.2 of the DSU

4.40 Article 6.2 of the DSU requires, in relevant part, that a request for the establishment of a panel:

"[I]dentify the specific measures at issue and provide a brief summary of the legal basis of the complaint sufficient to present the problem clearly."

4.41 The EC Request contains a number of quotations from Appellate Body and panel reports, in particular from *Korea – Dairy*⁴⁵ and *EC – Bananas III*⁴⁶, that explain this provision and emphasize its role and importance in dispute settlement. It has entirely missed, however, one aspect of these reports which is critical to the issue now before this Panel: the key distinction between *claims* – which must be included in the panel request – and the *arguments* in support of those claims – which need not be included. As the Appellate Body explained in *EC – Bananas III*:

"In our view, there is a significant difference between the *claims* identified in the request for the establishment of a panel, which establish the panel's terms of reference under Article 7 of the DSU, and the *arguments* supporting those claims, which are set out and progressively clarified in the first written submissions, the rebuttal submissions and the first and second panel meetings with the parties."⁴⁷

4.42 Furthermore, the Appellate Body in *EC – Bananas III* made clear that a panel request may adequately state a claim if the request simply cites the pertinent provision of the WTO agreement:

"We accept the Panel's view that it was sufficient for the complaining parties to list the provisions of the specific agreements alleged to have been violated without setting out detailed arguments as to which specific aspects of the measures at issue relate to which specific provisions of those agreements."⁴⁸

4.43 The Appellate Body confirmed this reading in *Korea – Dairy*. In that dispute, the problem with the panel request was that it cited too broadly to Article XIX of the GATT 1994 and various articles of the *Agreement on Safeguards*, all of which contained numerous sub-articles, so that it was difficult to determine which specific obligations in those provisions were at issue. The US panel request in this dispute, by contrast, cites to specific provisions of the WTO agreements at issue, and cannot be said to suffer a similar defect.

4.44 The European Communities also fails to note that *even if* a panel request is insufficiently detailed "to present the problem clearly," the Panel is not automatically deprived of jurisdiction over the matter. Rather, the Appellate Body has found that a panel must examine, based on the "particular circumstances of the case," whether the defect has prejudiced the ability of the responding party to defend itself. As the Appellate Body explained in *Korea – Dairy*:

⁴⁵ Appellate Body Report, *Korea – Dairy*.

⁴⁶ Appellate Body Report, *EC – Bananas III*.

⁴⁷ Appellate Body Report, *EC – Bananas III*, para. 141.

⁴⁸ *Id.*

"In assessing whether the European Communities' request met the requirements of Article 6.2 of the DSU, we consider that, in view of the particular circumstances of this case and in line with the letter and spirit of Article 6.2, the European Communities' request should have been more detailed. However, Korea failed to demonstrate to us that the mere listing of the articles asserted to have been violated has prejudiced its ability to defend itself in the course of the Panel proceedings. Korea did assert that it had sustained prejudice, but offered no supporting particulars in its appellant's submission nor at the oral hearing. We, therefore, deny Korea's appeal relating to the consistency of the European Communities' request for the establishment of a panel with Article 6.2 of the DSU."⁴⁹

4.45 Therefore, in evaluating claims regarding whether a panel request "presents the problem clearly," a Panel must consider the particular circumstances of the case, including whether the defending party has been prejudiced.

3. The European Communities' assertion that the US panel request does not identify the "specific measures at issue" is incorrect

4.46 The European Communities appears to have two concerns with the identification of the measures subject to this dispute. Neither of these concerns has merit.

4.47 First, the European Communities claims that, "It is, in particular, the reference [in the panel request] to an alleged 'suspension' that remains entirely in the dark."⁵⁰ Even without any context, and on the plain language of the panel request, it is difficult to see how the concept of a "suspension" of the consideration and granting of biotech approvals is at all ambiguous. But in light of well-known statements of EC officials acknowledging the existence of a *de facto* moratorium, the European Communities' claim that it is "in the dark" on the meaning of a "suspension" is not credible.

4.48 Along these same lines, the European Communities poses the following question:

"Is there supposed to be a decision or some other kind of normative or executive act, perhaps a moratorium legislation of the kind New Zealand had, by which the European Communities has proceeded to 'suspend'?"

Although the United States is unaware of any single executive decree or legislative act through which the moratorium has been implemented, such decree or act would be within the scope of the covered measures. Where the European Communities in this dispute denies the existence of a moratorium – a moratorium nonetheless acknowledged by its own officials – it cannot in turn try to profit from its lack of transparency by arguing that the complaining parties have not identified the moratorium with sufficient specificity.

4.49 Second, the European Communities claims that the US panel request is fatally flawed because it uses both the phrase "a suspension of consideration" and "a failure to consider". The European Communities does not explain why these two different wordings introduce any ambiguity concerning the measures subject to the request. Moreover, in the context of the panel request, the reason for using these two different wordings is quite clear.

⁴⁹ *Id.*, para. 131.

⁵⁰ EC request, para. 22.

4.50 The first phrase – suspension of consideration – is used to describe the European Communities' across-the-board moratorium affecting all biotech products:

"(1) as described above, the suspension by the European Communities of consideration of applications for, or granting of, approval of biotech products."

The second phrase – failure to consider – is used to describe the European Communities' conduct as it affects the specific products identified in the annexes to the panel request:

"(2) as described above, the failure by the European Communities to consider for approval applications for the biotech products mentioned in Annexes I and II to this request."

These are simply two different wordings for the same concept -- the word "suspension" fits better with the European Communities' conduct as it affects all biotech applications, while the phrase "failure to consider" fits better with specific applications. The European Communities does not and cannot explain how these different wordings amount to a failure to identify the specific measures at issue.

4.51 For the above reasons, the European Communities has presented no reason for finding that the US panel request does not meet the requirement of Article 6.2 to identify the specific measures at issue.

4. Contrary to the European Communities' allegations, the US panel request provides a brief summary of the legal basis of the complaint sufficient to present the problem clearly

4.52 The US panel request, which lists the specific provisions of the *SPS Agreement*, *TBT Agreement*, *Agreement on Agriculture*, and GATT 1994 alleged to be violated, provides a brief summary of the legal basis of the complaint sufficient to present the problem clearly, as required by Article 6.2.

4.53 The Appellate Body has made clear on several occasions that a panel request may adequately summarize the legal basis of the complaint under Article 6.2 by simply citing the pertinent provisions of the WTO Agreement.⁵¹ The European Communities cites *Korea – Dairy*, in which the Appellate Body stated that there may be circumstances in which a "listing of treaty articles would not satisfy the standard of Article 6.2."⁵² But in that proceeding the articles cited had multiple paragraphs, many of which had their own distinct obligations: for instance, the panel request cited Article XIX of the GATT 1994, containing three sections and five paragraphs, each with at least one distinct obligation, and Article 12 of the *Agreement on Safeguards*, which spans two pages and contains 11 paragraphs.⁵³

4.54 By contrast, the US panel request in this dispute lists specific provisions of the *SPS Agreement*, *TBT Agreement*, *Agreement on Agriculture*, and the GATT 1994. Where an article consisted of more than one paragraph, the US panel request specifically identified the particular paragraph number. Moreover, where a paragraph has subparagraphs, in most cases the panel request

⁵¹ E.g., Appellate Body Report, *EC – Bananas III*, para. 141; Appellate Body Report, *Korea – Dairy*, para. 124.

⁵² Appellate Body Report, *Korea – Dairy*, para. 124.

⁵³ *Id.*

goes on to specify the specific subparagraphs.⁵⁴ Unlike in the case of *Korea – Dairy*, there are no circumstances in this dispute that would render citation to the relevant specific provision of the WTO agreement insufficient under Article 6.2.

4.55 Previous panels and the Appellate Body have been very careful to distinguish between the claims that must be made in a panel request under Article 6.2 -- *i.e.*, the brief summary of the legal *basis* for the complaint sufficient to present the problem clearly -- and the *arguments* supporting those claims. The claims must be set forth in the panel request. The arguments do not. As the Appellate Body stated in *EC – Bananas III*:

"We accept the Panel's view that it was sufficient for the complaining parties to list the provisions of the specific agreements alleged to have been violated without setting out detailed arguments as to which specific aspects of the measures at issue relate to which specific provisions of those agreements. In our view, there is a significant difference between the *claims* identified in the request for the establishment of a panel, which establish the panel's terms of reference under Article 7 of the DSU, and the *arguments* supporting those claims, which are set out and progressively clarified in the first written submissions, the rebuttal submissions and the first and second panel meetings with the parties."⁵⁵

4.56 In this dispute, the European Communities is not faulting the United States for failing to set out the legal *basis* for the complaint. It is faulting the United States, incorrectly, for not including its *arguments* in support of that basis.

4.57 The European Communities presents two lines of argument why in this case the US panel request must have gone beyond listing the claims, to also include the arguments in support of those claims.

4.58 First, the European Communities counts up the number of provisions listed by the United States, and proposes that this number is somehow too high to be covered by the provision actually found in the text of the DSU, namely that a panel request that specifies the claims is in compliance with Article 6.2 of the DSU.

4.59 As an initial matter, the United States notes that it does not agree with the European Communities' count of the number of obligations covered in the US panel request. For example, the European Communities argues that Article 7 of the *SPS Agreement* includes two separate obligations. The second Article 7 obligation, however, is to comply with the obligations in Annex B of the *SPS Agreement*, and the US panel request specifies the specific provisions of Annex B alleged to be violated. Accordingly, the European Communities engages in double-counting by counting both the general obligation to comply with Annex B, and also the specific provisions of Annex B listed in the US panel request.

4.60 Moreover, the simple reason that the US panel request covers a number of obligations is that the European Communities' decision to adopt, without transparency, a *de facto* moratorium on the approvals of important agricultural products understandably results in a violation of several provisions

⁵⁴ The only exceptions are Annex B(5) of the *SPS Agreement*, and Articles 2.9 and 5.6 of the *TBT Agreement*, each of which contain four subparagraphs establishing related transparency obligations. The specific subparagraphs were not identified because the United States considers the EC measures to be inconsistent with each one.

⁵⁵ Appellate Body Report, *EC – Bananas III*, para. 141.

of the WTO Agreement. Article 6.2 of the DSU does not impose an entirely different standard on a panel request on the basis that the defending party has engaged in multiple violations of the WTO Agreement.

4.61 In addition, other than pointing to the number of obligations covered by the US panel request, the European Communities does not explain how it is confused, or in any way prejudiced, by the panel request. Surely, the European Communities cannot claim, for example, that it fails to understand (and thus is unable to begin to defend itself against) the proposition that a general moratorium on the approval of biotech products might violate the obligation in Article 5.1 of the *SPS Agreement* that SPS measures must be based on risk assessments. Nor, for example, can the European Communities claim not to understand (and thus not to be able to begin to defend itself against) the proposition that a 5-year moratorium would be inconsistent with the requirement in Annex C(1)(a) of the *SPS Agreement* to undertake and complete procedures to ensure the fulfilment of SPS measures "without undue delay."

4.62 Finally, the European Communities itself acknowledges that "several of those provisions [cited in the panel requests] are either mutually exclusive – such as those contained in the *SPS Agreement* and the *TBT Agreement* – or subordinated – such as those of the GATT 1994 in relation to the ones contained in the other agreements."⁵⁶ In the consultations and at the meetings of the DSB, the United States has made clear that it considers the moratorium to be an SPS measure. The European Communities, however, has refused to even acknowledge the existence of the moratorium, much less to acknowledge that the moratorium falls within the scope of the *SPS Agreement*. It is for this reason that the complaining parties in their panel requests have been required to cite both SPS provisions and the corresponding provisions of the *TBT Agreement*. In these circumstances, it is difficult to understand how the European Communities could claim any confusion or prejudice from citing provisions of both the *SPS Agreement* and *TBT Agreement*.

4.63 Second, the European Communities suggests that the "common practice" is for panel requests to go beyond stating the claims to laying out the arguments in support of those claims. The European Communities does not, however, even begin to explain how a "practice" could alter the textual requirements of Article 6.2 of the DSU, nor does it attempt to reconcile its suggestion with the fact that the panel request in *EC – Bananas III*⁵⁷ (which the Appellate Body considered to have been consistent with Article 6.2) did not set out the complaining parties' arguments in support of their claims. Furthermore, the European Communities gives no real basis for its assertion of a "practice"; it mentions exactly three panel requests, when in fact, as of 31 October 2003, there had been **119** panels established.⁵⁸ Certainly, citation to panel requests in such a tiny fraction of cases would not be sufficient to establish a "practice" of any kind.⁵⁹

4.64 In short, the European Communities has not presented any reasons why the US panel request, which clearly specifies the claims in this dispute, should be found inconsistent with the requirements of Article 6.2 of the DSU.

⁵⁶ EC Request, para. 40.

⁵⁷ WT/DS27/6.

⁵⁸ *Statistical Information on Recourse to WTO Dispute Settlement Procedures (1 January 1995 – 31 October 2003): Background Note by the Secretariat*, Job(03)/225, circulated 11 December 2003, part III(A).

⁵⁹ The United States notes that the European Communities has in any event not followed any such "practice" itself; see, e.g., the panel request in *US – 1916 Act*, WT/DS136/2, in which the European Communities did nothing more than provide citations to, and cursory paraphrases of, provisions of the WTO Agreement.

5. The US panel request does not prejudice the ability of the European Communities to defend itself

4.65 In *Korea – Dairy*, the Appellate Body denied Korea's Article 6.2 claim *in toto* because, although it had asserted prejudice, Korea offered no supporting particulars.⁶⁰ The European Communities does assert that it is prejudiced by the US panel request, but only in the vaguest and most conclusory manner.

4.66 The European Communities' only explanation of its alleged prejudice is that:

"[T]he lack of specificity of the identification of the measures at issue, coupled with the mere listing of an elevated number of provisions and the absence of co-relation between the two, has so far prevented the European Communities from starting preparing its defence in any meaningful way."⁶¹

4.67 This argument, however, is nothing more than a restatement of its argument, refuted above, that the request is insufficiently detailed with respect to actual arguments to support the legal basis of the complaint. In light of the Appellate Body's reasoning in *Korea – Dairy*, such a mere restatement is plainly insufficient to establish prejudice. If lack of detail in the panel request automatically meant "prejudice," there would be no need for a "prejudice" analysis.

4.68 Moreover, the United States finds it hard to accept that the European Communities has not already begun to "prepare its defence in a meaningful way." To be specific, is the European Communities arguing that it has not already begun to develop explanations of why it denies the existence of a moratorium despite the statements of EC officials to the contrary; of why no new biotech products have been approved for over 5 years if there has been no moratorium; and of how such a moratorium is consistent with the substantive, procedural and transparency obligations of the *SPS Agreement*? The European Communities in its ruling request does not make such claims, and, indeed, could not credibly do so.

4.69 Accordingly, even if the European Communities had succeeded in demonstrating that the US panel request does not meet the requirements of Article 6.2 of the DSU, which it has not, the European Communities has offered nothing to suggest that it has been prejudiced.

6. The European Communities failed to raise its Article 6.2 concerns at the earliest possible opportunity

4.70 Finally, the European Communities fails to recognize that procedural objections must be raised at the earliest possible opportunity, and not for the first time in a ruling request filed after the composition of the panel.⁶² In the *US – FSC* dispute, the United States requested a preliminary ruling that a claim be dismissed because of an inadequacy in the consultation request. The panel rejected that request, and the Appellate Body upheld that rejection, stating,

"It seems to us that, by engaging in consultations on three separate occasions, and not even raising objections in the DSB meetings at which the request for establishment of a panel was on the agenda, the United States acted as if it had accepted the establishment of the panel in this dispute, as well as the consultations preceding such

⁶⁰ Appellate Body Report, *Korea – Dairy*, para. 131.

⁶¹ EC Request, para. 50.

⁶² Appellate Body Report, *US – FSC*, para. 165.

establishment. In the circumstances, the United States cannot now, in our view, assert that the European Communities' claims ... should have been dismissed."⁶³

4.71 Likewise, at no time prior to the composition of this Panel did the European Communities so much as intimate that it considered the panel request in any way deficient, waiting until after the panel was composed to offer its objection. In upholding the panel's rejection of the US request for a preliminary ruling in *US – FSC* under very similar circumstances, the Appellate Body stated, "The procedural rules of the WTO dispute settlement system are designed to promote, not the development of litigation techniques, but simply the fair, prompt and effective resolution of trade disputes."⁶⁴ This Panel should reject the European Communities' effort to avoid the fair, prompt and effective resolution of this dispute through its groundless – and untimely – objections to the US panel request.

C. PRELIMINARY WRITTEN SUBMISSION OF CANADA

1. Introduction

4.72 Canada's panel request properly "identif[ies] the specific measures at issue and provide[s] a brief summary of the legal basis of the complaint sufficient to present the problem clearly." Not only has Canada adequately identified and described the specific measures, the European Communities has no justification for professing any surprise or confusion as to the nature of these measures. The European Communities is really asking this Panel to require Canada to identify, not the specific measures, but the specific evidence that Canada intends to raise in this proceeding.

4.73 The European Communities is also asking this Panel to read into Article 6.2 a requirement that is not there and that the Appellate Body has specifically rejected, namely, that Canada is obligated to summarize specific legal arguments to be presented in its first written submission. The Appellate Body has already rejected this approach, and this Panel should do so as well. Furthermore, not only does the European Communities misrepresent the extent of the complexity of the provisions cited by Canada in its panel request, the European Communities also attempts to import from the *Anti-Dumping Agreement* a standard into Article 6.2 that is not supported by the text of that provision.

4.74 Lastly, the European Communities does not provide any evidence or rationale to support a claim that it has been prejudiced in any way by Canada's panel request. The European Communities is fully aware of the matters referenced in Canada's panel request, and has had ample time to begin to prepare a defence. If it has failed to do so, the causes of that failure cannot be found in Canada's panel request.

4.75 In sum, the EC Request is without merit. It appears to be nothing more than the kind of "litigation technique" that the Appellate Body firmly rejected in *US – FSC*.

2. Requirements of Article 6.2 of the DSU

4.76 The EC Request contains a number of quotations from Appellate Body and panel reports that explain Article 6.2 and emphasize its role and importance in dispute settlement. However, it fails to reflect one aspect which is critical to the issues before this Panel: the key distinction between the claims – which must be included in the panel request – and the arguments in support of those claims – which need not be included.

⁶³ *Id.*

⁶⁴ *Id.*, para. 166.

4.77 Furthermore, with respect to the requirement for a panel request to provide a "brief summary of the legal basis of the complaint," the Appellate Body has made it clear that it may be sufficient for the purposes of Article 6.2 for a panel request to simply cite the pertinent provision of the WTO agreement. The Appellate Body has also made it clear that whether such a listing is sufficient will depend on the circumstances of each case.

4.78 Finally, the jurisprudence has established that, even where a panel request does not "present the problem clearly," the panel is not automatically deprived of jurisdiction over the matter. Rather, the panel must examine, based on the "particular circumstances of the case," whether the defect has prejudiced the ability of the responding party to defend itself.

4.79 Therefore, in evaluating claims as to whether a panel request presents the problem clearly, the Panel must consider the particular circumstances of the dispute, including whether the responding party has been prejudiced.

3. Canada's Panel request identifies the "specific measure at issue" as required by Article 6.2 of the DSU

4.80 As set out in Canada's panel request, the specific measures at issue are:

"[T]he general suspension by the EC of its own processes for the consideration of applications for, and the granting of, approval for biotech products;

the failure by the EC to consider or approve, without undue delay, applications for approval of the products identified in Annex I; and

the national measures identified in Annex II prohibiting the importation, marketing or sale of the specified EC-approved biotech products."

4.81 Because the European Communities has not asserted a failure on the part of Canada to identify with sufficient precision the second and third categories of measures listed in Canada's panel request, Canada assumes that the European Communities does not dispute that these measures have been identified with sufficient precision.

(a) The moratorium is identified with sufficient precision

4.82 The reference to "the general suspension by the EC of its own processes for the consideration of applications for, and the granting of, approval for biotech products" (hereinafter "moratorium") should be read in conjunction with the second paragraph of Canada's panel request. In that paragraph, Canada states that since October 1998, the European Communities has maintained a moratorium on the approval of biotech products. It is clear that the phrase "the general suspension by the EC of its own processes for consideration of applications for, and the granting of, approval for biotech products" is a more detailed description of the "moratorium" to which Canada earlier refers. Canada clearly identifies the relevant approval legislation for biotech products in footnote 1 to Canada's panel request.

4.83 In addition, Canada's panel request sets out specific examples of applications for approval of biotech products, including a brief description of the actions taken to block their consideration or approval. The repeated failures by the European Communities to consider or approve these applications are both cited as examples of the moratorium (in the second paragraph of the panel request) and as separate measures covered by the panel request. Thus, the phrase "general suspension

by the EC of its own processes for consideration of applications for, and the granting of, approval for biotech products" when read in the light of the second paragraph of the panel request, sufficiently identifies the "specific measure at issue."

4.84 The assertion by the European Communities that it is unable to identify the precise measure at issue is difficult to understand. The existence of the moratorium has been widely recognized and discussed by EC officials since the Declaration by five EC member States at the 2194th Council Meeting of EC Environment Ministers in June 1999.

4.85 Numerous EC officials, including Commissioners Wallström and Byrne, have publicly acknowledged the existence of the moratorium. Moreover, as the European Communities is well aware, no biotech products have been approved under the relevant EC legislation since October 1998. Thus, it is disingenuous for the European Communities to claim to be unable to identify the measure at issue.

4.86 What the European Communities is really seeking in its request is pre-submission discovery of the evidence that Canada will adduce in its first written submission. However, under Article 6.2, there is no requirement that a complaining party must set out the evidence that will be adduced to support the measure or the claims made in the panel request.

4.87 Canada agrees that what can be considered a "specific measure" will depend on the circumstances of the particular case, including the characteristics of the measure in question.

4.88 Unlike measures typically at issue in WTO dispute settlement, the moratorium has neither been formally adopted nor published promptly as required by Annex B of the *SPS Agreement* and Article X:1 of the GATT 1994. Had the European Communities adopted the moratorium as a formal legal measure and complied with the transparency requirements of the *SPS Agreement* and the GATT 1994, Canada would have been in a position to identify the particulars suggested by the European Communities in paragraph 22 of its Request. It is only because of the European Communities' own lack of transparency that Canada cannot provide the information the European Communities is demanding. The European Communities should not be able to use its own lack of transparency as a shield against a WTO challenge.

4. Canada's panel request provides "a brief summary of the legal basis of the complaint sufficient to present the problem clearly" as required by Article 6.2

(a) In view of the circumstances surrounding this case, Canada's listing of the relevant provisions complies with the requirements of Article 6.2

4.89 Whether merely listing the provisions of the specific agreements alleged to have been violated is sufficient for the purposes of Article 6.2 must be decided on a case-by-case basis, taking into account all of the circumstances surrounding that case. In the circumstances of this case, the listing of the treaty provisions alleged to have been violated is sufficient to present the problem clearly.

4.90 First, from the standpoint of the so-called multiplicity of the listed obligations, the EC Request recognizes that the majority of the provisions listed by Canada contain single obligations. While some of the provisions contain more than one obligation, this fact alone does not preclude their simple listing from being sufficient to present the problem clearly.

4.91 For instance, the European Communities notes that Canada has made claims with respect to paragraph 5 of Annex B of the *SPS Agreement*, and Articles 2.9 and 5.6 of the *TBT Agreement*.

According to the European Communities these three provisions contain twelve separate obligations altogether. However, a review of these provisions makes it clear that they reflect essentially the same four obligations albeit being imposed in three different contexts. The same holds true for the five obligations the European Communities alleges are found in paragraph 1(b) of Annex C of the *SPS Agreement* and Article 5.2.2 of the *TBT Agreement*. When one considers that the *SPS Agreement* and the *TBT Agreement* are alternative agreements the true nature of the burden placed upon the European Communities to understand Canada's claims is significantly lighter than the European Communities would have the Panel believe.

4.92 Furthermore, the European Communities notes that Article 2.2 of the *SPS Agreement* contains three distinct obligations. While this may be true, the European Communities fails to mention that, according to the jurisprudence, the three obligations found in Article 2.2 are more general expressions of the obligations found in Articles 5.1, 5.2 and 5.6 of the *SPS Agreement*. Thus, claims raised with respect to these three articles are essentially the same claims as those raised with respect to Article 2.2. The same holds true for Articles 2.3 and 5.5. Surprisingly, the European Communities appears to have the impression that Canada is making a claim with respect to the obligation in Article 5.5 to cooperate in the development of guidelines with respect to the practical implementation of that article. There is nothing in the description of the measures in Canada's panel request to suggest that this is part of Canada's claim.

4.93 The European Communities also lists Articles 7 and 8 of the *SPS Agreement* as containing multiple obligations. A review of these two provisions makes it clear, however, that they simply establish general obligations on the WTO Members to meet the specific requirements of Annexes B and C. The fact that Canada's panel request specifically mentions paragraphs 1, 2 and 5 of Annex B, and paragraphs 1(a), 1(b), 1(c), and 1(e), of Annex C, makes it clear that the inclusion of Articles 7 and 8 cannot be taken to mean that Canada is claiming a general violation of Annexes B and C. If that were the case, Canada's specific references to the listed paragraphs would be redundant.

4.94 In sum, there is nothing in the DSU or the jurisprudence to suggest that listing many provisions necessarily requires any more detail than listing relatively few provisions. Also, the European Communities' complaint about being faced by multiple obligations does not stand up to closer scrutiny, or provide support for its claim that Canada's panel request does not provide a brief summary of the legal basis of the complaint sufficient to present the problem clearly.

(b) Canada's panel request establishes an adequate link between the provisions listed and the measures at issue, consistent with Article 6.2

4.95 There is no requirement in the DSU that a panel request draw a link between the legal obligations at issue and "the facts of the case". Rather, the obligation in Article 6.2 is to identify the specific measures at issue and provide a brief summary of the legal basis. This is precisely what Canada's panel request does.

4.96 First, Canada's panel request states, after describing the measures at issue, that "[t]hese measures are inconsistent with the obligations of the EC" under four specific agreements, and specifies which provisions of those agreements are being violated. Canada has met the requirement to clearly identify the specific measures. The subsequent listing of the specific provisions being violated must be read in the overall context of the panel request. Some provisions are obviously relevant to some claims, and just as obviously irrelevant to other claims. Finally, because the *SPS* and *TBT Agreements* are mutually exclusive, it should be clear that the provisions of the *TBT Agreement* are listed in the alternative.

4.97 Second, it is inappropriate for the European Communities to challenge Canada's panel request on the basis of the alleged complexity of the three panel requests taken as a whole. Each panel request must be evaluated on its own merits in light of the requirements of Article 6.2. Canada's request is clear, specific and provides adequate information for the European Communities to understand the nature of the measures at issue and the legal basis for the complaint. The European Communities' reference to a multiplicity of provisions and legal obligations, and to 41 applications for approval of biotech products and nine EC member State national measures, misleads the Panel as to the actual scope of Canada's panel request. However, even if it were appropriate for the adequacy of the three panel requests to be judged as a whole under Article 6.2, the three panel requests all meet the standard of that provision.

4.98 Third, in examining the adequacy of Canada's panel request, the Panel should also have regard to other "attendant circumstances," such as the long history of bilateral consultations between Canada and the European Communities, and the lengthy list of questions submitted by Canada to the European Communities in advance of the WTO consultations held on 25 June 2003. When these numerous communications are taken into account, it quickly becomes clear that the European Communities has been apprised of the nature of this dispute, and of the allegations by Canada in its panel request, well before the panel was established on 29 August 2003.

4.99 Finally, the European Communities provides three recent panel requests filed by the complaining parties in other WTO disputes, and offers these as a means to "facilitate the task of the Panel in assessing what is the acceptable standard of precision for requests under Article 6.2." However, the European Communities fails to indicate that the three panel requests were all made in an anti-dumping context. The Appellate Body has pointed out that Article 6.2 and Article 17.5 of the *Anti-Dumping Agreement* are complementary, and that Article 17.5 contains "additional requirements." Specifically, the Appellate Body found that "[a] panel request made concerning a dispute brought under the *Anti-Dumping Agreement* must therefore comply with the relevant dispute settlement provisions of both that Agreement and the DSU."

4.100 To suggest that the Panel rely on these panel requests as the standard against which to judge the adequacy of Canada's panel request, is inappropriate. The three panel requests cited by the European Communities are simply irrelevant to a determination of the "acceptable standard of precision" for requests made under Article 6.2 alone.

(c) Article 6.2 does not require a complaining party to include a summary of its legal argument in its request to establish a panel

4.101 In stating that Canada's panel request "should indicate which provisions may be relevant for the examination of each measure, possibly describing the substantive aspects or the effects of the measures which are allegedly in breach of those provisions," the European Communities is actually complaining that Canada has not indicated what legal arguments it intends to pursue. According to the jurisprudence, there is no requirement to set out legal arguments in a panel request. The European Communities' arguments in this regard are clearly without merit and should be rejected.

5. Canada's panel request does not prejudice the ability of the European Communities to defend itself

4.102 Whether a responding party has suffered prejudice is a relevant consideration in determining if a panel request has met the requirements of Article 6.2. A responding party must demonstrate prejudice with "supporting particulars".

4.103 The European Communities does not offer any valid supporting particulars to justify a finding of prejudice. It appears that the European Communities is claiming prejudice on the basis that it "has been unable to start preparing its case in a meaningful way." In support of this assertion, the European Communities merely restates its arguments, refuted above, regarding the lack of specificity in the identification of the measures at issue and the multiplicity of claims being made. Such a mere restatement is plainly insufficient to establish prejudice. If lack of detail in the panel request automatically implied "prejudice," there would be no need for a separate "prejudice" analysis. Even if the European Communities could show that Canada's panel request does not meet the requirements of Article 6.2, it has offered nothing to show that it has been prejudiced.

4.104 Even if the European Communities' assertion that it "has been unable to start preparing its defence in any meaningful way" is true, which is highly doubtful, it has nothing to do with the lack of specificity in the identification of the measures at issue or the absence of a brief summary of the legal basis for the claims. Given that this panel was established in August 2003, the European Communities has had more than enough time to begin preparing its case. The consequences of its alleged failure to do so should be borne the European Communities, not by the complaining parties.

4.105 In particular, the European Communities has not provided any explanation for why it waited almost seven months since the filing of Canada's panel request to raise its concerns regarding claimed procedural deficiencies. This delay by the European Communities runs counter to the statements by the Appellate Body that responding Members must promptly bring claimed procedural deficiencies to the attention of the complaining Member, and to the DSB or the Panel, and that the procedural rules of WTO dispute settlement are designed to promote, not the development of litigation techniques, but the fair, prompt and effective resolution of trade disputes.

4.106 In light of this delay and the absence of any explanation for the delay, the European Communities' claim that it has suffered prejudice lacks credibility. Canada submits that this request is merely a litigation technique intended to undermine the fair, prompt and effective resolution of this dispute.

D. PRELIMINARY WRITTEN SUBMISSION OF ARGENTINA

1. Introduction

4.107 The European Communities claims that the request for the establishment of the panel did not present the legal basis of the complaint in a manner sufficiently clear to enable the European Communities to fully identify the specific measure at issue and to fully understand the legal basis of the complaint. Argentina will address these two claims on the basis of the textual obligations of Article 6.2, taking into account the general due process considerations related to the specific requirements of the article.

2. Object and purpose of Article 6.2

4.108 The main purpose of Article 6.2, as has been recognized by WTO jurisprudence, is directly related to the jurisdiction of a panel and due process considerations.⁶⁵ The process to assess the fulfilment of Article 6.2 requirement should be undertaken by a Panel on a *case by case basis*, in the light of the *attendant particular circumstances* and assessing the *prejudice* issue which remains at the heart of the due process consideration.

⁶⁵ See Appellate Body Report, *EC – Bananas III*, para. 142.

4.109 *Due process* requirements as previously defined by panels and the Appellate Body, are relevant for all parties in the dispute, including complaining parties. The Panel must consider the impact on the rights of Argentina and other complaining parties of an overly strict, formalistic interpretation of Article 6.2 as compared to a textual interpretation.

3. The European Communities' claim regarding partial lack of identification of the measure at issue

4.110 The European Communities' request on this point is limited to the claim of suspension of consideration of and failure to consider various applications for approval of agricultural biotech products, as presented in point (1) of the first page of Argentina's Panel request.⁶⁶ The European Communities has conceded that it has no preliminary objection related to the claims on national marketing and import bans and has put forward no argument related to Argentina's claim of undue delays in finalizing consideration of various applications for approval of agricultural biotechnology products.⁶⁷

4.111 The need to analyse the Panel request in its entirety has been expressly recognized in the recent Panel report on *Canada – Wheat Exports and Grain Imports*. Reading the Panel request as a whole, it is apparent that the measure the European Communities claims is incompletely identified has been preceded by the fourth paragraph of Argentina's Panel request, which states:

"This action taken by the European Communities and some of its member States adversely affects agricultural biotechnology products from Argentina"⁶⁸

4.112 This general and introductory paragraph refers to the action undertaken by the European Communities which Argentina is challenging in these proceedings. The relevant question at this point of the analysis is: which action by the European Communities led to the measure at issue? The answer may be found easily by referring to the second paragraph of Argentina's Panel request:

"The European Communities has applied a de facto moratorium on the approval of agricultural biotechnology products since October 1998. This de facto moratorium⁶⁹ has led to the suspension of and failure to consider various applications for approval of agricultural biotechnology products as well as to undue delays in finalizing the processing of applications for the approval of such products under Community legislation."^{70,71}

4.113 The *de facto* moratorium is the action constituting a conduct of *suspension* of consideration or *failure* to consider. The *de facto* moratorium is an omission attributed to the European Communities

⁶⁶ WT/DS293/17.

⁶⁷ See footnote 14 on EC request for preliminary ruling.

⁶⁸ WT/DS293/17, English version, paragraph fourth, page 1.

⁶⁹ WT/DS293/17, footnote 1: "*I. See Annex I*".

⁷⁰ (footnote original) *Ibid.*, footnote 2: "EC legislation on biotech product approval includes Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001, published in Official Journal No. 106 of 17 April 2001, pages 0001-0039 (and its predecessor Council Directive 90/220/EEC of 23 April 1990, published in Official Journal No. 117 of 8 May 1990 and amended by *Directive 94/15*, published in Official Journal No. 103 of 22 April 1994, and by *Directive 97/35*, published in Official Journal No. 169 of 27 June 1997), and Regulation (EC) No. 258/1997 of the European Parliament and of the Council of 27 January 1997, published in Official Journal No. 043 of 14 February 1997."

⁷¹ WT/DS293/17, p. 1, 2nd para.

which amounts to a breach of its obligations under WTO law.⁷² According to the dictionary, *de facto* means "in fact, in reality in actual existence...whether by right or not".⁷³ The word *de facto* qualifies moratorium which is at the heart of this dispute. *Moratorium*, according to a textual approach, means "a postponement or deliberate suspension of some activity".⁷⁴ The action to suspend may be easily understood by reading the subject of the suspension in the same paragraph, i.e. the link to various applications for approval of agricultural biotechnology products. The nature and extent of the legal argument related to the suspension, as well as the specificity of the suspension in relation to specific applications, is something to be developed as part of the argument.

4.114 Equally, the failure ("omission to do"⁷⁵) to consider various applications for approval is not difficult to understand. There are applications submitted for approval which are subject to the *de facto moratorium*.

4.115 The universe of the applications and the factual circumstances surrounding each of them, as well as the fact that specific applications cited by individual complaining parties may lead to different arguments during the Panel proceedings, is not a matter to be dealt with in a panel request or a request for a preliminary ruling.

4.116 It should be noted that the status of various applications is a matter discussed at length during the consultations. The European Communities cannot ignore now the kind of inquiry undertaken during the consultations, which led to the current wording in the panel request.

4.117 The European Communities further alleges that in other proceedings before the DSB, not only Argentina but the other complaining parties have been able to identify the matter at issue with a precision that, in the view of the European Communities, is absent in the case at hand. Argentina respectfully suggests that the Panel consider the following circumstances. First, Argentina is not in a position to comment on the cases cited as examples by the European Communities for the alleged deficiencies in the US and Canada panel requests. Second, Argentina notes that the three cases cited as examples were dumping cases, a subject which is governed by the specific provisions of the *Anti-Dumping Agreement* which contains rules that qualify the provisions of Article 6.2 of the DSU. Also, the very nature of the measures subject to challenge is different in each circumstance – duly enacted national provisions regulating the conduct of formal proceeding in the case of the *Anti-Dumping Agreement* on the one hand and an informal *de facto* moratorium on the application of national provisions on the other hand.

4.118 At this stage, it should be said that the alleged problem with the measure at issue is an attempt by the European Communities to request the development of a factual description of the moratorium which rightly pertains to the development of arguments and the fact-finding process. This attempt should be firmly rejected by the Panel, particularly taking into account the nature of the measure at issue. The type of measure at issue, the *de facto moratorium* leading to suspension or failure to consider applications, necessarily affects the extent and nature of information required to properly present the claim.

4.119 The request of Argentina singles out specific applications. Whether the totality of applications are at stage of suspension (i.e. have been considered and are now suffering a delay), or

⁷² See Appellate Body Report, *US – Corrosion-Resistant Steel Sunset Review*, para. 88.

⁷³ *The New Shorter Oxford English Dictionary*, 1993 Edition, page 615.

⁷⁴ *The New Shorter Oxford English Dictionary*, 1993 Edition, page 1829.

⁷⁵ *The New Shorter Oxford English Dictionary*, 1993 Edition, page 907.

alternatively were submitted but there is a failure to consider them, is an issue to be defined in the proceedings.

4. The alleged lack of brief summary of the legal basis

(a) Textual reading

4.120 The European Communities' challenge to the Argentine summary of the legal basis of the complaint, contained in document WT/DS293/17, has a wrong departure point as shown by a textual reading. The European Communities resorts to a dictionary definition of "summary" in its request for a preliminary ruling. However, it fails to take into account that Article 6.2 qualifies the word "summary" with the adjective "brief". The dictionary definition of "brief" indeed refers to something "limited...concise in expression ..."⁷⁶. This is a very different standard from the concept of a summary which is close to an argument, as posited by the European Communities in its preliminary request.

(b) Identification of the legal basis

4.121 The failure to identify a specific provision of an agreement allegedly violated certainly would be a problem. However, this is not the case at hand where all relevant provisions of the different agreements have been included in the Panel request.⁷⁷

4.122 Contrary to European Communities' allegations, a comparison between Argentina's request for a Panel and its request for consultations shows the much more precise degree of specificity in the Panel request.⁷⁸ Document WT/DS293/17 includes some, but not all, subparagraphs of articles from different agreements that were part of the consultation process. The case-law from *Korea – Dairy*⁷⁹ quoted by the European Communities is not relevant in this case, since in *Korea – Dairy* the terms of reference included quotations of general articles without any detail on particular subparagraphs within the article, in contrast with Argentina's request for a panel. In order to clarify Argentina's position and the erroneous citation to *Korea – Dairy*, it is useful to quote the European Communities' description in that case:

"Therefore, the EC requests that the panel consider and find that this measure is in breach of Korea's obligation under the provisions of the Agreement on Safeguards, in particular of Articles 2, 4, 5 and 12 of the said Agreement and in violation of Article XIX of GATT 1994".

4.123 This identification of the WTO legal provisions allegedly violated by Korea is strikingly different from the description provided in the current panel request. Therefore, the legal basis has been properly identified.

(c) The issue of multiple obligations

4.124 Although the EC Request addresses the issue of multiple obligations, it should be rejected for two reasons. First, the WTO precedent used in by the European Communities to support its views is completely different from the case at hand. In the precedent, *Korea – Dairy*, multiple obligations

⁷⁶ *The New Shorter Oxford English Dictionary*, 1993 Edition, page 282.

⁷⁷ WT/DS293/17, page 2, indents a) b) c) and d).

⁷⁸ WT/DS293/1.

⁷⁹ Section III.B EC request for preliminary ruling.

were embodied within the main articles quoted broadly by the complainant. In contrast, in the current case, Argentina has put forward the Panel's terms of reference with enough detail to identify articles and subparagraphs containing specific obligations infringed by the European Communities' *de facto moratorium*. Second, in the case at hand, the subparagraphs of specific agreements quoted by the European Communities do not contain multiple obligations, they simply set forth the necessary requirements to demonstrate an infringement of the WTO's provisions. The fulfilment of each requirement necessary to find an inconsistency is something to be developed through the arguments that the complaining parties will present to the Panel in their First Written Submission and subsequent communications.

4.125 To require the development of the rationale and argument underlying each claim is contrary to well-established and recently confirmed WTO jurisprudence, as in the case of *Canada – Wheat Exports and Grain Imports*. In other words, the European Communities' challenge is simply an attempt to impose a requirement to submit a narrative that is more proper for arguments than for a challenge of a legal basis for a claim.

5. The lack of prejudice

4.126 As established by the Panel in the *EC – Bed Linen*, prejudice has to be shown in order for an Article 6.2 claim to prevail. Argentina denies that the European Communities has suffered prejudice in this proceeding as a consequence of the Terms of Reference set out in its panel request. There is neither lack of specificity of the "measure at issue" nor inaccuracy in the identification of the WTO obligations violated by the European Communities.

4.127 The European Communities' claim of prejudice and alleged inability to prepare its defence lacks credibility when one considers the extensive consultations in this case. Argentina provided written questions to the European Communities and consulted as required by the DSU.

4.128 Moreover, the European Communities argues that because of the obscurity of the panel request, it is unable to answer the case. This argumentation must be proved in light of the requirements of Article 6.2 of the DSU. The European Communities' complaint is merely an unsubstantiated assertion of prejudice. WTO case law demonstrates that such assertions simply do not constitute demonstrated or substantiated prejudice for the purposes of Article 6.2 of the DSU.

4.129 Finally, prior panels have rightly determined that whether there is prejudice during the panel proceedings can only be determined at the end of such proceedings. Because the European Communities requested a preliminary ruling to be granted prior to the presentation of the First Written Submissions, it must carry the burden of proving that it has suffered prejudice at this early stage of the proceedings.

E. FIRST WRITTEN SUBMISSION OF THE UNITED STATES

1. Introduction

4.130 The European Communities has adopted approval procedures for agricultural products produced with the benefit of modern biotechnology. Up to October 1998, the European Communities implemented those procedures, and approved more than ten biotech products. Consumers in the European Communities have been enjoying the benefits of these products, without any adverse health or environmental effects.

4.131 Starting in October 1998, however, the European Communities suspended its own approval procedures. In particular, the European Communities suspended consideration of applications for, or granting of, approval of biotech products under the European Communities' approval system. Particular product applications might make some progress, in fits and starts, through the European Communities' approval system, but the European Communities has failed to allow any new biotech product to move to final approval since October 1998.

4.132 The European Communities' adoption of a moratorium on product approvals was not adopted in a transparent matter. Indeed, it was not published in any official journal or otherwise memorialized. Nonetheless, the moratorium is widely-recognized, including by leading EC officials. And, it is just as effective as any amendment to the European Communities' approval legislation formally enacted into law.

4.133 The United States submits that the European Communities' adoption of the moratorium is inconsistent with the European Communities' obligations under the WTO Agreement, and in particular the *SPS Agreement*. While Members are allowed to maintain approval systems – and the United States is not objecting to the European Communities maintaining such a system for biotech products – the procedures under that system must be undertaken and completed "without undue delay." It is hard to think of a situation that involves "undue delay" more than a complete moratorium on approvals. In this case, the European Communities can present no scientific basis for a moratorium on biotech approvals. In fact, many of the products caught up in the European Communities' moratorium have been positively assessed by the European Communities' own scientific committees. In short, having established a biotech approval regime, the European Communities is obligated to apply those procedures fairly and transparently, and without undue delay.

4.134 In addition to the moratorium on the approval of new biotech products, six EC member States have adopted marketing or import bans on biotech products that previously have been approved by the European Communities. These product-specific bans, like the moratorium, are not based on science and are thus inconsistent with the European Communities' obligations under the WTO Agreement.

4.135 In challenging the European Communities' moratorium under the DSU, the United States is simply calling on the European Communities to allow its own approval procedures to run their course. The United States is confident that once the European Communities allows its scientific and regulatory procedures to reach their conclusion, it will once again approve new biotech products, benefitting EC consumers and biotech producers around the world.

2. Statement of facts

(a) Biotechnology

4.136 Modern biotechnology has a number of proven benefits for human health and the environment, including higher agricultural output, more nutritional food products, and lower utilization of agricultural chemicals, fertilizers, and water in commercial farming.

4.137 Modern biotechnology can significantly increase agricultural output by protecting plants from factors that reduce yields, such as pests, diseases, spoilage and extreme weather conditions. A report issued by seven national and international academies of science ("Multinational Science Academies Report") concluded that modern biotechnology must play a role in addressing the shortage of food in the developing world, where 800 million people currently do not have access to sufficient food and malnutrition is a contributing factor in the deaths of six million children under the age of five each year. In its Statement on Biotechnology, the Food and Agriculture Organization of the United

Nations ("FAO") said, "genetic engineering has the potential to help increase production and productivity in agriculture, forestry and fisheries. It could lead to higher yields on marginal lands in countries that today cannot grow enough food to feed their people." A Joint FAO/World Health Organization ("WHO") report of scientific experts recognized that "developing countries look on [recombinant DNA] technology as a means of addressing the need to produce sufficient quantities of nutritionally adequate and safe food for their growing populations."

4.138 Biotechnology is also helping to increase the nutritional value of foods. The multinational science academies report recognized that "[f]oods can be produced through the use of [genetic modification] technology that are more nutritious, stable in storage, and in principle health promoting – bringing benefits to consumers in both industrialized and developing nations." Further, the Pontifical Academy of Sciences stated that "the nutritional enhancement of foods, either in terms of amino acid balance or in enhancing the presence of vitamins or their precursors ... can be attained more efficiently and precisely with the use of methods that are now available involving the direct transfer of genes."

4.139 Modern biotechnology can also provide numerous environmental benefits, including, as stated by the Research Directorate-General of the European Commission, "'cleaner' agriculture." Biotech products that are resistant to insect pests require less insecticide to achieve a given level of protection than products that are not resistant to such pests. The use of biotech crops also permits farmers to employ conservation tillage techniques that reduce soil disturbance and erosion and increase carbon sequestration. In addition, modern biotechnology is producing crops that are able to absorb nitrogen and phosphorous at elevated rates, thus reducing the amount of fertilizer that needs to be applied. Scientists are also developing crops that require less water, which will not only increase productivity in areas with little water but also reduce the need for large-scale irrigation, thus protecting supplies of fresh water and reducing harm to ground and surface water quality.

4.140 The safety of biotech products has been confirmed by scientific reports issued under the auspices of renowned international institutions, such as the FAO and WHO, seven national and international academies of science, and the Organization for Economic Co-operation and Development, as well as independent scientists in the United States, Africa and Europe. In fact, the European Commission itself has endorsed the safety of biotech products, declaring that "the use of more precise technology and greater regulatory scrutiny probably make [biotech products] safer than conventional plants and foods."

4.141 The scientific findings on the safety of biotech products are confirmed by empirical evidence. For the past decade, farmers in various parts of the world have been sowing and harvesting millions of acres of transgenic corn, soybeans, rapeseed, potatoes and cotton, all of which are used, to greater or lesser degrees, in the production of food products or animal feed. The multinational science academies report concluded that "[t]o date, over 30 million hectares of transgenic crops have been grown and no human health problem associated specifically with the ingestion of transgenic crops or their products have been identified." Similarly, the French National Academy of Science noted that transgenic crops are widely cultivated, and "there has never been a health problem regarding consumers or damage to the environment."

4.142 By 2002, five and a half to six million farmers were cultivating crops derived from recombinant DNA technology on 58.7 million hectares (145 million acres) of land. Since 1996, the global land area devoted to transgenic crops has grown thirty-five-fold. Transgenic crops are cultivated in sixteen countries, which together account for more than half the world's population. Worldwide, fifty one percent of soybeans are produced from transgenic seed, as well as twenty percent of cotton, twelve percent of oilseed rape (canola) and nine percent of corn.

(b) Moratorium on approvals of biotech products

4.143 Since October 1998 – the last date of a biotech product approval -- the European Communities has failed to approve any new biotech products under its novel foods or deliberate release legislation. The United States submits that this failure to approve all pending applications is the result of a *de facto* moratorium under which the European Communities has suspended the consideration of applications for, or granting of, approval of biotech products under its pre-market approval system.

4.144 The moratorium became widely known no later than June 1999, when it was announced by Environment Ministers of five member States. In particular, at a Council Meeting of EC Environment Ministers in June 1999, Environment Ministers of Denmark, Greece, France, Italy and Luxembourg issued a Declaration stating: "in exercising the powers vested in them regarding the growing and placing on the market of genetically modified organisms... they will take steps to have any new authorizations for growing and placing on the market suspended."

4.145 The statements of Commission and member State officials confirm the existence of a moratorium. For example, as early as July 2000, European Environment Commissioner Margot Wallström publicly admitted the existence of a "moratorium," calling it "illegal and not justified." This sentiment was reiterated at a press conference in October 2001 following a meeting of the Council of Environment Ministers when Wallström reportedly "admitt[ed] that no end was in sight for the moratorium, which she said was an illegal, illogical, and otherwise arbitrary line in sand." She added that there was no other EU legislation in the same situation in which "we just simply decline to take a decision."

4.146 European Commissioner for Health and Consumer Protection, David Byrne, stated in June 2000 that the reluctance of member States to approve the placing on the market of new biotech products "has resulted in a complete standstill in the current authorizations and a *de facto* moratorium on the commercial release of GMOs." Commissioner Byrne again acknowledged the existence of the moratorium in February 2003 when he implored member States that "we must lift the moratorium."

4.147 The statements of European Commission officials acknowledge not only the existence of the moratorium but also that it is maintained without scientific or legal justification. In fact, EC Environment Commissioner Margot Wallström herself remarked after pleading unsuccessfully with the Environment Council to lift the moratorium: "We have 11 GMO seed notifications approved. ... But then there was an arbitrary line drawn before I came into office [in 2000] to stop all approval for the 13 other pending applications. But many of these 13 are simply varieties of the first 11 approved. They are essentially the same products. There is no science that says these are more or less dangerous than others." Similarly, Beate Gminder, spokeswoman for Commissioner Byrne, stated that "[t]he moratorium has no legal basis."

4.148 Commission documents also confirm the existence of the moratorium. A Commission Working Document dated November 2000 states "the current authorization procedure for commercial release of GMOs, including those that may end up in the food chain, has ground to a standstill. A Commission Press Release dated July 2001 states that the adoption of new legislative proposals "will contribute towards the lifting of the *de facto* moratorium on the commercial release of GMOs." An October 2001 internal Commission working paper states that "[t]his reluctance to go forward with authorizations of GMOs has resulted in a *de facto* moratorium on the marketing of new GMOs and impacted on product approvals under the sector-based legislation." In July 2003, a Commission fact sheet on GMO regulation stated that "[t]he revised Directive [2001/18] and the two proposals for Regulations are expected to pave the way for a resumption of GM authorizations in the European

Union," implying that authorizations had been suspended. A document issued by the General Secretariat of the Council of the European Union stated that the proposed rules on traceability and labelling of biotech products could "possibly lead to the lifting of the current moratorium." More recently, in a January 2004, Communication to the Commission, Commission officials admitted that "no authorizations have been granted since October 1998" despite the adoption of an "interim approach" to biotech product approvals allegedly adopted in July 2000.

4.149 The existence of a moratorium on approvals of biotech products is further evidenced by the failure of the European Communities to approve a single biotech product since October 1998 under Directive 2001/18 (and its predecessor Directive 90/220), as well as under Article 4 of Regulation 258/97. Currently, twenty-seven applications for placing biotech products on the market are delayed at various stages of the approval process under Directive 2001/18 (and, prior to 17 October 2002, under Directive 90/220) and Regulation 258/97.

4.150 There are eighteen biotech products with notifications pending under Directive 2001/18 that were first submitted under Directive 90/220 and then failed to advance through the approval process. Of these eighteen products, nine were stalled at the Commission level at the time Directive 90/220 expired, some having languished for as long as six years and five months. All nine of these products received favourable initial assessments from the sponsoring member State and positive opinions from the Scientific Committee for Plants, which in each case found "no evidence to indicate that the placing on the market [of the product in question] is likely to cause any adverse effects on human health and the environment." The remaining nine notifications were delayed at the member State level under Directive 90/220 and have awaited consideration for as long as four years and ten months.

4.151 Under Regulation 258/97, the requests for five products have been delayed at the Commission level for as long as five years. Each of these products received favourable assessments for their sponsoring member State and two products also received positive opinions from the Scientific Committee on Food. An additional four requests are pending with the individual member States, some of which were submitted as early as July 1998.

(c) Member States' marketing or import bans

4.152 Six EC member States – France, Germany, Austria, Italy, Luxembourg, and Greece – have invoked the so-called "safeguard" provisions in Directive 90/220 and Regulation 258/97 with respect to biotech products that have been approved for sale on the European market. Five member States enacted marketing bans (Austria, France, Germany, Italy, and Luxembourg) and one (Greece) enacted an import ban.

4.153 In particular, Austria issued three measures prohibiting the "placing on the market" of three corn biotech products: Bt-176, MON810 and T25; France issued two Orders on November 16, 1998, prohibiting the "placing on the market" of two rapeseed biotech products: MS1/RF1 and Topas 19/2; Luxembourg issued a Ministerial Order on February 7, 1997, prohibiting the "use and sale" of biotech corn Bt-176; Germany issued a Ruling 31 March 2000, "suspending the approval" and the placing on the market of Bt-176; Italy issued a Decree on 4 August 2000, suspending the "commercialization and use" of the following corn products: Bt-11, MON810, MON809 and T25; and Greece issued a Decree 8 September 1998, prohibiting the importation of Agrevo oilseed rape (Topas 19/2).

4.154 In each case, the applicable scientific committee of the European Communities found that there was no scientific basis for the member State safeguard measure. Yet, those measures all remain in place.

3. Legal discussion

(a) General moratorium violates the *SPS Agreement*

4.155 The general moratorium is one component of the European Communities' biotech approval regime; in particular, the general moratorium is a moratorium on approvals under the novel foods and deliberate release legislation. The European Communities' biotech approval regime is unquestionably an SPS measure. Directive 2001/18 states that one of the objectives of the Directive is "to protect human health and the environment" when, among other things, "placing on the market genetically modified organisms as or in products within the Community." Similarly, its predecessor legislation, Directive 90/220, states that one of its objectives is "to protect human health and the environment" from, among other things, "placing on the market products containing, or consisting of, genetically modified organisms intended for subsequent deliberate release into the environment." Finally, Regulation 258/97 states that "[f]oods and food ingredients falling within the scope of the Regulation must not present a danger for the consumer" or be "nutritionally disadvantageous."

4.156 In addition to the purpose that is set out so clearly in the approval legislation, statements made by European Communities and member State officials reinforce that the purpose of the European Communities' approval regime, including the general moratorium, is to protect human, animal, or plant life or health from certain risks. Over the past five years, European Communities and member State officials have frequently stated that the moratorium has been imposed to protect "citizens" and "the environment." Moreover, a recent Commission "Working Document" indicated that the freeze of the current authorization procedure for biotech products has occurred in light of the fact that the "public is increasingly concerned about potential implications for *human health and the environment*."

4.157 These justifications for the European Communities' approval regime, including the general moratorium, fall within the definition of an SPS measure under the Agreement. For example, concerns that a biotech product might lead to an allergic or toxic reaction on the part of certain animals, *e.g.*, concerns that some varieties could harm beneficial organisms as well as target organisms, fall within the definition of Annex A, paragraph 1(a)—which covers measures applied to protect "animal or plant life or health" from risks arising from "disease-causing organisms." The concern that a biotech product might lead to an allergic or toxic reaction on the part of consumers, *e.g.*, concerns regarding unacceptable levels of pesticide residue in pesticide-producing plant varieties, allergic reactions based on consumption of a biotech variety that incorporates a genetic trait that can lead to such reactions, or the presence of toxins or other contaminants in foods containing biotech products, falls within the definition of Annex A, paragraph 1(b)—which covers measures applied to protect "human or animal life or health" from risks arising from "contaminants" or "toxins" in "foods, beverages or feedstuffs."

4.158 Similarly, concerns that widespread consumption of varieties containing antibiotic marker genes might lead to the development of antibiotic resistant strains of bacteria also fall under the definition of 1(b). Such concerns have been characterized as food safety issues. Thus, a measure based on these concerns is a measure designed to protect "human or animal life or health" from "disease-causing organisms" in "foods, beverages or feedstuffs." Additionally, concerns regarding the cross-contamination (or transfer) of biotech products to non-target organisms, *e.g.*, concerns that herbicide tolerance could be transferred from a biotech variety to a wild variety, fall within the scope of Annex A, paragraph 1(d)—which covers measures applied "to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests." Annex A defines "pests" to include weeds, defined in the *New Shorter Oxford English Dictionary* as "plant[s] that grow[] ... where [they are] not wanted." Thus, a measure based on this risk falls within the definition of Annex A, paragraph 1(d).

4.159 The general moratorium, as one component of the European Communities' biotech approval regime, qualifies as a "measure." Approval procedures are listed in the definition of SPS measure in Annex A as a specific example of an SPS measure. The fact that the moratorium component is not embodied in a single written document does not alter its status as a measure. Certainly, if the European Communities had acted transparently and amended its novel food and deliberate release regulations to provide for an indefinite suspension of approval procedures, the amendment would be a "law," "decree," or "regulation" and fall within the scope of an SPS "measure". The fact that the European Communities has adopted the moratorium in a nontransparent way, without official publication, in no way changes that result.

4.160 Moreover, the *SPS Agreement* includes in its definition of "measure" the terms "requirement" and "procedure", which are not necessarily in written form. For example, the *New Shorter Oxford English Dictionary* defines the term "procedure" as a "particular mode or course of action" or a "set of instructions for performing a specific task which may be invoked in the course of a program." Under the ordinary meaning of the term "procedure," a suspension by the European Communities of the consideration of applications for, or granting of, approval of biotech products is an unwritten procedure covered under the *SPS Agreement*.

4.161 In addition, the list of measures subject to the *SPS Agreement* is not exhaustive. Paragraph 1 of Annex A states, in relevant part, that "[s]anitary or phytosanitary measures *include* all relevant laws, decrees, regulations, requirements and procedures." The use of the word "include" indicates that the Agreement covers more than just the identified types of measures, and should be read to include other measures that may not fit squarely within the illustrative list.

4.162 Finally, the object and purpose of the *SPS Agreement*, and more broadly the WTO Agreement, supports a broad interpretation of what constitutes a "measure." The preamble of the Agreement provides that one object and purpose of the Agreement is to "minimize [the] negative effects [of SPS measures] on trade." If a WTO Member could avoid its SPS obligations by adopting a nontransparent, unwritten SPS measure that has a negative effect on trade, the objects and purposes of the *SPS Agreement* would not be fully realized.

4.163 The general moratorium also "affects international trade" and, thus, meets the second requirement under Article 1.1 of the *SPS Agreement*. Biotech products may not be placed on the market in the European Communities without first being approved under the required legislation. The European Communities' general moratorium has since October 1998 precluded the placing on the market of any and all biotech products in the European Communities, including imported biotech products. The general moratorium, thus, is effectively an import ban that affects any and all foreign biotech products and, thus, the "international trade" in those products.

4.164 The European Communities has failed to comply with the requirements of Article 8 and Annex C, paragraph 1(a) of the *SPS Agreement*. These provisions require that "with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, ... such procedures are undertaken and completed without undue delay"

4.165 The European Communities' approval process for biotech products is subject to the requirements of Article 8 and Annex C. First, the European Communities' process is an "approval procedure" under the Agreement. Annex C defines "approval procedures," as including, *inter alia*, "procedures for sampling, testing and certification." Because biotech products must be approved before they can be placed on the market, the procedures are analogous to the types of procedures specifically articulated in Annex C, *e.g.*, procedures for certification.

4.166 Second, these procedures are imposed to "ensure" that the requirements of the European Communities' approval legislation for biotech products are met. Third, the European Communities' approval legislation is a "sanitary or phytosanitary measure" as defined in Annex A, paragraph 1 of the *SPS Agreement* because it is applied for the purpose of protecting human, animal, or plant life or health or preventing or limiting other damage within the territory of the Member from certain enumerated risks in Annex A.

4.167 The term "undue delay" is not defined in Annex C. Examination of the "ordinary meaning" of the words "in their context and in the light of [the] object and purpose" of the treaty, as required by the customary rules of treaty interpretation reflected in Article 31 of the Vienna Convention, helps provide content to the term. The ordinary meaning of "undue" is "inappropriate, unsuitable, improper; unrightful; unjustifiable. Going beyond what is warranted or natural; excessive; disproportionate." The ordinary meaning of delay is "hindrance to progress; (a period of) time lost by inaction or inability to proceed; impede the progress of, make late, hinder." Thus, the ordinary meaning of "undue delay" under paragraph 1(a) of Annex C is the "unjustifiable" and "excessive" "hindrance" in undertaking or completing an approval procedure. The ordinary meaning of "undue delay" suggests that both the reason for the delay and its duration are relevant considerations in determining whether the delay is "undue".

4.168 Although it may be difficult in particular cases to decide whether approval procedures are undertaken and completed without undue delay, the United States submits that an across-the-board suspension of approval procedures must be considered an "undue delay" under Annex C. As recognized by EC officials, there is no scientific basis for the failure to move forward under the procedures and timelines provided in the European Communities' own legislation. Moreover, many of the biotech products caught up in the European Communities' general moratorium have already been subject to positive assessments by the sponsoring member State and the European Communities' own scientific committee.

4.169 Where the European Communities' own legislation provides procedures and timelines for the approval of biotech products, an indefinite suspension of that approval procedure, without any scientific justification, must be considered "undue delay" under Annex C.

4.170 The European Communities has also violated Article 7 and Annex B, paragraph 1 of the *SPS Agreement*. Article 7 specifically states that "Members shall notify changes in their sanitary or phytosanitary measures and shall provide information on their sanitary or phytosanitary measures in accordance with the provisions of Annex B" Annex B, paragraph 1, states that "Members shall ensure that all sanitary and phytosanitary regulations which have been adopted are *published promptly* in such a manner as to enable interested Members to become acquainted with them." As the European Communities has failed to publish, and, therefore, to "publish[] promptly," the existence of the general moratorium, the European Communities has acted inconsistently with its obligations under Article 7 and Annex B.

4.171 The general moratorium is also inconsistent with each of the related procedural obligations in Annex C(1)(b) of the *SPS Agreement*, considering each element of this provision as follows:

- "the standard processing period of each procedure is published or that the anticipated processing period is communicated to the applicant upon request": Although the European Communities' novel food and deliberate release directives contain processing periods, under the general moratorium those processing periods are not followed. Instead, the European Communities has imposed an indefinite delay. However, since the European Communities does not acknowledge the moratorium,

the standard processing period is not published, and the anticipated processing period is not communicated to the applicant.

- "when receiving an application, the competent body promptly examines the completeness of the documentation and informs the applicant in a precise and complete manner of all deficiencies": Under the general moratorium, the European Communities does not promptly examine documentation and inform the applicant of all deficiencies. To the contrary, applications under the EC directives are stalled, without explanation.
- "the competent body transmits as soon as possible the results of the procedure in a precise and complete manner to the applicant so that corrective action may be taken if necessary": Under the general moratorium, results of procedures are not promptly communicated to applicants so that corrective action may be taken. Instead, applications are stalled in the approval process without explanation.
- "even when the application has deficiencies the competent body proceeds as far as practicable with the procedure if the applicant so requests": Under the general moratorium, the European Communities does not proceed as far as practicable in the approval process. Instead, one again, application are stalled in the approval process.
- "and that upon request, the applicant is informed of the stage of the procedure, with any delay being explained": Under the general moratorium, delays are not explained. To the contrary, the European Communities does not even inform applicants of the existence of the moratorium.

4.172 To the extent the European Communities' suspension of consideration of applications for, or granting of, approval of biotech products (the general moratorium) is preventing the sale or marketing of biotech products, the general moratorium violates Article 5.1 of the *SPS Agreement*. In order for a measure to be based on a risk assessment in accordance with Article 5.1, the following two criteria must be met: (1) "the study put forward as a risk assessment [must] meet the requirements of a risk assessment set forth in Article 5.1 and Annex A of the *SPS Agreement*"; and (2) "the sanitary measures ... selected [must be] *based on* this risk assessment" The European Communities has not met either requirement. Each is analysed separately below.

4.173 First, the European Communities has failed to put forth either of the two types of risk assessments defined in Annex A, paragraph 4. The general moratorium was imposed to protect against risks that fall within Annex A, paragraph 1(a) (measures applied to protect animal or plant life or health from disease-causing organisms), paragraph 1(b) (measures applied to protect human or animal life or health from contaminated or toxic food or feedstuffs) and paragraph 1(d) (measures to prevent or limit damage from entry or spread of pests). The European Communities, however, did not utilize either type of risk assessment when it imposed the general moratorium. Indeed, there is no evidence in the public record that the general moratorium is based on any scientific assessment whatsoever, much less one of the two types of risk assessments defined by Annex A, paragraph 4.

4.174 Second, the general moratorium is not "based on" a risk assessment as required by Article 5.1. As the Appellate Body explained in *EC – Hormones*, Article 5.1 requires that a measure there be a "rational relationship" between the measure at issue and the risk assessment. The European Communities cannot argue that the general moratorium bears a relationship, rational or otherwise, to a risk assessment when there is no evidence that any risk assessment ever existed.

4.175 The general moratorium is also inconsistent with the European Communities' obligation under Article 2.2 of the *SPS Agreement*. Article 2.2's "sufficient scientific evidence" obligation requires that there be a "rational or objective relationship between the SPS measure and the scientific evidence. The basic obligations provided in Article 2.2 have been viewed as being specifically applied in Article 5.1. Therefore, panels and the Appellate Body have found that where a Member maintains a measure in violation of Article 5.1 – that is, where the measure is not based on a risk assessment as required under Article 5.1 and Annex A, paragraph 4 – the Member, by implication, "also act[s] inconsistently with its more general obligation in Article 2.2."

4.176 The general moratorium also violates Article 5.5 of the *SPS Agreement*, which requires that Members aim to be consistent in their application of the appropriate level of sanitary or phytosanitary protection against risks to human, animal, or plant life or health. The European Communities, however, has identified different levels of sanitary and phytosanitary protection in two different yet "comparable" situations: (i) the level of protection in respect of biotech products that exists under the general moratorium; and (ii) the level of protection in respect of products produced using biotech processing aids.

4.177 The European Communities does not regulate products produced with biotech processing aids as such. In contrast to new biotech processing aids, the European Communities has imposed a general moratorium on other new biotech products, resulting in an appropriate level of protection of zero risk.

4.178 First, these distinct levels of protection are applied in comparable situations. The same substances may be present in products produced using biotech processing aids as are present in biotech products themselves. Once present in the final product, the biotech products and products produced using biotech processing aids have the same potential adverse health risks and risks of establishment or spread of disease or pests and associated biological and economic consequences.

4.179 Second, the difference between the level of protection for biotech products and the level of protection for products produced with biotech processing aids is "arbitrary or unjustifiable." As discussed above, elements of the biotech products used in the production of the final products may be present in the final product. In such cases, the same potential risks to human health are present for new biotech processing aids and other new biotech products.

4.180 Third, the European Communities has applied the general moratorium in a manner that results in "discrimination or a disguised restriction on international trade." The European Communities' application of the general moratorium exhibits all three "warning signals" and an "additional factor" which indicate that the measure discriminates or provides a disguised restriction on international trade.

4.181 First, as discussed above, the difference between the levels of protection for biotech products and products produced with biotech processing aids is "arbitrary or unjustifiable." Second, the degree of difference between the levels of protection is substantial – biotech products are subject to a high level of protection (*i.e.*, zero tolerance for risk, effectively banning new biotech products) whereas products produced with biotech processing aids are not subject to European Communities' regulation at all. Third, the general moratorium is not based on a risk assessment.

4.182 Finally, the "additional factor" is a disproportionate effect of the general moratorium on producers outside the European Communities as compared to producers within the European Communities. In 2001, the European Communities accounted for less than four-tenths of one percent of the worldwide land area devoted to growing biotech products. In contrast, the United States, Argentina, Canada, and China accounted for ninety-nine percent of the total land area devoted to

biotech products in 2001. For producers in these countries, the moratorium on approvals of biotech products has had a substantial negative effect.

4.183 The European Communities also has violated Article 2.3 of the *SPS Agreement*. The general obligations set out in Article 2.3 are applied more specifically under Article 5.5. As such, the Appellate Body has found that where all three elements under Article 5.5 have been fulfilled, the measures, by implication, necessarily violate the more general obligations set out in Article 2.3.

(b) Product-specific moratoria violate the *SPS Agreement*

4.184 The United States argues additionally that the product-specific moratoria are separate measures which are also inconsistent with the European Communities' obligations under the *SPS Agreement*. In particular, the United States is also challenging the European Communities' failure to consider for approval each of the twenty-seven applications for biotech products that are pending in the approval process.

4.185 Because the product-specific moratoria and the general moratorium are similar measures in that both refer to the European Communities' failure to consider biotech products for approval, the analysis of the application of the *SPS Agreement* and the violations of that Agreement are also based on similar arguments. Accordingly, arguments set forth in the section above concerning the general moratorium are incorporated by reference.

4.186 Additionally, the European Communities has put forth risk assessments for fourteen of the pending applications, which received favourable assessments from the member States to which these products were submitted and/or from the Scientific Committee on Plants or the Scientific Committee on Food. These opinions encompass both types of risk assessments referenced under Article 5.1 and paragraph 4 of Annex A as they examine: (1) the likelihood of the *establishment or spread of a pest*, and (2) the potential for adverse effects on human or animal health arising from the presence of *toxins or disease-causing organisms in food or feedstuffs*. All fourteen of these scientific assessments of pending applications concluded that there was no evidence that these biotech products would pose a risk to human, animal or plant life or health, or cause other damage.

4.187 Although the European Communities has put forth risk assessments for fourteen of the twenty-seven pending applications for approval of biotech products, the product-specific moratoria are not "based on" these risks assessments as required by Article 5.1. Specifically, there is no "rational relationship" between the European Communities' risk assessments and the product-specific moratoria. To the contrary, there is an irrational relationship between the opinions of the scientific committees, which found no evidence that these products pose a risk to human or animal health or the environment, and the product-specific moratoria, which, in effect, ban these products from the EC market. Because the product-specific moratoria are not "based on" the European Communities' risk assessments, the measures are inconsistent with Article 5.1 of the *SPS Agreement*.

(c) EC member State marketing or import bans violate the *SPS Agreement*

4.188 Like the moratoria (general and product-specific), the member State measures are (1) sanitary or phytosanitary measures, which (2) affect international trade. The general purpose of the member State measures can be inferred from the text of the European Communities' legislation that the member States invoked when they enacted their import or marketing bans. In particular, Article 16 of Directive 90/220 allows member States provisionally to "restrict or prohibit the use and/or sale of [an approved] product" if the "member State has justifiable reasons to consider that [the] product ... constitutes a risk to *human health or the environment*." Similarly, Article 12 of Regulation 258/97

allows Members to "temporarily restrict or suspend the trade in and use of" an approved product if it has information that the approved product "endangers *human health or the environment*." As each of the member States enacted their measures pursuant to Article 16 of Directive 90/220 or Article 12 of Regulation 258/97, all of the measures were enacted for the purpose of protecting human health or the environment. Second, and more importantly, the sanitary or phytosanitary purpose of the member State measures can be found in the measures themselves, as well as in the justifications offered by the member States at the time the measures were adopted.

4.189 The nine member State measures also "affect international trade," either "directly or indirectly," and, thus, meet the second requirement under Article 1.1. By blocking the sale of such products within the country that maintains the measure, the measures effectively block the importation of the products. As such, each of the measures indisputably "affects international trade."

4.190 The nine measures imposed by six member States are sanitary or phytosanitary measures which are not "based on" "risk assessment[s]" as required by Article 5.1 of the *SPS Agreement*. Although each of the six member States that have imposed bans on approved biotech products offered reasons for their measures – though unjustified according to the scientific committees – none of the member States put forth a "risk assessment" as defined in Annex A, paragraph 4. Rather, the justifications offered by the member States typically expressed concerns about adverse effects of the banned products, or biotech products in general, but did not include risk assessments of the banned products.

4.191 The only risk assessments put forth for the banned products are the positive scientific assessments rendered by member States to which the products were submitted and the European Communities' own scientific committees, as well as the European Commission Decisions approving the products. In the case of each member State ban, these favourable assessments were reaffirmed when the scientific committees considered and rejected the information provided by the member States. Thus, the member State measures do not bear a "rational relationship" to the European Communities' positive risks assessment, and are not "based on" a risk assessment, in violation of Article 5.1.

4.192 The member State measures are also inconsistent with the obligations under SPS Article 2.2, because they are not based on a risk assessment as required by Article 5.1 and Annex A, paragraph 4.

(d) Greek import ban violates Article XI

4.193 The terms of the Greek measure make it unambiguously clear that the measure is an "import ban": "We prohibit the importing into the territory of Greece of seeds of the genetically modified rape-plant line bearing reference number C/UK/95/M5/1." As an import ban, the Greek measure is a *prima facie* violation of Article XI:1 of the GATT 1994.

F. FIRST WRITTEN SUBMISSION OF CANADA

1. Introduction

4.194 In this dispute, Canada challenges:

- (a) The general suspension by the European Communities of its own processes for the consideration of applications for, or the granting of, approval for biotech products since 1998 (referred to hereinafter as the *moratorium*);

- (b) In relation to the genetically modified varieties of canola/oilseed rape identified in Annex I of Canada's Panel Request (referred to hereinafter as the *Specific Products*), the failure by the European Communities to consider or approve, without undue delay, applications for approval of such products (referred to hereinafter as the *product-specific marketing bans*); and
- (c) The five national measures identified in Annex II of Canada's Panel Request prohibiting the importation, marketing or sale of, in total, six varieties of genetically modified canola/oilseed rape and maize/corn that have been approved under the European Communities' approval regime for biotech products (referred to hereinafter as *EC member State national measures*).

4.195 Biotech products cannot be marketed in the European Communities unless they have been approved. The approval process involves an assessment of the risks to human health and the environment. The *moratorium* effectively suspends the operation of key steps in this approval process, resulting in an across-the-board marketing ban on biotech products that had not received approval as of October 1998, regardless of whether these products pose risks to human health or the environment. Canada challenges the *moratorium* as a distinct measure that is inconsistent with the *SPS Agreement*.

4.196 The *moratorium* has directly affected the operation of the approval process in relation to the *Specific Products* resulting in the *product-specific marketing bans*. The *Specific Products* include the following varieties of herbicide-tolerant genetically modified canola/oilseed rape: Ms1xRf1, Ms1xRf2, Ms8xRf3 and GT73. Canada challenges the *product-specific marketing bans* as distinct measures inconsistent with the *SPS Agreement* and, in the alternative, the *TBT Agreement*. Canada also challenges the *product-specific marketing bans* as inconsistent with Article III:4 of the GATT 1994.

4.197 Finally, Canada challenges five *EC member State national measures* (enacted by France (2), Greece, Austria and Italy) banning biotech products as inconsistent with the *SPS Agreement* and, in the alternative, the *TBT Agreement*. Canada also challenges these national measures as inconsistent with Article III:4 and, in the case of Greece, Article XI:1 of the GATT 1994.

2. Scientific background

4.198 As has been recognized by the European Communities, the nature of the risks associated with biotech products is similar to the nature of the risks associated with conventionally bred plants. It is not the process through which a plant with novel traits is developed that determines the risk, but rather the characteristics of the inserted gene(s) and the host plant, the environment in which the plant is released and the use to which the plant is put. As the nature of the risks associated with biotech products varies considerably from plant variety to variety, general assertions about the risks of biotech products, as a class, cannot be made. Each biotech product needs to be evaluated on a case-by-case basis, taking into consideration the factors outlined above.

3. EC Legislation and the moratorium

- (a) The approval legislation

4.199 The European Communities' approval regime for biotech products consists of two principal legal instruments: Directive 2001/18 (and its predecessor, Directive 90/220) governing "the

deliberate release into the environment of genetically modified organisms" and Regulation 258/97 regulating "novel foods and novel food ingredients".

4.200 Absent approval, biotech products covered by the European Communities' approval regime may not be placed on the market in the European Communities. The approval regime outlines, *inter alia*, the procedures with which a company must comply in order to obtain approval to place a biotech product on the market and the standards by which an application for approval is judged. In summary form, those procedures are:

- the manufacturer or importer of the product submits an application to the competent authority of the EC member State where the product is to be placed on the market for the first time;
- the competent authority conducts an initial assessment ("IA") to ensure that the product complies with the technical requirements of the relevant legislation and to determine whether the product should be placed on the market;
- the IA report is sent to the Commission and circulated to the other member States for their review and comment. If the assessment was favourable, and no EC member State or the Commission objects to the application, the competent authority consents to placing the product on the market;
- if an EC member State or the Commission objects to placing the product on the market, the Commission must adopt a decision in accordance with specific procedures laid down in the approval legislation after consultation with member State representatives;
- typically, the Commission requests an opinion of the relevant Scientific Committee. Once the scientific opinion has been received, the Commission submits a draft measure to a Regulatory Committee composed of representatives of the EC member States for its opinion;
- if the Regulatory Committee fails to render an opinion, or if it renders an opinion that conflicts with the Commission's draft measure, the Commission "shall, without delay," submit its proposal relating to the measures to be taken to the Council of Ministers;
- the Council of Ministers may, by qualified majority, adopt the proposed measure. It may also, by qualified majority, reject the proposed measure. If a qualified majority does not exist for either adoption or rejection, the Council is unable to act;
- if the Council of Ministers has not acted within three months from the date of the referral, the Commission "shall" adopt the proposed measure;
- if a product is approved for placement on the market by one of the mechanisms set out above, either the competent authority that conducted the initial assessment or the Commission must issue its consent to the placing of the product on the market.

4.201 EC legislation contains "safeguard" clauses that allow EC member States to provisionally restrict or prohibit the use or sale of an approved biotech product in its territory if that member State

has evidence that the product constitutes a risk to human health or the environment. It is under these safeguard clauses that the *EC member State national measures* have been adopted.

(b) Moratorium on approvals of biotech products

4.202 Since October 1998, the European Communities has imposed a *moratorium* on the approval of biotech products. The existence of the *moratorium* is evidenced by the European Communities' failure to approve any biotech products for nearly five years and by numerous statements from EC officials.

4.203 As a result of the weighted voting structure in the relevant Regulatory Committee, EC member States have effectively stalled the consideration or the granting of approval of biotech products. Moreover, where EC member States have been successful in blocking approval by the Commission through their voting behaviour at the Regulatory Committee stage, the Commission has failed to refer the matter to the Council to break the deadlock, even though, as noted above, it is required to do so.

4. The moratorium

(a) The moratorium violates the *SPS Agreement*

4.204 The *moratorium* meets both the form and purpose elements necessary to be considered an SPS measure under the *SPS Agreement*. In terms of form, the *moratorium* consists of concerted acts and omissions of the European Communities and its member States to stall decision-making with respect to biotech product applications at key stages of the approval process. Thus, the *moratorium* effectively renders inoperative the approval procedures under Regulation 258/97 and Directives 2001/18 and 90/220, resulting in an indefinite suspension of the placing on the market of biotech products. This indefinite suspension converts the pre-marketing approval requirement established by Regulation 258/97 and Directives 2001/18 and 90/220 into an across-the-board marketing ban on biotech products that had not been approved as of October 1998. As a ban is clearly a "measure", the *moratorium* is also a "measure" for the purposes of the *SPS Agreement*.

4.205 The purpose of the *moratorium* is to protect against risks identified in paragraph 1 of Annex A to the *SPS Agreement*. As the *moratorium* is not based on a specific legal instrument that expressly sets out the justification for this measure, the purpose of the *moratorium* must be inferred from the context. First, the declarations of the EC member States confirm that the purpose of the *moratorium* is to protect human health and environment from risks arising from biotech products. Second, it is reasonable to infer that the purpose of the *moratorium* is to protect against the same risks to human health and the environment against which the European Communities' approval legislation is intended to protect. A review of the purposes of the European Communities' approval legislation demonstrates that this legislation is designed to protect against the risks identified in paragraph 1(a) through (d) of Annex A of the *SPS Agreement*. Consequently, the *moratorium* meets the purpose element of an SPS measure.

(i) *The moratorium violates Article 5.1*

4.206 The European Communities has offered no risk assessment as a justification for effectively suspending the approval procedures for biotech products. Therefore, the *moratorium* is not "based on" a risk assessment as required by Article 5.1.

(ii) *The moratorium violates Article 5.6*

4.207 Due to the nature of the *moratorium*, it is not clear whether the *moratorium*, rather than the European Communities' approval legislation, is intended to reflect the European Communities' appropriate level of sanitary and phytosanitary protection ("level of protection"). For the purposes of its Article 5.6 argument, Canada assumes that the European Communities' level of protection is that which the European Communities has expressed in its biotech approval regime and general food safety legislation (a high level of protection). However, if Canada is mistaken on this point, and the European Communities' level of protection is that which is reflected in the *moratorium* (zero-risk level), then Canada advances, *in the alternative*, its argument with respect to Article 5.5.

4.208 The European Communities has violated Article 5.6 of the *SPS Agreement* because the *moratorium* is more trade restrictive than required to achieve the European Communities' level of protection. An alternative SPS measure is reasonably available; the alternative measure achieves the European Communities' level of protection; and the alternative measure is significantly less restrictive to trade.

4.209 First, the obvious alternative SPS measure is for the European Communities to comply with its existing approval regime for biotech products and permit biotech products to be considered for, and granted or denied, approval in accordance with the procedures established by that regime. Second, the European Communities' appropriate level of protection is reflected in the relevant EC legislation and appears to be a "high level of protection". It is reasonable to assume that the European Communities' own approval regime for biotech products would achieve the European Communities' level of protection if the European Communities and its member States allowed it to function as designed. Third, the alternative measure is significantly less restrictive to trade. If the European Communities permitted its approval regime to function as designed, biotech products would at least be considered for approval on a case-by-case basis and on the basis of scientific evidence. Consequently, biotech products would have an opportunity to be placed on the market, which is clearly "significantly less restrictive to trade" than the across-the-board marketing ban resulting from the *moratorium*.

(iii) *The moratorium violates Article 2.2*

4.210 As the *moratorium* is not "based on" a risk assessment contrary to Article 5.1, the *moratorium* is not based on scientific principles and is maintained without sufficient scientific evidence, contrary to Article 2.2. Similarly, as the *moratorium* is more trade-restrictive than required to achieve the European Communities' level of protection contrary to Article 5.6, it is not "applied only to the extent necessary to protect human, animal or plant life or health", contrary to Article 2.2.

(iv) *The moratorium violates Article 5.5*

4.211 The European Communities' level of protection appears to be a "high level of protection". However, if this assumption is not correct and the European Communities' level of protection for biotech products with pending applications is that reflected by the *moratorium*, namely a zero-risk level, the European Communities has violated Article 5.5 of the *SPS Agreement*.

4.212 The European Communities has adopted different appropriate levels of protection in several "different situations" that can be compared under Article 5.5: (i) the level of protection in respect of biotech products with pending applications that have been stalled as a result of the *moratorium* ("biotech products with pending applications"); (ii) the level of protection in respect of biotech products that were approved for commercialization prior to the imposition of the *moratorium*

("previously approved biotech products"); and, (iii) the level of protection in respect of novel non-biotech products such as those produced by conventional plant breeding techniques ("novel non-biotech products").

4.213 The European Communities has adopted different appropriate levels of protection in respect of biotech products with pending applications, previously approved biotech products and novel non-biotech products. The European Communities' level of protection in respect of biotech products with pending applications appears to be a zero-risk level. In contrast, the European Communities' level of protection in respect of previously approved biotech products and novel non-biotech products is less than zero-risk level in that such products are not subject to an across-the-board marketing ban. Moreover, biotech products with pending applications, previously approved biotech products and novel non-biotech products are in comparable situations because they share "common elements or elements sufficient to render them comparable." The types of risks to human health and the environment posed by biotech products with pending applications are the same as or similar to the types of the risks posed by the other two identified classes of products.

4.214 The differences in the European Communities' levels of protection for the situations identified above are "arbitrary or unjustifiable". The European Communities' level of protection in respect of biotech products with pending applications (zero-risk level) is higher than the level of protection in respect of previously approved biotech products (low tolerance, but not zero-risk,). The European Communities' own officials admit that there is no scientific basis for treating pending applications differently from those previously approved. Likewise, the European Communities' level of protection in respect of biotech products with pending applications is higher than its level of protection in respect of novel non-biotech products (certainly less than zero-risk level) despite the fact that biotech products and their non-biotech counterparts pose the same or similar types of risks to human health and the environment. Therefore, the difference in levels of protection is "arbitrary or unjustifiable".

4.215 The European Communities' measure embodying the differences in the levels of protection set out above, result in "discrimination or a disguised restriction on international trade." First, as discussed above, the differences between the levels of protection are "arbitrary or unjustifiable." Second, the difference between the levels of protection is substantial – for biotech products with pending applications the level of protection is the most stringent possible (zero-risk) whereas for previously approved biotech products and novel non-biotech products the level of protection is not zero risk. Third, the *moratorium* is not based on a risk assessment, contrary to Articles 5.1 and 2.2. Thus, all three warning signals are present. The difference between the levels of protection also exhibits an "additional factor". The *moratorium* disproportionately affects non-EC producers as compared to EC producers given that majority of biotech products are produced in the United States, Argentina, Canada, and China.

4.216 The presence of three warning signals and an additional factor demonstrate that the differences between the levels of protection in the comparable situations set out above, results, in the case of biotech products with pending applications, in discrimination or a disguised restriction on international trade contrary to Article 5.5.

(v) *The moratorium violates Article 2.3*

4.217 As the European Communities, by maintaining the *moratorium*, has acted inconsistently with Article 5.5, by implication it has also acted inconsistently with Article 2.3.

(vi) *The moratorium violates Article 8 and paragraph 1(a) of Annex C*

4.218 The *moratorium* has led to a systematic failure by the European Communities to undertake and complete its approval procedures for biotech products without "undue delay", contrary to the first obligation of paragraph 1(a) of Annex C. The approval procedures suspended by the *moratorium* are "approval procedures" to "check and ensure the fulfilment of sanitary or phytosanitary measures."

4.219 The ordinary meaning of "undue delay" suggests that both the reason for the delay and its duration are relevant in determining whether the delay is "undue". In the context of Annex C, the justification for a delay must be consistent with the provisions of the *SPS Agreement*, in particular, that SPS measures must be "based on scientific principles" and not "maintained without sufficient scientific evidence" as required by Article 2.2. In this case, there is no sound justification for European Communities' failure to undertake and complete the approval procedures for biotech products. Thus, the delay in undertaking and completing the approval procedures for biotech products is "unjustified".

4.220 In the case of the *moratorium*, the delay in undertaking and completing the approval procedures for biotech products is caused by a general suspension of those procedures. An unjustified general suspension of an approval procedure is on its face an "excessive" delay. In this case, the fact that the general suspension has been in place for more than 5 years compounds the excessiveness of the delay.

(vii) *The European Communities has violated Article 7 and Paragraph 1 of Annex B by failing to "publish promptly" the moratorium*

4.221 For the same reasons that the *moratorium* is an SPS measure, the *moratorium* is a "sanitary or phytosanitary regulation" for the purpose of paragraph 1 of Annex B. As the European Communities has failed to publish the existence of the *moratorium* at all, let alone to do so "promptly," it has acted inconsistently with Article 7 and Annex B.

5. The product-specific marketing bans

(a) *The product-specific marketing bans violate the SPS Agreement*

4.222 The moratorium and the product-specific marketing bans are closely related, though distinct, measures. The product-specific marketing bans arise as a result of the moratorium being applied to individual biotech product applications. They are also proof of the moratorium. Because the measures are closely related, the analysis of the application of the *SPS Agreement* and the violations of that Agreement with respect to the two classes of measures are based on similar arguments. Consequently, the arguments under the moratorium with respect to Articles 5.1, 5.6, 2.2, 5.5, 2.3, 8, and paragraph 1(a) of Annex C apply mutatis mutandis to the product-specific marketing bans.

(b) *The product-specific marketing bans violate Article III:4 of the GATT 1994.*

4.223 The *product-specific marketing bans* violate Article III:4 by according the *specific products* treatment less favourable than the treatment accorded their respective "like" non-biotech counterparts, domestically-grown canola/oilseed rape.

4.224 First, the *product-specific marketing bans* are laws, regulations or requirements affecting the internal sale, offering for sale, purchase, distribution and use of the *specific products*. The *product-specific marketing bans* are inextricably linked to the requirement for pre-marketing approval set out

in European Communities' approval legislation. The failure of the European Communities to consider or approve, without undue delay, the *specific products* has affected the "internal sale, offering for sale, purchase, transportation, distribution or use" of these products because those activities require prior approval. As such, the *product-specific marketing bans* fall within the scope of "laws, regulations and requirements" as that term is used in Article III:4.

4.225 Second, the *specific products* are "like" their respective domestically-grown non-biotech counterparts when taking into consideration, in the light of the circumstances of this case, the four criteria used to determine "likeness".

- A comparison of the *specific products* with domestically-grown non-biotech canola/oilseed rape reveals that their physical differences are minor, and occur only at the genetic level. The *specific products* are otherwise physically indistinguishable from domestically-grown non-biotech canola/oilseed rape. For each *Specific Product*, the European Communities has conducted science-based risk assessments revealing that there is no evidence to suggest that the *Specific Products* are less safe than their domestic non-biotech counterparts. If a biotech product has undergone a science-based risk assessment, and the conclusions of that assessment are that the product does not pose any greater risk to human health or the environment than that product's non-biotech counterpart, there is no reason to consider that product to be different from its non-biotech counterpart in terms of the products' properties, nature and quality, particularly where physical differences between the biotech product and its non-biotech counterpart can be perceived only at the molecular level.
- The *specific products* and their domestic non-biotech counterparts are intended to be used interchangeably as food, feed and industrial processing materials, as the case may be.
- While Canada agrees that, in principle, consumer tastes and preferences is a relevant criterion to the determination of "likeness" under Article III:4, in this case it should be given little practical weight, if any. No reliable evidence exists regarding the consumer tastes and preferences for the *specific products* as compared to their domestically-grown non-biotech counterparts. In these circumstances, consumer tastes and preferences cannot be considered a reliable indicator of "likeness" given the amount of conflicting information publicly available. Finally, Canada also notes that the treatment in question arises in the course of an approval process intended to assess the safety of specific products. In that particular context – and consistent with the Appellate Body's contextual and case-by-case approach – consumer tastes and preferences should play, at most, a very limited role.
- Lastly, no differentiation is made in respect of the tariff classifications between biotech products and their non-biotech, conventionally bred, counterparts.

4.226 When taken as a whole, the factual evidence relating to each of the four criteria makes it clear that the *specific products* and their domestically-grown non-biotech counterparts must be considered to be "like products". Their physical properties are, in all essential aspects, virtually identical; their end uses are identical; evidence with respect to consumer tastes and preferences is inconclusive, and, in this particular context, can only be given very limited weight relative to the other criteria; and their tariff classification is identical. Based on the foregoing, the *Specific Products* are "like" their

respective non-biotech counterparts of national origin for the purpose of Article III:4 of the GATT 1994.

4.227 Third, the *specific products* are accorded treatment less favourable than that accorded their respective non-biotech counterparts of national origin. The *product-specific marketing bans* prohibit the importation and marketing of each respective *specific product*. In contrast, domestically-grown non-biotech canola/oilseed rape is sold freely on the EC market. This cannot be considered as providing "equality of competitive opportunities" to the *specific products*, as required by Article III:4. Accordingly, the imported *specific products* have been accorded treatment less favourable than "like" products of national origin in violation of Article III:4 of the GATT 1994.

(c) The *product-specific marketing bans* violate the *TBT Agreement*

4.228 As demonstrated above, the *product-specific marketing bans* are SPS measures and are therefore covered by the *SPS Agreement*. If, however, the Panel finds that the *product-specific marketing bans* are not SPS measures, then Canada submits, *in the alternative*, that they are subject to the requirements of the *TBT Agreement*.

4.229 The *product-specific marketing bans* and the relevant EC legislation are "technical regulations" and "conformity assessment procedures", respectively. The *product-specific marketing bans* give rise to violations of the following TBT provisions: Articles 2.1, 2.2, 5.1.1, 5.1.2, and 5.2.1, first part.

6. The EC member State national measures

(a) The EC member State national measures violate the *SPS Agreement*

4.230 The *EC member State national measures* meet both the form and purpose elements necessary to be considered SPS measures. In terms of form, the *EC member State national measures* clearly fall within the scope of "laws, decrees, regulations, requirements and procedures". The two French measures and the Italian measure are in the form of "decrees". The Greek measure takes the form of a "ministerial decision" and the Austrian measure is an "ordinance", both of which can be equated with the types of measures expressly enumerated in paragraph 1 of Annex A of the *SPS Agreement*.

4.231 The purpose of the *EC member State national measures* is to protect against risks identified in paragraph 1(a) through (d) of Annex A of the *SPS Agreement*. This can be inferred from the EC legislation invoked by the member States as the basis for instituting such measures (safeguard clauses of the approval legislation), the measures themselves, and statements by government officials in relation to the passage or adoption of such measures.

(i) The *EC member State national measures* violate Article 5.1

4.232 The *EC member State national measures* are not "based on" a risk assessment, as required by Article 5.1 of the *SPS Agreement*. Although the four EC member States imposing the *EC member State national measures* gave reasons to the Commission when notifying their respective *national measures*, they did not file any supporting scientific evidence or analysis that meets the requirements of the definition of a risk assessment set out in the *SPS Agreement*. While the four EC member States pointed to alleged shortcomings in the risk assessments previously conducted as part of the approval process, or raised general concerns with respect to risks to human health or the environment, they did not present a comprehensive analysis of the available scientific evidence as to the risks arising from these products.

4.233 In contrast, the EC member States where the applications for the six products subject to the *national measures* were originally submitted – and the European Communities' scientific committees asked to examine the applications – produced valid risk assessments. However, these risk assessments supported the *approval* of the product applications, and, when requested by the Commission to review the EC member States' reasons for instituting bans on the approved products, the European Communities' scientific committees rejected those reasons in each case. Consequently, there is simply no rational relationship between these risk assessments and the *EC member State national measures*.

(ii) *The EC member State national measures violate Article 5.6*

4.234 As discussed in relation to the *moratorium*, for the purposes of its Article 5.6 argument, Canada assumes that the level of protection throughout the European Communities is that which the European Communities has expressed in its legislation. However, if Canada is mistaken on this point, and the level of protection is that which is reflected in the *EC member State national measures*, then Canada advances, *in the alternative*, its argument with respect to Article 5.5.

4.235 The *EC member State national measures* banning the importation or commercialization of the canola/oilseed rape varieties Ms1xRf1 and Topas 19/2, and the corn/maize varieties T25, Bt-11, MON809 and MON810, are more trade-restrictive than required to achieve the European Communities' appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility, contrary to Article 5.6 of the *SPS Agreement*. An alternative SPS measure is reasonably available; the alternative measure achieves the European Communities' level of protection; and the alternative measure is significantly less restrictive to trade.

4.236 First, it is reasonable to assume that the European Communities' own regulatory regime, and in particular the safeguard procedures, constitutes "another measure, reasonably available taking into account technical and economic feasibility". Second, the European Communities' level of protection, as reflected in the relevant EC legislation, appears to be a "high level of protection", not zero-level risk. It is reasonable to assume that the European Communities' own approval process, which approved the products subject to the *national measures*, was and is designed to achieve the European Communities' stated level of protection. It is also reasonable to assume that the safeguard procedures, if allowed to function as intended, would achieve the European Communities' stated level of protection. In this case, the approval process and safeguard procedures achieve the European Communities' legitimate objective because the biotech products subject to *national measures* have been marketed for several years elsewhere in the European Communities, as have other, similar biotech products that were approved prior to the *moratorium*, without any evidence arising that would tend to throw doubt on their safety. Third, it is incontrovertible that a complete ban on a product is significantly more trade-restrictive than the pre-marketing approval regime under which the products subject to the *national measures* have already been approved. Accordingly, all three elements of a violation of Article 5.6 have been met.

(iii) *The EC member State national measures violate Article 2.2*

4.237 As the *EC member State national measures* are not based on a risk assessment, contrary to Article 5.1, they are not based on scientific principles and are maintained without sufficient scientific evidence, contrary to Article 2.2. Similarly, as the *EC member State national measures* are more trade-restrictive than required to achieve the European Communities' level of protection, contrary to Article 5.6, they are not applied only to the extent necessary to protect human, animal or plant life or health, contrary to Article 2.2.

(iv) *The EC member State national measures violate Article 5.5*

4.238 The European Communities' level of protection with respect to safeguard measures appears to be a "high level of protection", but not a zero-level risk. However, if this assumption is not correct, and the level of protection for the six biotech products subject to the *EC member State national measures* is the level of protection reflected by those measures, namely a zero-level risk, then the *EC member State national measures* violate Article 5.5 of the *SPS Agreement*.

4.239 The European Communities has adopted different appropriate levels of sanitary and phytosanitary protection in several "different situations" that can be compared under Article 5.5: (i) the level of protection in respect of the six biotech products subject to the *EC member State national measures* ("biotech products subject to *national measures*"); (ii) the level of protection in respect of biotech products that have been approved for commercialization in the European Communities ("other EC-approved biotech products"); and (iii) the level of protection in respect of novel non-biotech products ("novel non-biotech products").

4.240 The European Communities has adopted different levels of protection in respect of biotech products subject to *national measures*, other EC-approved biotech products and novel non-biotech products. The European Communities' level of protection in respect of biotech products subject to *national measures* appears to be a zero-risk level. In contrast, the European Communities' level of protection in respect of other EC-approved biotech products and novel non-biotech products is less than a zero-risk level. Other biotech products that have been approved by the European Communities, including other canola/oilseed rape and corn/maize varieties, have not been banned in the four EC member States. Pre-market approval for novel non-biotech products is not required unless the product is to be used as food or food ingredients, in which case, a functioning approval process applies. Moreover, biotech products subject to *national measures*, other EC-approved biotech products and novel non-biotech products are in comparable situations because they share "common elements or elements sufficient to render them comparable." The types of risks to human health and the environment posed by biotech products subject to the national bans are the same as or similar to the types of the risks posed by the other two identified classes of products.

4.241 The differences in the European Communities' levels of protection for the situations identified above are "arbitrary or unjustifiable". The European Communities' level of protection in respect of biotech products subject to *national measures* (zero-risk level) is higher than the level of protection in respect of other EC-approved biotech products (low tolerance but not zero-risk), despite the fact that the actual level of risk present for each of these two groups of biotech products is the same. Likewise, the European Communities' level of protection in respect of biotech products subject to *national measures* (zero-risk level) is higher than its level of protection in respect of novel non-biotech products (certainly not a zero-risk level) despite the fact that these products exhibit the same risk profiles, thus giving rise to the same potential for adverse health effects or risks of the same or similar associated biological or economic consequences.

4.242 The European Communities' measures embodying the differences in the levels of protection set out above, result in "discrimination or a disguised restriction on international trade." First, the differences between the levels of protection are "arbitrary or unjustifiable." Second, the difference between the levels of protection is substantial – for biotech products subject to *national measures* the level of protection is the most stringent possible (zero-risk) while for other EC-approved biotech products and novel non-biotech products the level of protection is not zero risk. Third, the *EC member State national measures* are not based on risk assessments, contrary to Articles 5.1 and 2.2. Thus, all three warning signals are present.

4.243 There are two "additional factors" that support a finding of discrimination or a disguised restriction on international trade. First, the five *national measures* have a disproportionate impact on the producers of these biotech products located outside the EC member States' territories, as compared to producers within the EC member States. Second, not only have the EC member States failed to produce the requisite risk assessments, they have ignored both the initial risk assessments performed by the EC member States where the applications for approval were filed and the opinions submitted by the European Communities' scientific committees in support of those applications, and, later, the opinions submitted in response to the invocation of the safeguard procedures underpinning the *national measures*.

(v) *The EC member State national measures violate Article 2.3*

4.244 As the *EC member State national measures* are contrary to Article 5.5, they also, by implication, violate Article 2.3.

(b) The EC member State national measures violate GATT 1994

(i) *Four EC member State national measures violate Article III:4*

4.245 Four *EC member State national measures* (those of France, Italy and Austria; the Greek measure is addressed below in relation to Article XI:1) violate Article III:4 by according the biotech products subject to those measures treatment less favourable than the treatment accorded their respective "like" non-biotech counterparts, domestically-grown canola/oilseed rape and corn/maize.

4.246 First, the four *EC member State national measures* at issue all fall within the scope of the meaning of the phrase "laws, regulations or requirements". These measures clearly "affect" the "internal sale, offering for sale, purchase" and "use" of the biotech products in question.

4.247 Second, the biotech products in question are "like" their respective domestically-grown non-biotech counterparts when taking into consideration, in light of the circumstances of this case, the four criteria used to determine "likeness":

- A comparison of the biotech products in question with their domestically-grown non-biotech counterparts reveals that their physical differences are minor, and occur only at the genetic level. The biotech products in question are otherwise physically completely indistinguishable from the domestically-grown non-biotech varieties. The minor physical differences, in so far as they are relevant at all, cannot be considered to "influence the competitive relationship between [these] products in the marketplace", and cannot therefore detract from an overall finding of "likeness".
- The biotech products in question and their domestic non-biotech counterparts are intended to be used interchangeably as food, feed and industrial processing materials, as the case may be.
- As with the *product-specific marketing bans*, while Canada agrees that, in principle, consumer tastes and preferences is a relevant criterion and that the Panel should not ignore it, ultimately, it should be given little practical weight, if any, in determining the "likeness" of the biotech products in question as compared to their domestically-grown non-biotech counterparts. No reliable evidence exists regarding the consumer tastes and preferences for the biotech products in question as compared to their domestically-grown non-biotech counterparts. In this case, consumer tastes and

preferences cannot be considered a reliable indicator of "likeness" given the amount of conflicting information publicly available.

- Lastly, no differentiation is made in respect of the tariff classifications between the biotech products in question and their non-biotech counterparts.

4.248 When taken as a whole, the factual evidence relating to the four criteria makes it clear that the biotech products in question are "like" their domestically-grown non-biotech counterparts. Their physical properties are, in all essential aspects, virtually identical; their end uses are identical; evidence with respect to consumer tastes and preferences is inconclusive; and their tariff classification is also identical. Thus, the second element of the Article III:4 test is satisfied.

4.249 Third, the products in question are accorded treatment less favourable than that accorded their respective non-biotech counterparts of national origin. The four *EC member State national measures* have modified the conditions of competition in the relevant market to the detriment of imported products. In effect, the biotech products in question are completely prevented from competing in the French, Austrian, and Italian markets, as compared to their domestically-grown non-biotech counterparts, which enjoy unfettered access to the same markets.

(ii) *Greece's import ban on Topas 19/2 violates Article XI:1*

4.250 The Greek ministerial decision of 9 September 1998 imposed an import ban on the EC-approved biotech canola/oilseed rape variety Topas 19/2. The decision constitutes an "other measure" under Article XI:1 of the GATT 1994 and, is inconsistent with the requirements of that provision.

(c) The *TBT Agreement* applies to the EC member State national measures

4.251 As demonstrated above, the *EC member State national measures* are SPS measures and are therefore covered by the *SPS Agreement*. If, however, the Panel finds that the *EC member State national measures* are not SPS measures, then Canada submits, *in the alternative*, that they are subject to the requirements of the *TBT Agreement*.

4.252 The *EC member State national measures* are "technical regulations": they apply to identifiable products; lay down product characteristics; and compliance with them is mandatory. The *EC member State national measures* violate Articles 2.1, 2.2, 2.9.1, 2.9.2 and 2.9.3 of the *TBT Agreement*.

G. FIRST WRITTEN SUBMISSION OF ARGENTINA

1. Introduction

4.253 The European Communities' system for the approval of biotech agricultural products (Directive 2001/18 and its predecessor Directive 90/220) or "novel foods" (Regulation 258/97) requires that, a specific procedure must be followed before such products can be marketed for consumption in the territory of the European Communities. The complaint by Argentina is based on the following considerations: (1) Since October 1998, the European Communities has either not considered or has suspended applications for approval of all biotech agricultural products under its system of approval prior to release or marketing, and in particular applications for approval of products of interest to Argentina; (2) the European Communities has caused undue delay by failing to consider and/or not completing the processing of applications submitted with regard to various

biotech agricultural products; (3) some EC member States have banned the access to their markets for specific biotech agricultural products.

4.254 In short, the suspension of consideration of the applications, lack of approval or undue delay constitute individual manifestations of a single measure which forms the subject of this complaint – a *de facto* moratorium. Likewise, several specific products of interest to Argentina have been affected by suspension or lack of consideration or undue delay, since no decision has been made on their approval to date. This *de facto* moratorium is a measure that has the following characteristics: (a) it has never been set forth in the form of positive legislation – a regulation or directive – but has been applied and maintained as a practice in the European Communities since 1998; (b) from 1998 to the present, no new biotech agricultural product has been approved for marketing, which entails the systematic suspension of the approval procedures and the failure to consider individual applications for authorization or approval of biotech agricultural products; (c) the moratorium has affected the various applications for approval of individual biotech agricultural products, thus causing an undue delay in the completion of the processing of those applications; (d) it is not supported by scientific evidence; (e) since 1998 it has manifested itself in repeated delays and extensions of deadlines on the part of the European Communities, under the continued pretext of the approval of new legislation: amendment of Directive 90/220 by Directive 2001/18, the need to have additional legislation covering different aspects and new requirements, etc.; and (f) reveals an arbitrary and unjustified discrimination against biotech agricultural products. The *de facto* moratorium implemented by the European Communities as well as the bans adopted by some of its member States are measures inconsistent with the provisions of the *SPS Agreement*, the GATT 1994, or alternatively, the *TBT Agreement*.

2. Inconsistency with the *SPS Agreement*

(a) Inconsistency of the *de facto* moratorium with the *SPS Agreement*

(i) *The de facto moratorium as a measure under the SPS Agreement*

4.255 Argentina considers that the *de facto* moratorium constitutes a sanitary and phytosanitary measure within the meaning of the *SPS Agreement*. For the *SPS Agreement* to be applicable to a measure, the measure in question has to meet two requirements: (a) the measure in dispute must be a sanitary or phytosanitary measure; and (b) the measure must be able to affect international trade. In the opinion of Argentina, the *de facto* moratorium meets both requirements.

4.256 According to the first paragraph of Annex A of the *SPS Agreement*, for the *de facto* moratorium to meet the first requirement, it must satisfy two conditions: (i) it must have as its objective at least one of the objectives cited in sections (a) to (d) of paragraph 1 of Annex A; and (ii) it must also be reflected in one of the instruments cited in the first paragraph of Annex A. The *de facto* moratorium meets both conditions.

4.257 In Argentina's view, the *de facto* moratorium fits the descriptions contained in paragraph 1(a) to 1(d) of Annex A. First, the European Communities itself has explicitly acknowledged that the purpose of the moratorium is to protect against risks to life and health and to protect the environment. The European Communities has also admitted that its policy with regard to biotech agricultural products relates to the protection of life and health. Second, given the fact that the *de facto* moratorium was imposed in the context of the various EC regulations, each of which has different mechanisms for evaluating the potential damage to health or the environment, it is covered by the first paragraph of Annex A.

4.258 With regard to the second condition, the European Communities' moratorium has not been introduced through one of the traditional instruments employed by WTO Members to give expression to their decisions, but has been established *de facto* by the European Communities. Nevertheless, the European Communities' own authorities have acknowledged its existence. It should also be noted that the phrase in the second part of paragraph 1 of Annex A, "*including, inter alia,*", clearly indicates that the list that follows is not intended to be exhaustive.

4.259 With regard to the second requirement, the *de facto* moratorium has had effects on international trade. It should suffice to note that, since 1998, various biotech agricultural products have been denied access to the EC market.

(ii) *The de facto moratorium is inconsistent with Article 5.1*

4.260 Article 5.1 establishes the obligation on Members to conduct a risk assessment. In this particular case, the European Communities is required to conduct at least one of the two types of risk assessment mentioned in paragraph 4 of Annex A. The *de facto* moratorium was implemented by the European Communities without reference to any type of scientific evidence. Furthermore, the *de facto* moratorium has been applied even in cases in which the European Communities had received favourable scientific opinions from the pertinent scientific committees. Therefore the European Communities has violated Article 5.1, and, in accordance with WTO jurisprudence, the violation of Article 5.1 also entails a violation of Article 2.2.

(iii) *The de facto moratorium is inconsistent with Article 2.2*

4.261 The inconsistency of the *de facto* moratorium with Article 2.2 is partly the result of an inconsistency between the *de facto* moratorium and Article 5.1. However, Argentina claims that the *de facto* moratorium violates Article 2.2, irrespective of its analysis in the light of Article 5.1. Article 2.2 requires Members to base their sanitary or phytosanitary measures on scientific principles. The European Communities has no scientific basis for, nor scientific evidence that might support, the *de facto* moratorium. This lack of any scientific basis means that the moratorium is inconsistent with Article 2.2. Besides, the *de facto* moratorium has been maintained for more than five years (1998-2003) without sufficient scientific evidence. Article 2.2 also uses the terms "only to the extent necessary," and thus no sanitary or phytosanitary measure can be applied in such a general and comprehensive form as the European Communities has done with the *de facto* moratorium. Moreover, such a broad and general imposition on all biotech products contradicts the "case-by-case" evaluation which the European Communities itself claims has to be upheld.

(iv) *The de facto moratorium cannot be justified under the exception provided for in Article 5.7*

4.262 The Appellate Body in *Japan – Agricultural Products II* stated that Article 5.7 sets out four requirements which must be met in order to adopt and maintain a provisional SPS measure: (1) the measure is imposed in respect of a situation where "relevant scientific information is insufficient"; (2) the measure is adopted "on the basis of available pertinent information"; (3) the Member "seek[s] to obtain the additional information necessary for a more objective assessment of risk"; and (4) the Member "review[s] the ... measure accordingly within a reasonable period of time".

4.263 With regard to the first requirement, there is no basis in this case for using "insufficient scientific evidence" as an excuse for the *de facto* moratorium under Article 5.7. As all biotech agricultural products approved by the European Communities prior to the *de facto* moratorium had to undergo a case-by-case scientific assessment, the biotech agricultural products that have not been approved since 1998 should also have undergone an approval process that included a risk assessment.

In fact, some of these products received a favourable scientific opinion recommending their approval. With regard to the second requirement, the European Communities has not adopted this measure "provisionally" and has not based its actions on the information available because the European Communities has maintained this measure for more than five years and ignored the scientific evidence provided by its own bodies. With regard to the third requirement, at no time has the European Communities attempted to obtain additional information. On the contrary, the European Communities has only argued that it needs to impose even more requirements on applications, amend its legislation, or introduce additional legislation on another issue. With regard to the fourth requirement, the *de facto* moratorium has never been reviewed since 1998.

4.264 In conclusion, Argentina considers that the *de facto* moratorium is not based on scientific evidence, and that the European Communities cannot justify this measure under the exception provided by Article 5.7. Consequently, Argentina requests that the *de facto* moratorium be found to be inconsistent with Article 2.2.

(v) *The de facto moratorium is inconsistent with Article 5.5*

4.265 In respect of the first sentence of Article 5.5, the Appellate Body in *EC – Hormones* has indicated that there are three cumulative elements that must be proven to claim a violation of this rule: (i) application of different levels of protection to different situations; (ii) arbitrary and unjustifiable differences in protection; and (iii) discrimination and a disguised restriction on international trade.

4.266 With respect to the first element, this element is made up of two aspects: "different levels of protection" and "different" yet comparable situations. With respect to the concept of "different levels of protection", Argentina notes that the level of protection of the *de facto* moratorium is equivalent to a "zero risk" level. With respect to the concept of "different situations", the comparability of different situations arises from the fact that such situations share some common element or elements that make a comparison possible. The European Communities has applied different levels of protection to two "comparable" situations, that is, with respect to the approval for marketing of biotech products before and after the *de facto* moratorium and with respect to the new biotech products and new "non-biotech" products, thereby satisfying the first element of the conditions for the violation of Article 5.5.

4.267 The second element also needs to be analysed with regard to the two comparable situations. With respect to the approval for marketing of biotech products before and after the *de facto* moratorium, there is an equivalent level of risk between the products concerned. Nevertheless, through the moratorium the European Communities has imposed a level of protection so high that it has resulted in an absolute ban on imports without any scientific evidence. With respect to new biotech products and new "non-biotech" products, the latter can be freely placed on the market within the European Communities, except when intended for human or animal consumption, whereas the former are affected by the *de facto* moratorium. In Argentina's opinion, the second element required for a violation of Article 5.5 is apparent from the lack of scientific evidence in the opinions of the relevant EC committees to support these differences in levels of protection imposed by the European Communities.

4.268 To determine whether a measure meets the third element, in *Australia – Salmon* the Appellate Body considered three "warning signals" and certain "additional factors". The three "warning signals" were: (a) the arbitrary and unjustifiable character of the differences in the levels of protection; (b) a rather substantial difference in the levels of protection; and (c) the inconsistency of the sanitary or phytosanitary measure with Articles 5.1 and 2.2. The *de facto* moratorium applied by the European Communities possesses the three "warning signals" indicated above and an additional factor, as explained below.

4.269 With regard to biotech products before and after the *de facto* moratorium, there is a substantial degree of difference in the level of protection accorded by the European Communities, without any justification in terms of the level of risk involved. In addition, the difference in the levels of protection applied is "arbitrary and unjustifiable." Finally, the European Communities has not based the *de facto* moratorium on a risk assessment. With regard to new biotech agricultural products and new "non-biotech" products, the degree of difference in the level of protection is considerable since it represents a low level of protection for the latter and a level that implies an import ban for the former. In addition, the difference in the level of protection is arbitrary and unjustifiable. Likewise, the *de facto* moratorium is not based on a risk analysis and has an adverse effect on new biotech agricultural products, the vast majority of which are produced outside the European Communities.

4.270 Moreover, the *de facto* moratorium contains an "additional factor", which is the disproportionate impact that the *de facto* moratorium has had on producers of biotech agricultural products outside the European Communities vis-à-vis producers within the European Communities.

(vi) *The de facto moratorium is inconsistent with Article 2.3*

4.271 As noted by the Appellate Body in *Australia – Salmon*, once it has been confirmed that the *de facto* moratorium infringes Article 5.5, that measure will also be inconsistent with Article 2.3.

(vii) *The de facto moratorium is inconsistent with Article 7 and Annex B:1*

4.272 The European Communities' measure implemented since 1998 is a *de facto* measure, which was never set forth in any regulation, or published, thus constituting a violation of Article 7 and paragraph 1 of Annex B.

(viii) *The de facto moratorium is inconsistent with Article 10.1*

4.273 This provision is mandatory and not simply an obligation to cooperate. The European Communities' suspension of consideration of applications, its failure to approve biotech agricultural products and the unjustifiable delays in processing constitute a restraint of trade in those products amounting to an absolute ban on access, which has had and continues to have a considerable impact on Argentina, a developing country, in breach of the provisions of Article 10.1. Argentina, like other developing countries, has special needs, in that Argentina is highly dependent on agricultural production and exports.

4.274 On the grounds set forth above, the *de facto* moratorium is inconsistent with the *SPS Agreement*, specifically with Articles 5.1, 2.2, 5.5, 2.3, 7, 10,1 and paragraph 1 of Annex B.

(b) Inconsistency of the "suspension of processing and failure to consider individual applications for approval of specific biotech agricultural products of particular interest to Argentina" with the *SPS Agreement*

(i) *Suspension of the approval processes for biotech agricultural products of particular interest to Argentina*

4.275 Since October 1998, the European Communities has suspended consideration of applications for approval of all biotech agricultural products under its approval system. This suspension is apparent from the fact that before the end of 1998, the European Communities had approved a considerable number of biotech agricultural products, whereas since that date the European Communities has not approved a single such product. Among the pending applications stalled at

various stages of the approval process under Directive 2001/18 (or, prior to 17 October 2002, under Directive 90/220) and Regulation 258/97, are: GA21 maize, NK – 603 maize, Bt-531 cotton, RR 1445 cotton, and A2704-12 and A5547-127 soya.

4.276 The suspension of processing and failure to consider individual applications for the approval of specific biotech agricultural products of particular interest to Argentina [hereafter "the suspension"] must be also analysed in the light of the *SPS Agreement*, in accordance with Article 1.1. Four of the enlisted biotech received positive scientific opinions by the respective EC Scientific Committees, favouring their approval. The fifth biotech product did not even get to the stage of risk assessment.

(ii) *The suspension is inconsistent with Article 5.1*

4.277 The following requirements must be met for a sanitary and phytosanitary measure to be consistent with Article 5.1: (i) a risk assessment must exist; and (ii) the measure must be "based" on that risk assessment. Argentina considers that the suspension is inconsistent with Article 5.1 because neither the member States nor the European Commission authorities have complied with the above-mentioned requirements.

4.278 With regard to the first requirement, the European Communities did not undertake any type of risk assessment provided by paragraph 4 of Annex A as the basis for the suspension. Therefore, there is no risk assessment within the meaning of Article 5.1. With regard to the second requirement, WTO jurisprudence has established that "based on" is appropriately taken to refer to a certain objective relationship between an SPS measure and a risk assessment. In the present case, a distinction must be made between the two hypothetical cases: (i) absence of such a relationship because no scientific assessment was conducted; and (ii) absence of such a relationship in spite of the fact that a scientific assessment was conducted. In the first case, the requirements have not been met because no risk assessment was performed (the case of soya A2704-12 and A5547-127). In the second case, the requirements have not been met because the favourable risk assessment was not taken into consideration as a basis for the suspension (as in the case of maize and cotton).

(iii) *The suspension is inconsistent with Article 2.2*

4.279 On the basis of the provisions of Article 2.2 and the WTO jurisprudence with regard to the relationship between Articles 2.2 and 5.1, if a sanitary measure is not based on a risk assessment as required by paragraphs 1 and 2 of Article 5, it can be assumed more generally that the measure is not based on scientific principles and that it is being imposed without sufficient scientific evidence. Therefore, Argentina maintains that the suspension does not meet the requirements of Article 2.2.

(iv) *The suspension is inconsistent with Article 5.5*

4.280 The scope of Article 5.5 has been addressed in previous disputes, which have confirmed that a complainant must demonstrate the existence of three distinct and cumulative elements: (a) the Member that imposed the measure at issue adopted levels of protection against risks to human, animal or plant life or health in various different situations; (b) these levels of protection exhibit arbitrary or unjustifiable differences in different situations; and (c) these differences result in discrimination or a restriction of international trade.

4.281 The first element consists of two aspects: "different levels of protection" and "different situations". The comparability of different situations derives from the fact that the situations have one or more elements in common that make comparison possible. The European Communities has established different levels of protection in two "comparable" situations, that is different levels with

respect to biotech products for products introduced before and after the moratorium, as well as different levels for new "non-biotech" products and new biotech products. The second element is also present in the measure adopted by the European Communities because, given that the levels of risk are the same in both comparable situations, it is inconsistent to apply different levels of protection as has been done by the European Communities. The third element is also present. To determine whether the third element had been present in *Australia – Salmon*, the Appellate Body took into account three "warning signals" and certain "additional factors". The suspension applied by the European Communities, as well as the moratorium has the same three "warning signals" and one additional factor with respect to both comparable situations.

4.282 For the reasons indicated above, the suspension is inconsistent with Article 5.5 of the *SPS Agreement* with regard both to the treatment of biotech products before and after 1998, and the treatment of new biotech agricultural products as compared with new "non-biotech" products.

(v) *The suspension is inconsistent with Article 5.6*

4.283 WTO jurisprudence indicates that to establish a violation of Article 5.6, it is necessary to determine whether there exists another sanitary or phytosanitary measure that: (1) is reasonably available taking into account technical and economic feasibility; (2) achieves the Member's appropriate level of sanitary or phytosanitary protection; and (3) is significantly less restrictive to trade than the contested sanitary or phytosanitary measure. These three elements are cumulative.

4.284 The first element is present, because the European Communities' procedures, as applied up to 1998, constitute a "measure with technical and economic feasibility" that offers an alternative to the suspension of procedures imposed later by the European Communities. With respect to the second element, the European Communities' procedures presuppose the existence of a level of protection, which prior to 1998, served as a basis for the approval of products. Argentina claims that, if the European Communities' level of protection has been changed, the procedures should also have been changed accordingly. With respect to the third element, the previous implementation of the legislation allowed the approval and consequent access to the market of biotech agricultural products of interest to Argentina, whereas the suspension from 1998 to the present has operated as a restriction on access to the EC market.

4.285 For all the reasons set forth above, Argentina maintains that the suspension implemented by the European Communities from 1998 to the present is inconsistent with Articles 5.1, 2.2, 5.5 and 5.6 of the *SPS Agreement*.

(c) *Inconsistency with the SPS Agreement of the "undue delay" in the processing of individual applications for approval of biotech agricultural products of particular interest to Argentina*

4.286 Argentina will now proceed to demonstrate the inconsistencies between the control, inspection and approval procedures of the European Communities and Article 8 and Annex C of the *SPS Agreement*.

(i) *Analysis in light of the provisions of Article 8 and paragraph 1(a), 1(b), 1(c) and 1(e) of Annex C*

4.287 In the case of each of the biotech agricultural products of particular interest to Argentina, the application of the European Communities' legislation has involved violations in terms of the obligations under Annex C, and in particular paragraph 1(a), 1(b), 1(c) and 1(e).

4.288 As the moratorium is a sanitary or phytosanitary measure within the meaning of paragraph 1 of Annex A the European Communities' approval procedures must comply with Article 8 and Annex C. The delay has resulted from the complete suspension of consideration of the applications, and ultimately suspension of the application of the control, evaluation and approval procedures provided for biotech agricultural products of particular interest to Argentina.

4.289 The European Communities' legislation sets deadlines for each of the required steps. It is possible to estimate an approximate length of time within which it seems "reasonable" that the procedures could be completed. The suspension of procedures has resulted in delays that can in no case be justified in light of the periods of time stipulated in the European Communities' legislation, and these delays are not based on sufficient scientific evidence.

4.290 With regard to paragraph 1(a) of Annex C, although Regulation 258/97 defines a procedure that does not differentiate in terms of implementation between biotech products and new non-biotech products, the undue delay has occurred only in connection with the former products. Another example is the treatment accorded to products of this same type before and after the *de facto* moratorium. With regard to paragraph 1(b), in some cases the authority failed to determine promptly whether the documentation was complete, and in other cases it failed to inform the applicant of the results of the procedure or of the current stage of the procedure. Paragraph 1(c) limits information requirements to what is necessary for appropriate control, inspection and approval procedures. The European Communities has violated this paragraph by delaying the examination of applications submitted or by requiring successive submissions under the terms of subsequent legislation. Paragraph 1(e) which establishes the obligation to ensure that the requirements for control, inspection and approval of individual specimens of a product are limited to what is "reasonable and necessary"; however, the detailed requirements of the European Communities do not appear to meet the criteria of reasonableness and necessity. Moreover, the European Communities' own bodies have failed to exercise their authority, which failure to act cannot be deemed reasonable or necessary. Furthermore, when the European Communities was pursuing its policy of replacing Directive 90/220 with its successor Directive 2001/18, and even when the latter Directive was in force, no consideration was given to the new applications submitted.

3. Inconsistency with GATT 1994

(a) Inconsistency with Article III:4

4.291 The suspension of the approval processes for biotech agricultural products of particular interest to Argentina is inconsistent with Article III:4 since the treatment accorded to biotech agricultural products is less favourable than that accorded to "non-biotech" agricultural products. In this regard, Argentina considers that: (a) the products are "like products" within the meaning of Article III:4; (b) the suspension is a "requirement" that affect "the sale, offering for sale, purchase, transportation, distribution or use of these products in the internal market"; and (c) "less favourable treatment" has been accorded.

(i) "Like products" within the framework of Article III:4

4.292 "Like" does not mean "identical." Likeness must be determined on a case-by-case basis, using four general criteria, in accordance with GATT/WTO case law. Therefore, Argentina has selected four criteria for examination: (i) the physical properties of the products; (ii) the extent to which the products are capable of serving the same or similar end-uses; (iii) the extent to which consumers perceive and treat the products as alternative means of performing particular functions in order to satisfy a particular want or demand; and (iv) the international classification of the products

for tariff purposes. The Appellate Body in *EC- Asbestos* found that each of the criteria should be analysed. Argentina considers that biotech and "non-biotech" agricultural products share these four criteria, as explained below.

4.293 With respect to (i), as a risk assessment has determined that there is no difference between the risks presented by the biotech agricultural products of particular interest to Argentina and those presented by their "non-biotech" counterparts, from the standpoint of their physical properties, there is no difference between these products. With respect to (ii), biotech products and their counterpart "non-biotech" products have similar end-uses. The relevant European Communities' scientific committees, in evaluating the biotech agricultural products, confirmed that their end-use could be the same as that of "non-biotech products". With respect to (iii), in the EC market, the *de facto* moratorium and the suspension have had the effect of barriers to trade and competition. These types of measures can induce or lead to errors in consumer perception of biotech products. With respect to (iv), there is no difference in tariff classification between biotech products and their "non-biotech" counterparts.

(ii) *The suspension is a "requirement" affecting "the sale, offering for sale, purchase, transport, distribution and use of products on the domestic market"*

4.294 The suspension is a "requirement". The GATT/WTO jurisprudence indicated that a government action that imposes no legal obligation may be considered a "requirement" under this provision. The suspension is also capable of affecting the sale, offering for sale, etc., because it affects the conditions of competition. Therefore, this second element is satisfied.

(iii) *"Less favourable treatment" is accorded*

4.295 As a result of the suspension, these products are not being approved even though some of them have received a favourable opinion from the relevant European Communities' scientific committees. Therefore, this third element is satisfied.

4.296 On the grounds set forth above, Argentina considers that the "suspension of processing and failure to consider individual requests for approval of specific biotech agricultural products of particular interest to Argentina" violates paragraph 4 of Art. III of the GATT 1994.

4. Inconsistency with the *TBT Agreement*

(a) *Alternative application of the TBT Agreement*

4.297 As the moratorium constitutes a sanitary or phytosanitary measure, the *SPS Agreement* is applicable. It must be emphasized that the *SPS* and *TBT Agreements* are mutually exclusive, as stipulated by Article 1.5 of the *TBT Agreement* and Article 1.4 of the *SPS Agreement*. Nevertheless, if the Panel considers that it should not analyse Argentina's claim under the *SPS Agreement*, Argentina will argue alternatively under the *TBT Agreement*.

4.298 The *TBT Agreement* applies to "technical regulations" and "conformity assessment procedures" as defined in Annex 1, paragraphs 1 and 3, respectively. In this regard, Directive 2001/18 (and its predecessor Directive 90/220) and Regulation 258/97 are "technical regulations" pursuant to Annex 1, paragraph 1; and the approval procedures of this same regulation constitute "conformity assessment procedures" pursuant to Annex 1, paragraph 3.

(b) Inconsistency with the *TBT Agreement* of the application of the European Communities' legislation in relation to the approval of biotech agricultural products of particular interest to Argentina

(i) *The European Communities' legislation constitutes "technical regulations" pursuant to paragraph 1 of Annex I*

4.299 The Appellate Body in *EC – Asbestos* has established the three following criteria for determining whether a document fits the definition of "technical regulation" in the *TBT Agreement*: (a) the document must apply to an identifiable product or group of products; (b) the document must lay down one or more characteristics of the product; and (c) compliance with the product characteristics must be mandatory. Directive 2001/18 (as well as its predecessor Directive 90/220) and Regulation 258/97 are technical regulations that meet these three requirements.

4.300 With regard to the first criterion, this requirement is met since the regulation in question refers to "genetically modified organisms", that is, an identifiable group of products. With regard to the second criterion, it is also met since the characteristic established by the European Communities' legislation is the absence of adverse effects on human health and the environment. The third requirement is also met, as a reading of the legislation makes clear its mandatory nature.

(ii) *The procedures under the European Communities' legislation constitute conformity assessment procedures*

4.301 The procedures under the European Communities' legislation constitute conformity assessment procedures as defined by point 3 and the Explanatory Note of Annex 1, because the requirements therein were established "to determine that relevant requirements in technical regulations ... are fulfilled".

(iii) *The application of the European Communities' legislation is inconsistent with Article 2.1*

4.302 The way in which the European Communities has applied its legislation to biotech products of particular interest to Argentina is inconsistent with Article 2.1. Since Article 2.1 basically develops the same obligations as Article III.4 of the GATT 1994, we refer to the arguments made in the relevant part of this submission.

(iv) *The application of the European Communities' legislation is inconsistent with Article 2.2*

4.303 For the application of a technical regulation to be consistent with Article 2.2, it must comply with three requirements: (a) pursue a legitimate objective; (b) fulfil that objective; and (c) not be more trade-restrictive than is necessary to fulfil that legitimate objective, taking account of the risks non-fulfilment would create. The EC regulation is inconsistent with Article 2.2 in light of these requirements.

4.304 With respect to the first requirement, the way in which the EC regulation has been and continues to be applied is inconsistent with this provision, even though the technical regulations at issue include health among their legitimate objectives. With regard to the second requirement, the objective of protecting against the potential risks associated with the products has already been satisfied by seeking the opinion of the relevant European Communities' scientific committees. However, the European Communities has chosen to disregard this scientific evidence. With regard to the third requirement, the biotech products of particular interest to Argentina have already received a favourable scientific opinion, which implies that these products do not pose any risks that differ from

those posed by their "non-biotech" counterparts. Nonetheless, these products have not been approved, which is clearly more restrictive than necessary and creates barriers to international trade.

(v) *The application of the European Communities' legislation is inconsistent with Articles 5.1.1, 5.1.2, 5.2.1, 5.2.2.*

4.305 The application of the European Communities' legislation is inconsistent with Article 5.1.1 since it is applied in such a way as to ensure less favourable treatment of biotech products than of like "non-biotech" products. The application of the European Communities' legislation is also inconsistent with Article 5.1.2, since it has had the effect of imposing an absolute ban on imports of biotech products and created unnecessary obstacles to international trade. The obligation of Article 5.2.1 to complete the procedures "as expeditiously as possible" has not been fulfilled by the European Communities, because since 1998 there have been neither approvals nor processing of applications. The way in which the European Communities has applied the EC procedures since 1998 fails to meet the requirements of Article 5.2.2, since the decision to suspend or postpone the processing of applications does not fulfil such obligations as to "proceed as far as practicable with the conformity assessment"; nor have the competent EC bodies fulfilled their obligations "promptly."

(vi) *Inconsistency of the application of the European Communities' legislation with Article 12*

4.306 This provision is part of the "special and differential treatment" envisaged in WTO agreements. The provision is mandatory and more than a mere obligation to cooperate. The obligation applies to both the preparation and the application of technical regulations, standards and conformity assessment procedures.

4.307 The suspension constitutes a restriction on trade that has had effect of an absolute ban on access into the EC market of the biotech products of interest to Argentina. This has had and is still having a considerable impact on Argentina, a developing country. Like other developing countries, Argentina has special trade, financing and development needs, as Argentina is heavily dependent on agricultural production and exports. Argentina is also the world's second-largest producer of biotech agricultural products, and it ranks first among developing countries producers.

4.308 On the grounds set forth above, we alternatively request that the application by the European Communities of its own legislation to biotech agricultural products of particular interest to Argentina be declared inconsistent with the *TBT Agreement*, and specifically with Articles 2.1, 2.2, 5.1.1, 5.1.2, 5.2.1, 5.2.2 and 12 thereof.

5. Bans by various EC member States

4.309 The specific bans that Germany, Austria, Italy and Luxembourg have applied to the entry of biotech agricultural products are inconsistent with WTO rules. All the products concerned have been approved by the relevant EC authorities. The European Communities' legislation allows member States to provisionally restrict or prohibit the use and/or sale of a product on their territory. Several member States sought to protect themselves under this provision. However, the relevant EC bodies have considered these actions by the member States and ruled against these member States' actions.

(a) The member State bans are inconsistent with the *SPS Agreement*

(i) *The EC member State bans as measures under the SPS Agreement*

4.310 To constitute a sanitary or phytosanitary measure as defined by Article 1.1, the measure in question has to meet two requirements: (a) the measure in dispute must be a sanitary or phytosanitary measure, and (b) the measure must be able to affect international trade.

4.311 To be considered as such, a sanitary or phytosanitary measure must contain two elements. First, it must have as its objective at least one of the objectives cited in paragraphs 1(a) to 1(d) of Annex A, and second, it must also be reflected in one of the instruments cited in the second part of paragraph 1 of Annex A. In respect of the first element, the sanitary or phytosanitary objective of the measures applied by the member States can be inferred from the relevant EC legislation. With respect to the second element, Argentina reiterates its previous arguments with respect to the non-exhaustive nature of the instruments listed. The measures applied by the member States also affect international trade, because each and every one of them denies the affected biotech products access to the market of member State taking the action.

(ii) *The member State bans are inconsistent with Article 5.1*

4.312 In not having performed the risk assessment established in this provision, the member States have not fulfilled their obligations under Article 5.1 and paragraph 4 of Annex A. Furthermore, even though the relevant European Communities' scientific committees ruled against them, the EC member States have not lifted the bans and have violated Article 5.1.

(iii) *The member State bans are inconsistent with Article 2.2*

4.313 The inconsistency of the member State bans with Article 2 arises due to its inconsistency with Article 5. However, the bans also violate Article 2 for the following reasons. This provision implies that a rational relationship must exist between the sanitary measure and the scientific evidence. This rational relationship clearly does not exist in this case, since not only do the EC member State bans have no scientific evidence to support them but there is even scientific evidence against them. The bans furthermore conflict with the obligation in Article 2 that a measure be applied "only to the extent necessary", and this conflict cannot be justified under the exception of Article 5.7.

(iv) *The member State bans are inconsistent with Article 5.5*

4.314 As stated above, three elements must be demonstrated in order to establish that this provision has been violated. All three elements are present with regard to the bans imposed by the EC member States.

4.315 With regard to the first element, while all the products affected by the bans have been authorized under the procedures of the European Communities and the member States concerned participated in the approval process, these member States are maintaining their bans. They claim that their measures are justified because they have a level of protection different from that used by the European Communities for the same products. However, as these products have the same level of risk, the member States are applying different levels of protection in comparable situations.

4.316 With regard to the second element, given that the levels of risk are the same, it is inconsistent to apply different levels of protection. Yet this is what some EC member States have done with

respect to biotech agricultural products approved under EC procedures and those banned under national regulations.

4.317 An inspection of the actual text of the regulations concerned shows that there is an explicit restriction on international trade, the third element of an Article 5.5 violation. The member State bans display the three "warning signals" and one additional factor. With regard to the "warning signals", the difference between the levels of protection applied by the EC member States is "arbitrary and unjustifiable." Furthermore, there is a considerable and unjustified degree of difference between the level of protection applied to authorized biotech products and the banned products. Finally, the member States did not base these bans on a risk assessment. With regard to the "additional factor", the effect of the bans imposed on the biotechnology-producing countries is significant and adverse. Similarly, the bans are not based on a risk assessment and have an adverse effect on biotech products, the vast majority of which originate outside the European Communities.

(v) *The member State bans are inconsistent with Article 2.3*

4.318 Pursuant to the WTO's jurisprudence, Argentina maintains that as the member State bans have been shown to be inconsistent with Article 5.5, they also violate Article 2.3.

(vi) *The member State bans are inconsistent with Article 5.6*

4.319 We reiterate our previous assertions with respect to the three requirements under this article. These three requirements are present, and thus the bans at the level of the EC member States violate Article 5.6.

4.320 With regard to the first element, the member States in question could have imposed alternative measures to the extreme of an absolute ban. With regard to the second element, an appropriate level of protection was established by the European Communities' own regulations as they functioned until 1998. If a member State considered it necessary to redefine the appropriate level of protection, it could invoke the "special safeguard", but always subject to a final scientific opinion that would justify the different level of protection. With regard to the third element, any measure other than a ban would have had a less restrictive effect. The "special safeguard" itself, given its provisional nature, has a less restrictive effect.

4.321 On the grounds set forth above, Argentina maintains that the bans established by the member States are inconsistent with Articles 5.1, 2.2, 5.5, 2.3 and 5.6 of the *SPS Agreement*.

(b) The member State bans are inconsistent with the GATT 1994

(i) *Inconsistency with Article III:4*

4.322 The bans of some EC member States infringe Article III:4 because the above-mentioned three requirements identified by the Appellate Body for establishing a violation of Article III:4 are met. With regard to the first element, we reiterate our previous arguments relating to the suspension. With regard to the second element, the member State bans have clearly been implemented through positive legislation: "regulations," "ministerial orders," [and] "decrees" and relate explicitly to restrictions on the entry of biotech agricultural products into the respective markets. With regard to the third element, the bans constitute an absolute ban on imports of those products, whereas like "non-biotech" products and other biotech products are not subject to restrictions in the internal markets of these member States.

(c) Inconsistency of the EC member State bans with the *TBT Agreement*

4.323 It must be emphasized that the *SPS* and *TBT Agreements* are mutually exclusive, as stated above. However, if the Panel concludes that it should not analyse the matter under the *SPS Agreement*, Argentina argues in the alternative that the EC member State bans are inconsistent with the *TBT Agreement*.

(i) *The European Communities' legislation for approval of biotech agricultural products constitutes "technical regulations" pursuant to paragraph 1 of Annex 1*

4.324 As explained above, the Appellate Body has established three criteria for determining whether a document fits the definition of a "technical regulation" in the context of the *TBT Agreement*. The member State bans are technical regulations that satisfy the three requirements. The first criterion is met since the bans at issue refer explicitly to specific biotech agricultural products. With regard to the second criterion, the Appellate Body in *EC – Sardines* ruled that the product characteristics may be imposed in positive or negative form. In the bans at issue, the EC member States have opted for a negative description. The third criterion is also satisfied, as a reading of the regulations establishing the member State bans clearly indicates their mandatory nature.

(ii) *The bans applied by some EC member States to specific biotech agricultural products of particular interest to Argentina are inconsistent with Article 2.1*

4.325 Since Article 2.1 basically develops the same obligations concerning treatment as in Article III:4 of the GATT 1994, we refer to our arguments in the relevant part of this submission.

(iii) *The application of the European Communities' legislation is inconsistent with Article 2.2*

4.326 For the application of a technical regulation to be consistent with Article 2.2, it must comply with three requirements: (a) pursue a legitimate objective; (b) fulfil that objective; and (c) not be more trade-restrictive than is necessary to fulfil that legitimate objective, taking account of the risks non-fulfilment would create. The EC member States bans are inconsistent with Article 2.2, because they fail to meet all of these three requirements. With regard to the first requirement, the member State bans are inconsistent because, even though the legitimate objectives of technical regulations include health, this does not authorize the EC member States to ignore the existing risk assessments of specific biotech products in order to achieve potentially legitimate objectives. With regard to the second requirement, although the objective of protecting against the potential risks associated with these products has already been met by seeking the opinion of the relevant European Communities' scientific committees, the member States did not take this scientific evidence into account, nor did they produce any evidence that might have refuted those opinions. With respect to the third requirement, although the biotech products of particular interest to Argentina had already received a favourable scientific opinion and thus the legitimate objective was satisfied, these products have been the subject of a ban on imports that is clearly more restrictive than necessary, thus creating barriers to international trade.

(iv) *The bans imposed by EC member States on specific biotech agricultural products of particular interest to Argentina are inconsistent with Article 2.9 of the TBT Agreement*

4.327 Article 2.9 applies whenever two conditions are present: (a) whenever there is no relevant international standard; and (b) whenever the technical regulation may have a significant effect on other Members' trade. Both conditions are present in the case of the member State bans in question. No relevant international standard exists. The bans are having a significant effect on other Members'

trade, because they are preventing the products from entering the markets of the EC member States that established the bans.

4.328 With respect to Article 2.9.1, Argentina has received no notice in any publication at any stage. Therefore, Article 2.9.1 has clearly been violated. The EC member State bans are also inconsistent with Article 2.9.2 because no notification has been made to the WTO Secretariat. Nor was there compliance with the requirement in Article 2.9.4, because Members were not allowed reasonable period of time to make comments in writing. None of the EC member States that established bans on products of particular interest to Argentina has alleged any of the circumstances mentioned in Article 2.10 that allow Members to avoid their obligations under Article 2.9.

4.329 Thus, should the Panel consider that it is not required to analyse the question under the *SPS Agreement*, Argentina maintains that the identified EC member States, by instituting bans on specific biotech agricultural products, have violated Articles 2.1, 2.2, 2.9.1, 2.9.2 and 2.9.4 of the *TBT Agreement*.

H. FIRST WRITTEN SUBMISSION OF THE EUROPEAN COMMUNITIES

1. Introduction

4.330 Argentina, Canada and United States have initiated these proceedings to challenge what they allege to be a general "moratorium" in the European Communities concerning the approval of genetically modified organisms (GMO) and products derived therefrom, the alleged failure to approve a number of specific applications for the placing on the market of certain GMOs, and certain temporary measures adopted by six EC member States concerning GMOs that have already been authorized in the European Communities.

4.331 The European Communities wish to underline from the very beginning that it has not adopted any general position either in favour or against any of the products subject to these proceedings. In accordance with its regulatory framework, the European Communities assesses each individual GMO on its own merits, in order to evaluate the potential benefits and risks of these novel products. The European Communities does certainly not seek to impose its prudent approach on other countries, who are free to form their own views on the balance of benefits and risks. Similarly, the present WTO challenge should not be used as a means for the complaining parties to impose their approach on the European Communities or indeed any other countries, especially at a time where countries around the world are still trying to clarify their respective positions on this complex issue. The European Communities can only regret that the complaining parties have chosen to start a dispute settlement procedure based on flawed premises, rather than to promote international co-operation as a means to build a sound international framework for addressing the GMO issue.

4.332 In their submissions, the complaining parties seek to evade or ignore the whole socio-political, legal, factual and scientific complexity of the case. The complaining parties wilfully ignore the social controversies that led to the revision of the European Communities' regulatory framework in the period 1998-2001 (a framework that is not challenged). They also ignore the scientific and regulatory debates at the international level that have taken place over the past years, including the process that led to the conclusion of the Cartagena Protocol on Biosafety. The Protocol is based on the understanding that the inherent characteristics of GMOs require them to be subject to rigorous scrutiny so as to ensure that they do not cause harm to the environment or human health, or cause socio-economic disruptions. Moreover, the complaining parties avoid to discuss the specific steps taken in the authorization procedures for GMOs in connection with each individual product, and they instead blur the picture referring to the existence of a "moratorium". Finally, the complaining parties

try to artificially compress this complex dispute into the SPS framework, ignoring the fact that the aims of the European Communities' policies on GMOs go beyond the protection against the specific risks covered by the *SPS Agreement*. The European Communities submits that the Panel will need to analyse all the aspects of the case in their full complexity before the true simplicity of the dispute can be properly recognized.

4.333 Finally, the European Communities would like to remark that it has chosen to respond to the main claims of the three complaining parties through a single first written submission. The submission is not designed to respond to each and every argument of the complaining parties but rather to address the most serious of the distortions inherent in the complaining parties' presentation of the facts and to highlight the fundamental legal errors on which their cases are constructed. The European Communities will provide a full refutation in subsequent procedural steps, when the complaining parties will hopefully clarify the substance of their challenge and their claims. For the avoidance of doubt, the European Communities should not be considered to have accepted any factual or legal submissions by the complaining parties which are not specifically addressed in its submission. Nor should the fact that the European Communities responds to the submissions of the complaining parties globally be taken as an acceptance that anyone of them may make or develop claims that it has not itself made or developed in its panel request and first written submission.

4.334 The European Communities' overall approach in its first written submission can be summarized as follows:

- the GMOs which are the subject of these proceedings each have characteristics which are recognized by the international Community to pose potential threats to human health and the environment, and they cannot be treated as "like" or "equivalent to" their non-GMO counterparts;
- in addressing the potential risks for each of these GMOs the Community regulatory framework has operated on a case-by-case basis, and there has been no formal (*de jure*) or informal (*de facto*) moratorium in respect of the authorization process or any part of it;
- the approach of the European Communities to the identification, assessment and prevention of risks to human health and the environment from each of these GMOs has been fully consistent with evolving and applicable international standards, and any finding to the contrary would seriously undermine the effectiveness of those standards, which are premised on the application of a prudent and precautionary approach;
- it is of fundamental importance that the nature of the action or alleged inaction of the European Communities in respect of each of the GMOs be correctly understood. The WTO agreements contain different provisions relating to different kinds of measures and it is not admissible to re-designate them artificially to allow for the application of provisions that the complaining parties find more convenient but which are not in reality applicable;
- in particular, in respect of each of the GMOs the steps which have been taken to protect the environment and to conserve biodiversity are reasonable and legitimate, are not necessarily sanitary or phytosanitary in character, and fall in whole or in part outside the scope of the *SPS Agreement*;

- to the extent that any steps taken to protect against risks to human, animal or plant life or health in respect of each of the GMOs could be said to be subject to the *SPS Agreement*, there has been no undue delay or breach of any part of that Agreement on the part of the European Communities or any member States, and in any event such steps are provisionally justified on the basis of the insufficiency of scientific evidence;
- all steps taken by the European Communities and its member States in respect of each of the GMOs are consistent with the *TBT Agreement* and the GATT 1994, and in any event are justified in accordance with Article XX of the GATT 1994.

2. Factual part

(a) Scientific background

4.335 A genetically modified organism (GMO) is an organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination. Contrary to conventional methods of altering genetic material, genetic modification allows for the crossing of natural species barriers, or for the transfer of single or few genes instead of whole genomes.

4.336 Techniques of genetic modification include the use of the bacteria as the delivery mechanism, micro-injection and high velocity ballistic delivery. All techniques have in common that they are actually not able to control where the foreign gene will be inserted and whether that insertion will be stable.

4.337 Development of GMOs began in 1970 and has since then has rapidly evolved in what could be called generational steps. First generation GMOs are mainly crops with either herbicide-tolerant traits or insecticidal properties or the combination of both (so-called stacked genes). More recent generations, most of which are not yet being commercialised include nutritionally enhanced crops and crops that are used for industrial or medical purposes (so-called phytofarming). The European Communities recognizes the potential benefits of the new technology, and subscribes to the approach taken in the preamble to the Biosafety Protocol, which states that "modern biotechnology has great potential for human well-being if developed and used with adequate safety measures for the environment and human health".

4.338 Research so far has identified a number of potential harmful effects resulting either from the very process of genetic modification itself (wrong or unstable insertion) or from the successfully modified end product. Potential harmful effects on human health include toxicity, allergenicity, horizontal gene transfer and antibiotic resistance. Potential harmful effects on the environment, in addition to the above (to the extent they can affect animal or plant life or health) include non-target effects, invasiveness and development of resistance, unintended effects arising through GMO related management practices, and effects on biodiversity. These effects depend on the nature of the specific GMO in question and on the intended use. Where GMOs have been released into the environment, such harmful effects might be irreversible. The need for a pre-marketing case by case assessment, thus, is obvious. In addition, research has only started to identify these issues and long term effects are largely unknown.

(b) International and comparative regulatory arrangements

4.339 In light of these risks, governments around the world, since the first commercialisation of GMOs in the early nineties, have started to address the question of how to regulate GMOs. Regulatory approaches range from complete bans to "laissez faire." Most, however, consist in setting up an approval system specific to GMOs, based on a case-by-case detailed risk assessment. Often such systems are based on a precautionary approach, and decisions are sometimes made dependent on considerations other than scientific factors, such as, for instance, socio-economic considerations. Furthermore, approval may be subject to post-market surveillance requirements. Given the constant evolution of the science on GMOs, regulatory approaches are under constant review in many countries.

4.340 With a view to seeking international consensus governments have also addressed the issue in various international fora. Most importantly, after long and difficult negotiations, they have adopted the Cartagena Protocol on Biosafety in 2000 (103 signatories including Canada and Argentina). The Protocol addresses the safe transfer, handling and use of living modified organisms that may have adverse effect on biodiversity. It establishes an Advance Informed Agreement (AIA) for imports of living modified organisms (LMOs) intended for deliberate release into the environment, incorporates the precautionary principle and details information and documentation requirements.

4.341 In addition, work on specific issues related to GMOs is ongoing in specialized agencies and other international bodies or organisations such as Codex Alimentarius, FAO, WHO, UN, OECD, ASEAN and the African Union. The guidance documents established by these fora, in particular, recognize the need for a case-by-case decision on individual GMOs based on a scientific risk assessment and on risk management considerations.

4.342 Against this background the European Communities submits that it is not plausible to argue that GM products are – or should be treated as – equivalent to non-GM products.

(c) The European Communities' regulatory framework

4.343 The evolution of the European Communities' own legislative framework on GMOs has to be seen against this background. Legislation on the release into the environment of GMOs has been put in place as early as 1990 with the adoption of Directive 90/220, with sector specific legislation, and most specifically, Regulation 258/97 on Novel Foods (including GM foods), following later. The above described developments in scientific research and in international regulatory standards have soon made it necessary for the European Communities to review its legislation. The review process which started in 1998 has led to the replacement of Directive 90/220 through Directive 2001/18 and to the adoption, most recently of further legislation concerning specifically GM food and feed and traceability and labelling.

4.344 Directive 90/220 (and its successor Directive 2001/18) as well as Regulation 258/97, which are the legislative acts relevant to the issues raised in this case, establish approval procedures for the release into the environment of GMOs and for the marketing of GM food. Approval granted on the basis of these acts is valid throughout the European Union. The procedures provide for case-by-case decisions based on scientific risk assessments. Essentially, the assessment takes place at two levels and in two stages: Once an application is lodged in a EC member State, its authorities ('the lead competent authority') make an initial assessment. If it is positive, the dossier is sent up to the Community level from where it is circulated to all other member States. If all agree with the initial assessment, the lead member State grants final consent. If objections are raised, and no agreement can be found, a decision has to be taken at Community level. The Commission consults a scientific

committee (nowadays, the European Food Safety Authority) before presenting a proposal for a decision to a so-called Regulatory Committee consisting of member States representatives. If the proposal does not get a qualified majority in this Committee, the Commission presents a proposal to the Council of Ministers for adoption (or rejection) by qualified majority. If the Council does not act within three months the Commission adopts the decision. While approval is valid throughout the European Union, the legislation provides for the possibility for member States to adopt safeguard measures prohibiting the release/marketing in their own territory.

4.345 As mentioned above, the rapid developments in science as well as in the international regulatory debate, made it necessary for the European Communities to substantially revise its legislation. Directive 90/220, in particular, lacked harmonised standards for the risk assessment and provisions on post-market monitoring and traceability. The proposal for a revised Directive, which the Commission presented in 1998, went through the legislative procedure of co-decision by the European Parliament and the Council, an elaborate process of negotiation between the two bodies, which resulted in the adoption of Directive 2001/18 in the year 2001. The Directive entered into force in October 2002. It provided that pending applications were to be re-submitted in an up-dated form replying to the new requirements by January 2003.

4.346 To the extent that the applicants for authorizations under Directives 90/220 and 2001/18 and Regulation 258/97 are dissatisfied with any act or failure to act of the national authority of a member State or of a Community institution they are free to bring proceedings for administrative or judicial review of such acts. In respect of the 43 products which are the subject of these WTO proceedings the European Communities is aware of proceedings brought in respect of national measures (safeguard provisions) only in the case of Italy. No applications have been made to the European Court of Justice challenging any actions or alleged failure to act of the Community institutions in respect of any of the products.

(d) Individual product applications

4.347 A detailed examination of each of the product applications listed by the complaining parties shows that, contrary to the complaining parties' claims, there has never been a "general suspension" and the individual applications have not been stalled at any moment. As the detailed chronologies and exhibits submitted by the European Communities prove, no single pattern can be identified and each single product has merited and merits an analysis on its own. The evaluation processes have continued through the past years, with the EC authorities at national and European Communities' level trying to take account of the changing legislative and regulatory framework as well as the evolving scientific debate in treating the pending applications.

4.348 Each application has thus its own individual history, with assessments being conducted and concerns being raised, in a process that involved exchanges between competent authorities and between the authorities and the applicant companies. It should be noted that many applications had to be re-submitted under Directive 2001/18 by January 2003 (which is not challenged by the complaining parties) for a fuller assessment. Also, many of the applications listed by the complaining parties have been withdrawn or not re-submitted, usually for purely commercial reasons. It is worth mentioning that in some cases the applicants did not want to be associated with the GM products anymore.

4.349 All pending applications have in the past been subject to requests for additional information of varying kinds. Often requests were related to insufficient data in the dossier to allow for a proper risk assessment as required by the existing legislation. In quite a few cases, however, some requests in the past were also related to requirements which were not yet foreseen in the legislation existing at

the time, and, in particular, to monitoring and traceability issues. Such requests were made in anticipation of the new legislation to be adopted and were based on voluntary commitments on the applicant's side (so-called "interim approach").

4.350 On the applicants' side, in many cases, considerable delays have been taken in replying to requests for additional information. These delays may also have to be seen against the background of the permanent structural changes on the production side of the market. Mergers, acquisitions, transfers of production rights have taken place, changing often the protagonist of the application. This caused sometimes substantial time delays in pursue of the procedure.

4.351 Since the entry into force of Directive 2001/18, the individual applications are now being processed smoothly and are moving through the different instances of the procedures as described above. In some cases, requests for additional information have been put to the applicants related to insufficient data (as required by the legislation) in the application dossier.

3. Legal arguments

(a) Preliminary issues

4.352 The European Communities has considerable difficulties with the complaining parties' identification and characterization of the challenged measures and with their arguments on the applicable law.

4.353 As regards the identification of the measures, all three complaining parties are alleging the existence of a "general moratorium" affecting all GMOs, as well as the existence of a separate measure consisting in "suspensions" affecting certain specific GMOs. Aside from the fact that the complaining parties fail to explain how the European Communities would be applying simultaneously those two separate measures, they try unsuccessfully to identify an instrument or other text in which such a "moratorium" is brought into effect. In reality, the European Communities does not impose nor does it intend to impose any "moratorium" on GMOs, let alone a ban. As the complaining parties' case concerns the conduct of approval procedures (i.e. the delay in completing such procedures), the relevant WTO rules should be those obligations that concern procedures rather than those that deal with the adoption of substantive measures. Once the acts complained of are correctly characterised as delay, it is clear that they cannot amount to a ban. The fact that GMOs cannot be marketed until approved is an intrinsic feature of the European Communities' GMO legislation, which is not challenged in these proceedings, and it has to be clearly distinguished from allegations about delays in the assessment procedures.

4.354 As regards the applicable law, the European Communities does not agree that the *SPS Agreement* is the only relevant agreement for the purposes of this dispute. The scope of the *SPS Agreement* is limited to measures adopted to prevent an exhaustive list of narrowly defined risks. To the extent that a domestic measure is aimed at the protection against other risks, or that it pursues other different objectives, the *SPS Agreement* is not applicable.

4.355 The issues arising out of the existence of GMOs go far beyond the risks envisaged and regulated by the *SPS Agreement*. A rigorous interpretation of the definitions in Annex A.1 of the *SPS Agreement* unequivocally shows that measures addressing issues such as antibiotic resistance or changes in the ecological balance are not among the measures that the *SPS Agreement* intends to discipline. Since the European Communities, through its actions, aims at the fulfilment of objectives that go beyond the specific situations that determine the applicability of the *SPS Agreement*, such

Agreement does not provide a sufficient legal framework for the examination of the European Communities' behaviour.

4.356 The above conclusion does not imply that the *SPS Agreement* is irrelevant for the present dispute, nor it means that the European Communities' behaviour cannot be scrutinised under any WTO rule. The European Communities is of the view that the *SPS Agreement* is relevant in relation to some of the issues that are examined by EC authorities in the course of GMO approval procedures (including safeguard mechanisms). However, the *SPS Agreement* cannot exclude the applicability of other WTO rules to different, non-SPS, aspects of the challenged measures. GATT 1994 and, where relevant, the *TBT Agreement*, can be used to examine those other aspects of the European Communities' behaviour. In that regard, it should be noted that the effect of Article 1.5 of the *TBT Agreement* is to exclude the cumulative application of the *TBT* and the *SPS Agreements* to measures that squarely fit in the definitions of Annex A.1 of the *SPS Agreement*. Article 1.5 certainly does not imply, in the case of a composite measure that is only *partly* pursuing SPS aims, that the *TBT Agreement* is entirely irrelevant and that a narrow examination of one single element of the measure under the *SPS Agreement* can lead to a conclusion on the WTO-consistency of the measure as a whole. Clearly, any measure or part of any measure adopted for reasons that fall outside the scope of the *SPS Agreement* cannot be inconsistent with that agreement.

4.357 The European Communities therefore claims that the measures subject to these proceedings must be revised separately under more than one WTO agreement, according to their nature and aims, before reaching a conclusion on their overall consistency with WTO obligations. Furthermore, the European Communities claims that the general exceptions contained in Articles XX and XXI of the GATT 1994 also apply to the *TBT Agreement*.

4.358 Finally, as a general remark, the European Communities would like to stress the importance of international regulatory acts in the field, in particular the Cartagena Biosafety Protocol. According to the Appellate Body, the rules of customary law "call for an examination of the ordinary meaning of the words of a treaty, read in their context, and in the light of the object and purpose of the treaty involved". The Biosafety Protocol can assist the Panel in the process of interpreting WTO rules, in accordance with the Appellate Body findings in *US – Shrimp*.

(b) The product-specific delays

(i) *The measure*

4.359 At the outset, the European Communities would underline that nineteen of the applications listed by the complaining parties have been withdrawn or abandoned. The European Communities submits that the Panel should consider the claims concerning those applications as inadmissible. Findings on those specific applications cannot serve any useful purpose, as required by Article 3 of the DSU, since the European Communities cannot take any action with regard to those product applications.

(ii) *SPS Agreement*

4.360 The European Communities submits that among the various provisions which the complaining parties allege to have been violated under the *SPS Agreement* only Article 8 together with Annex C can be applied to the facts of the case, to the extent that the European Communities' approval procedures address risks coming under point 1 of Annex A of the *SPS Agreement*. The alleged failure to deal with certain product applications is not an SPS measure, the nature of the latter (as defined in Annex A point 1) requiring the existence of an act, however formal or informal. The

alleged failure to reach a final decision on certain product applications, therefore, can only be challenged as the *application* of an SPS measure, but not as an SPS measure itself.

4.361 Only Article 8 and Annex C address issues of *application* of an SPS measure (with the latter being the approval system as established by the European Communities' GMO legislation). All other violations alleged by the complaining parties relate to an SPS measure *as such*. Given that the alleged failure to act does not constitute an SPS measure, the provisions invoked by the complaining parties are not applicable.

4.362 There is no violation of Article 8 and the various provisions of Annex C cited by the complaining parties, and, in particular, there have not been any "undue delays" within the meaning of Annex C point 1 (a).

4.363 The concept of "undue delays" is to be interpreted in accordance with the general rules of international law on treaty interpretation and can be understood to be referring to a period of time lost by inaction or inability to proceed which is unjustifiable. It is clear also that the meaning of the words "undue delay" cannot be inferred from the domestic legislation of WTO Members. It is not the purpose of the *SPS Agreement* to transform any departure from national legislation to the level of a breach of international law. Argentina's and the United States' argument, therefore, that "undue delay" can be inferred from the alleged fact that procedural delays set out in the European Communities' legislation have not been respected, must be dismissed.

4.364 On the basis of the facts outlined above it is clear that the approval process for individual applications in question, has not been "generally suspended" (as the complaining parties allege) at any time since 1998. Where delays have occurred in individual instances due to requests for additional information such delays (to the extent they are, at all attributable to the European Communities) have been justified by the nature of these requests.

4.365 On a level of principle, the European Communities submits that it is legitimate to request additional information necessary for the completion of a risk assessment and/or compliance with certain standards of risk management or risk communication as they have been established by a regulator and as they apply to the given product in question. That principle applies generally to any product that goes through an approval or inspection procedure designed to ensure that this product is safe. It applies *a fortiori* when the product in issue is based on a new technology which is generally untried and untested and which is recognized by the international Community to have characteristics which inherently require prudence and caution.

4.366 Such requests do not become "illegitimate" if and because they are not expressly set out in the legislation applicable at the time of the application nor do they become "illegitimate" where they are put in the form of a legislative requirement to re-submit an up-dated dossier (a requirement that has not been challenged by the complaining parties in their panel requests).

(iii) *GATT 1994 – Article III:4*

4.367 Canada and Argentina have invoked Article III:4 of the GATT 1994 in relation to the alleged product specific delays. The European Communities disagrees that its conduct with regard to specific product applications constitutes a breach of said article. First of all, the measures challenged by Canada and Argentina are alleged delays in dealing with specific requests for approval. These measures are not in themselves "laws, regulations or requirements". Second, a violation of Article III can only occur if it can be shown that imported products are treated less favourably than domestic like products. The European Communities has not taken more time to authorize the importation of the

GMOs at issue than to authorize their domestic cultivation or processing. Therefore, there is no difference in treatment. Third, conventional, non-GM products are not subject to the same approval procedure, and the international community has recognized that GM products require their own, distinct authorization procedure. As a result, the only "like" products for comparison can be GM products and not their non-biotech counterparts.

(c) The "general suspension"

(i) *The measure*

4.368 The complaining parties seem to argue is that in the European Communities there exists an alleged practice of suspending the consideration of applications and approvals, in the form of a repeated pattern of systematic behaviour. Such a practice is not based on any document even informal or non binding in nature.

(ii) *There is no general suspension*

4.369 The European Communities has shown through extensive factual evidence that there is no general suspension and there has never been one any at any point in time. There is no consistent practice in respect of all the applications as a whole. Each has been taken on its own merits.

4.370 The "evidence" put forward by the complaining parties regarding the absence of final approvals in the past 5 years is incorrect, inconclusive and inconsistent. It is incorrect, because (as is uncontested) GM products have been authorized to be put on the market during this time. It is inconclusive, because the absence of an approval does not mean that an approval process has been suspended. It is inconsistent, because the United States only refers to a limited number of products (instead of all) and only to an alleged situation in the past (and not to the present). Canada, on its part, cannot reconcile its presentation of processes being "stalled" with the plain fact that dossiers are moving through the different instances.

4.371 The "evidence" of various "statements" from different sources presented by the complaining parties is mostly irrelevant and otherwise inconclusive. On the basis of WTO jurisprudence on statements as evidence, only official statements of the European Communities could at all be relevant. Those statements of the European Commission which come closest to being "official statements," do not announce nor confirm a suspension of the approval processes.

4.372 In any event, even assuming that on the basis of that "evidence", and in spite of the actual facts, it could be said that there was in the past a systematic suspension of the approval process, such a pattern or practice would not as such constitute a challengeable measure under the *WTO Agreement*.

(d) The EC member State safeguard measures

(i) *SPS Agreement*

4.373 As regards the measures taken by the EC member States, which affect GMOs already authorized in the European Communities, these are provisional measures pending a full assessment at European Communities' level, which will eventually lead either to a modification of the Community-wide authorization or a termination of the national safeguard measures. The safeguard measures are therefore provisionally and temporary in their character. This is confirmed by the measures themselves, by the explicit terms of the legal provisions on which they are based (Article 16 of

Directive 2001/18 and Article 12 of Regulation 258/97) and finally by the European Court of Justice (case C-236/01).

4.374 Consequently, these measures should be reviewed under Article 5.7 of the *SPS Agreement* to the extent that they are falling under the *SPS Agreement*. Indeed, Article 5.7 is specifically designed to discipline a subset of SPS measures, namely temporary measures, to the exclusion of other SPS provisions wrongly invoked by the complaining parties such as Article 5.1.

4.375 Far from being an exception, Article 5.7 is the relevant provision to examine temporary measures. All three complaining parties have failed to assert in their panel requests that any of the measures adopted by the member States are inconsistent with Article 5.7 of the *SPS Agreement*. Therefore, their claims on the safeguard measures must be dismissed. Moreover, there is no burden of proof on the European Communities concerning the four conditions in Article 5.7. In any event, the European Communities contends that the four conditions are met: first, the scientific evidence was insufficient; second, the member States based their measures on available pertinent information; third, member States and the European Communities are engaged in an ongoing process by which they are seeking to obtain the additional information necessary for a more objective assessment of the risk; and fourth, the measures are subject to a review within a reasonable period of time.

4.376 As said before, Article 5.7 of the *SPS Agreement* contains specific rules regarding provisional measures, and it is by reference to these rules, not the rules in Article 5.1, that the member State measures must be assessed. However, should Article 5.1 be considered relevant, the European Communities stresses the importance of the terms "appropriate to the circumstances" that qualify the obligation to base measures on a risk assessment. Those terms logically imply a certain degree of flexibility, especially in cases where scientific knowledge is still developing and the potential risks being assessed are important. Furthermore, SPS measure must be "based on" (not "conform to") a risk assessment, and a given risk assessment may reasonably support more than one possible SPS measure. As a matter of fact, there is no obligation for WTO Members to follow mainstream scientific opinions.

4.377 The complaining parties' claims under Articles 5.6 and 5.5 of the *SPS Agreement* must also be rejected. As regards the former Article, the complaining parties' arguments are based only on the basis of a wrong assumption about the appropriate level of protection that is being sought. Furthermore, it is self-evident that the necessity of the measure would have to be judged by reference to the insufficiency of scientific evidence, and the reasonable period of time necessary. As regards Article 5.5, its application is effectively excluded by Article 5.7 of the *SPS Agreement* and, in any event, the European Communities has not behaved in an arbitrary manner or made unjustifiable distinctions. The differences in treatment alleged by the complaining parties are between entirely *different* GMOs or between GMOs and conventional products and are not arbitrary or unjustified.

4.378 Finally, since the complaining parties' claims under Articles 2.2 and 2.3 of the *SPS Agreement* are in fact derived from their claims under Articles 5.6 and 5.5, they must equally be dismissed.

(ii) *The GATT 1994*

4.379 Argentina and Canada allege that the member States measures violate Article III:4 of the GATT 1994. The European Communities rejects such claims as unfounded. The prohibitions established by the member States, which are no more than temporary territorial exceptions to the original EC authorizations, cannot but apply in the same way to GMOs which are domestically produced or processed within the Community territory and to those that are imported. A "treatment less favourable" for imported than for domestic products is thus intrinsically impossible in this case.

Furthermore, as mentioned above, the European Communities considers that in the context of marketing approval legislation, the "like" product has to be a product which is similarly subject to the approval procedure. Choosing a category of like product which is outside the approval procedure amounts to attacking the ratio of the distinction operated by the legislation, which is not being challenged in these proceedings. Moreover, the European Communities also contests that the "like products" comparison can be carried out on the basis of such broad categories and generic terms such as "respective domestically-grown non-biotech counterparts" and "imported biotech products and 'non-biotech' domestic products", without any proof being provided on the specific properties, nature, quality, end-uses, consumers' tastes and habits of each specific product at stake.

4.380 Canada also contends that the Greek measure is in breach of Article XI:1 of the GATT 1994. It is however clear that the nature and aim of the Greek measures does not differ from those of the other national measures called into question by Canada. Indeed, the aim pursued by Greece is the temporary restriction of the introduction or use of a given GMO within its territory, no matter the origin of the product.

(iii) *The TBT Agreement*

4.381 Finally, no TBT violation can be found in relation to the challenged member States measures.

4.382 The European Communities considers that the member State measures are not technical regulations within the meaning of the *TBT Agreement*. The definition of "technical regulation" in the Agreement refers essentially to a *normative* type of measures, that is, one that lays down in relatively abstract terms certain rules, with which products must comply. However, each member States measure is in fact an *individual administrative act* relating to a specific product from a specific applicant or manufacturer. Each of those measures amounts to a simple ban on a product *in its natural state*, and they do not therefore contain "product characteristics" in the general and abstract sense in which that term is used in Annex 1, point 1 of the *TBT Agreement*.

4.383 In any event, neither Article 2.1 nor Article 2.2 of the *TBT Agreement* would provide support to the complaining parties' case. On the one hand, even if non-GM products could be considered to be "like" a GM products (*quod non*), Article 2.1 of the *TBT Agreement* can only apply to differences in treatment between products that are, by their nature, susceptible of being covered by the technical regulation in question. On the other hand, the assertion that the member States measures do not contribute to achieving their objectives is unsubstantiated and it fails to take into account the review of the relevant EC legislation and the parallel review of the EC authorizations concerning the products affected by the member States measures.

(e) The special and differential treatment claims

4.384 The European Communities does not accept that there is violation of the "special and differential treatment" obligations in Article 10.1 of the *SPS Agreement* and Article 12 of the *TBT Agreement*. Argentina deduces those violations merely from the alleged breach of other provisions of the agreements, which the European Communities contests. Furthermore, trade statistics show that imports from developing countries that have widely adopted GM agriculture have not decreased.

(f) Article XX of the GATT 1994

4.385 Last but not least, the European Communities submits that if the Panel found any of the challenged measures to be inconsistent with any of the provisions invoked by the complaining parties,

those measures should be found to be justified under Article XX of the GATT 1994 because (1) they come under one of the particular exceptions of paragraphs (b), (d) or (g) and (2) they do not constitute an arbitrary or unjustifiable discrimination between countries where the same conditions prevail or disguised restrictions on international trade.

4. Conclusion

4.386 In conclusion, the European Communities requests the Panel to reject the complaining parties' claims and to find that:

- The delays in the examination of the applications which are the subject of these proceedings are not in violation of the *SPS Agreement*, the *TBT Agreement* or the GATT 1994;
- There is no general suspension of the process of authorizing GMOs and GM products;
- The EC member States national measures are not in violation of the *SPS Agreement*, the *TBT Agreement* or the GATT 1994.

I. FIRST ORAL STATEMENT OF THE UNITED STATES

1. General comments on European Communities' first written submission

4.387 First, much of the European Communities' submission addresses issues that have little, if any, connection to the legal questions in dispute in this proceeding. The European Communities' submission stresses the European Communities' view that biotechnology involves complexity. However, the European Communities does not claim, and indeed could not claim, that any of the scientific issues discussed in its background section justified either a general moratorium or the product-specific moratoria. Instead, the European Communities claims that there was no moratorium at all. To make this claim, the European Communities asks us to believe that the European Communities' own highest officials misunderstand the European Communities' approval system, and that the failure to approve any biotech products between October 1998 and August 2003 was mere coincidence.

4.388 Moreover, if the European Communities has scientific questions about biotechnology, those questions can be and should be addressed within the context of the European Communities' own approval system, and in a manner consistent with its WTO obligations. Indeed, this is just how the European Communities approached scientific and technical issues for the biotech products that the European Communities approved prior to October 1998.

4.389 Similarly, the European Communities does not claim, and could not claim, that any proceedings in other international fora absolve the European Communities from complying with its WTO obligations regarding biotech products. Most notably, the European Communities discusses the Biosafety Protocol at length. The European Communities itself, however, acknowledges that the Protocol explicitly provides that parties may not disregard their existing international obligations in their implementation of the Biosafety Protocol. Furthermore, the Biosafety Protocol foresees a functioning regulatory system in each Party country; it does not provide an excuse for refusing to make prompt, transparent decisions.

4.390 The second general comment regarding the European Communities' submission concerns its arguments on the applicability of the *SPS Agreement*. In this discussion, the European Communities

argues at length, and in the hypothetical, that the European Communities might adopt measures that are not covered within the scope of the *SPS Agreement*. But, once again, the European Communities does not link its discussion to the legal issues in this dispute. The pertinent question is whether the measures that the European Communities has actually adopted, and that are covered in this dispute's terms of reference, are within the scope of the *SPS Agreement*. And, the European Communities' measures in this case are plainly included within the scope of the *SPS Agreement*.

4.391 The third general comment is that the European Communities has attempted to de-emphasize the general moratorium. The United States wishes to reemphasize, as made clear in its opening submission, that the general moratorium is at the core of this dispute. The United States brought this dispute because the European Communities at the highest levels announced a general moratorium on biotech approvals, and followed through on those pronouncements by failing to approve any biotech products for over 5 years.

2. General moratorium violates the *SPS Agreement*

4.392 The European Communities' discussion of the general moratorium is remarkable in that it is concerned solely with whether or not the general moratorium qualifies as a "measure" under the *SPS Agreement*. Should the Panel find, as the complaining parties all submit, that the general moratorium is indeed a measure under the *SPS Agreement*, the European Communities has not contested that the general moratorium: results in "undue delay" in breach of Article 8 and Annex C; is inconsistent with its obligations under Article 7 and Annex B to publish measures promptly; is inconsistent with its obligations under Article 8 and Annex C(1)(B) to keep applicants informed of the progress of applications; is not based on a risk assessment as required under Article 5.1; and results in arbitrary or unjustifiable distinctions in the levels of protection in breach of Article 5.5.

4.393 The evidence that the general moratorium exists is overwhelming. To summarize the facts in the first written submission of the United States: Up to October 1998, the European Communities had approved at least ten biotech products. But between October 1998 and August 2003, the European Communities failed to approve a single biotech product under its novel foods or deliberate release legislation, even though many of those products had been favourably assessed by the European Communities' own scientific committees.

4.394 The moratorium became widely known no later than June 1999, when it was announced by Environment Ministers of five member States. In particular, at a Council Meeting of EC Environment Ministers in June 1999, Environment Ministers of Denmark, Greece, France, Italy and Luxembourg issued a Declaration stating: "in exercising the powers vested in them regarding the growing and placing on the market of genetically modified organisms... they will take steps to have any new authorizations for growing and placing on the market suspended."

4.395 The statements of Commission and member State officials confirm the existence of a moratorium. For example, the European Communities' official representative to the SPS Committee acknowledged the existence of the moratorium. At the meeting of the SPS Committee held on 31 October-1 November 2001, the summary of the meeting notes the following European Communities' response: "The recent meeting of the European Environmental Council had started a very important discussion on proposals presented by the Commission to *restart* the authorization procedure." The EC representative's statement that there were proposals to *restart* biotech authorization procedures is plainly an acknowledgment that those procedures had been suspended.

4.396 Commission documents also confirm the existence of the moratorium. Most recently, in an official Background document to the Agriculture and Fisheries Council of Ministers held on 26 April

2004, the following statement appears: "The adoption of a decision to authorize Bt-11 would bring an end to the current *moratorium* on genetically modified food and feed in Europe."

4.397 The European Communities first written submission in fact goes quite a long way toward conceding the existence of the moratorium. In describing the reasons for adopting a modified directive, the European Communities' submission states: These issues [meaning issues relating to alleged scientific uncertainty] affected some of the pending applications as **a number of member States made it clear that they were not in a position to vote in favour of granting market authorizations** for individual products without these issues being addressed first." This statement is quite close to a confirmation of the basic point that the complaining parties are making in this dispute: namely, that at a certain point in time, certain member States decided that they simply were not going to vote for new product approvals. Under the European Communities' rules of qualified majority voting, a minority of member States can block European Communities' action. Blocks by qualified majority in the regulatory committee may be overridden by a simple majority vote in the Commission. But, as the record here shows, the European Communities has decided not to submit final decisions for a majority vote by the Commission. In addition, if one of those "number of member States" that are unwilling to grant market authorizations were the original recipient of the application, then that single member State may block a Deliberate Release application all by itself.

4.398 Turning to the European Communities' arguments as to why there was no general moratorium, the European Communities first argues that it cannot be "legally affected" by "casual statements of any of its numerous representatives". But the complaining parties are not relying on "casual statements of numerous representatives"; the statements cited by complaining parties are statements made by the European Communities' highest officials, by its member States, and by its official bodies. Moreover, the European Communities itself concedes, as it must, that such statements can be considered as evidence of the existence of a measure.

4.399 The European Communities' second response is to submit application histories for each of the products covered by the moratorium. This information, however, is entirely consistent with the European Communities' imposition of a general moratorium. First, the information submitted by the European Communities confirms that there were in fact no approvals of biotech products between October 1998 and the establishment of the Panel's terms of reference in August 2003.

4.400 Second, we would like to point out a few applications in which even the European Communities' own exhibits show quite clearly how the moratorium operates. The European Communities' submission writes that the two oilseed rape products were approved for cultivation, import, and marketing under the 90/220 Directive at "Community level." However, the European Communities' submission entirely fails to note that under Directive 90/220, the "Community level" approval is not effective unless and until the member State that initially received the application takes a final step of placing the product on the market. In this case, that member State, which was France, never allowed the product to be placed on the market. Thus, these products in fact were never approved for cultivation, import, and marketing in the European Communities.

4.401 We would also like to refer to the example of Bt Cotton. Spain, the member State that initially received the application, forwarded it with a positive opinion to the European Communities in November 1997. The EC Scientific Committee on Plants made a favourable assessment in July 1998. However, in February 1999, the regulatory committee did not approve the application by a qualified majority vote. Under the European Communities' own rules, an application that fails to achieve a qualified majority of votes in the regulatory committee must be submitted to the EC Council for an additional vote, and such submission must be made, to quote Article 21 of the EC Directive, "without delay." But the European Communities' own chronology states that the next action is nearly three

months later, in May 1999. And the action taken is not, as required under EC legislation, the submission of the application to the EC Council. Instead, the chronology states: "Launching of Inter-Service Consultation on draft Council Decision." To our knowledge, this term, and this step, are not provided for under the European Communities' regulations. The chronology is then blank until July of 2001. We would submit that "Inter-Service Consultation" is just another word for the moratorium.

4.402 Finally, we would like to address the application under the Novel Foods regulation for Bt-11 sweet corn. This product received a favourable opinion from the European Communities' Scientific Committee on Food over two years ago, in April 2002. The European Communities' submission states that the Commission was finally ready on 19 May of this year to accept a proposal allowing the use of Bt-11 sweet corn for food use. The United States would like to make very clear that the measure that we are requesting that the Panel examine is the measure in existence at the time when the Panel and its terms of reference were established, which is the measure in effect as of 29 August 2003. Also, the United States would not view an approval of Bt-11 as a lifting of the European Communities' moratorium or as an indication that the EU will begin to meet its WTO obligations by making decisions on all other pending applications without undue delay. But any issues relating to whether or not steps taken by the European Communities after August 2003 have brought the European Communities into compliance with its WTO obligations are not before the Panel.

4.403 We would also note that the Bt-11 approval, should it occur, is entirely consistent with, and in fact supports, the existence of the general moratorium. As noted above, both the European Commission and the Council have stated that the entry into force of the European Communities' new traceability and labelling rules for biotech products might finally allow for the lifting of the moratorium. Those new rules went into effect on 19 April 2004. The fact that the Commission then approved Bt-11 just one month later is, at least in our view, certainly no mere coincidence. To the contrary, this timing indicates that, as the European Communities itself has acknowledged everywhere but in its First Written Submission, the European Communities' approval system was held up not by any problems with particular applications, but by events outside the scope of its approval legislation. Moreover, the EC Council itself acknowledges the existence of the "moratorium" – it uses this very word – in a statement concerning the scheduled Bt-11 approval.

4.404 As discussed in the first written Submission of the United States, the European Communities' approval regime, including that part of the regime modified by the general moratorium, is plainly a "sanitary or phytosanitary" measure. However, in light of the European Communities' hypothetical discussion of the types of risks covered by its Deliberate Release legislation, the United States would like to make the following points. The European Communities notes that its Deliberate Release directive repeatedly uses the word "environment". The idea, however, that all environmental issues are outside the scope of the *SPS Agreement* is plainly wrong. Article 5.2 of the Agreement explicitly requires the consideration of relevant ecological and environmental conditions in an assessment of SPS risks. In addition, the definition in the *SPS Agreement* of an SPS measure includes "Any measure applied to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests." The agreement explicitly provides that animal includes "wild fauna", and that "plant" includes "forests and wild flora." Certainly, the protection of wild fauna, forests, and wild flora are elements of environmental protection.

4.405 The European Communities' last defence is to argue that even if the European Communities, as a matter of fact, adopted a general moratorium on approvals of biotech products, such a moratorium is legally precluded from qualifying as a "measure" under the *SPS Agreement*. The European Communities' argument is based on two panel reports that considered the status under the *Anti-Dumping* and *Subsidies Agreements* of investigating authorities' so-called "practices". But, the conclusions in those reports are not applicable to the determination of whether an actual moratorium

on approvals (as opposed to a "practice") is a measure. Unlike the complaining parties in those disputes, the complaining parties here are not saying that a pattern of decisions itself *constitutes* a measure. Instead, the co-complaining parties have pointed to an unbroken pattern of decisions (or rather, to an unbroken pattern of lack of decision) as the inevitable *result* of the moratorium, which is itself an independent measure.

3. Product-specific moratoria violate the SPS Agreement

4.406 Turning to the European Communities' product-specific moratoria, whether one views them as separate measures or simply as undue delay in the approval process of these individual products, the European Communities once again asserts that no such measures ever existed and that no application faced any undue delays. The primary basis for the European Communities' denial of the product-specific moratoria is the vague statement that "what has happened in many of these applications is that, at different stages of the procedure, requests for additional information have been put to applicants." Nonetheless, contrary to the European Communities' assertions, its own exhibits show that applications stalled in its approval system without justification.

4.407 Earlier in this statement, we noted the examples of how Bt Cotton and two oilseed rape products had stalled in the approval process. We would also like to point out the example of Roundup Ready Cotton. Spain, the member State that initially received the application, forwarded it with a positive opinion to the European Communities in November 1997. The European Communities' Scientific Committee on Plants made a favourable assessment in July 1998. In February 1999, the Roundup Ready cotton application, like Bt cotton, did not receive a qualified majority vote in the regulatory committee. Like for Bt cotton, the next step in the European Communities' chronology is the "Launching of Inter-Service Consultation on draft Council Decision" in May 1999. There is no further entry in the chronology until January 2003, which is more than 2½ years later. Again, this is another example of a major delay that was not caused, as the European Communities' claims, by a pending request to the applicant for additional information.

4.408 These chronologies also highlight how the product-specific moratoria are inconsistent with the related procedural obligations in Annex C(1)(b) of the SPS Agreement. In the Bt Cotton, Roundup Ready Cotton, and oilseed rape applications, the applicant is not informed in a precise and complete manner of all deficiencies, or of the results of the approval procedure. To the contrary, when the regulatory committee fails to approve an application by a qualified majority vote, or when the EC Commission enters into "Inter-Service Consultations" rather than sending an application on to the Council, the applicant is given no explanation, and thus no opportunity to correct any deficiencies. The same is true when, as for the oilseed rape products, the member State that originally received the application fails to take the final step of placing a product on the market.

4. Member State measures violate the SPS Agreement

4.409 Like the moratoria (general and product-specific), the member State measures are SPS measures which affect international trade. Each of the six member States have imposed bans on approved biotech products, but none of the member States put forth a "risk assessment" as defined in Annex A, paragraph 4. These measures are thus not "based on" "risk assessment[s]" as required by Article 5.1 of the SPS Agreement.

4.410 In fact, the only risk assessments put forth for the banned products are the positive scientific assessments rendered by member States to which the products were submitted, and then by the European Communities' own scientific committees. In the case of each member State ban, these favourable assessments were reaffirmed when the scientific committees considered and rejected the

information provided by the member States. Thus, the member State measures do not bear a "rational relationship" to the European Communities' positive risks assessment, and are not "based on" a risk assessment, in violation of Article 5.1.

4.411 The European Communities puts forth a number of defences of the member State measures – each is without merit. First, the European Communities makes the vague and cryptic argument that "It results from that analysis [of Sections II.A.4, III.B.3 and II.D.4 of its submission] that each of the member State measures was adopted for some reasons that fall within the scope of the *SPS Agreement*, and some reasons that do not fall within the *SPS Agreement*." The United States is not able to discern from this assertion what reasons the European Communities is referring to that it considers outside the scope of the *SPS Agreement*. But no matter. The important point is that the European Communities does not dispute, and in fact agrees, that each of the member States measures was adopted for "some reasons" that fall within the scope of the *SPS Agreement*.

4.412 Second, the European Communities argues that each of the measures fall within the scope of Article 5.7 of the *SPS Agreement*. But the European Communities does not specify how Article 5.7 might apply. Its only argument is that under the terms of the EC legislation, the member State measures are labeled as provisional. The mere label of a measure, however, is most certainly not sufficient to bring it within the scope of Article 5.7.

4.413 To the contrary, as the Appellate Body has found, a measure must meet four requirements to fall within the scope of Article 5.7. Each of the member State measures, however, fails to meet any of these four requirements. First, the measures were not imposed because scientific information is "insufficient." To the contrary, the European Communities and its scientific committees found sufficient information to evaluate and render positive assessment for each of the banned products. Second, the measures were not based on "available pertinent information." To the contrary, as the European Commission stated in a memo, the member State measures "have been examined by the Scientific Committee on Plants, which in all cases deemed that the information submitted by the Members States did not justify their bans." Third, there is no evidence that the member States have sought to "obtain additional information" concerning the banned products in order to make a "more objective assessment of the risk." In this regard, we note that all the member State measures were adopted in the period 1997 to 2000, in other words more than four years ago. Finally, by failing to seek and obtain additional information, the member States have also failed to review the measure in light of such information "within a reasonable period of time".

4.414 Third, the European Communities argues that even if the member State measures fall outside the scope of Article 5.7, that the measures are nonetheless consistent with Article 5.1 because they are based on a risk assessment. The European Communities' only support for this position, however, is the conclusory statement that the "member States may have drawn their own conclusions from the relevant risk assessments." The only "relevant risk assessments" of which the United States is aware, however, are those by the EC scientific committees providing positive assessments of the banned products. The European Communities has failed to identify any other "relevant risk assessments", nor to explain how the member State marketing or import bans could be based on such assessments. In short, the European Communities' argument that the member State measures are consistent with Article 5.1 is without merit.

J. FIRST ORAL STATEMENT OF CANADA

1. Introduction

4.415 Until October 1998, the European Communities had a functioning approvals process for agricultural products produced from modern biotechnology. Since then, it has maintained a moratorium on the approval of new biotech products. The moratorium has been maintained in the face of uncontroverted opinions of the European Communities' own scientists that (i) there is sufficient evidence to reach conclusions about the safety of these products, and (ii) that there is no evidence to show that these products pose a risk to human health or the environment. In addition, several EC member States are maintaining national bans on biotech products that had been approved by the European Communities prior to the institution of the moratorium.

4.416 The European Communities' principal defence is that the moratorium does not exist. As for its member State national measures, the European Communities' principal defence is that Canada should have challenged these under Article 5.7 of the *SPS Agreement*. None of these arguments have any merit.

2. Issues relating to the moratorium

4.417 In this section, Canada will demonstrate the following three propositions: the European Communities maintains a moratorium on the approval of biotech products; the moratorium is a challengeable measure; and, the moratorium is a SPS measure for the purposes of the *SPS Agreement*.

(a) The European Communities maintains a moratorium

4.418 Since 1998, with one, very recent, exception, the European Communities has failed to approve a single application for biotech products although there are over 30 applications in the approval pipeline. Many of these applications have received not one, but two, favourable risk assessments by the European Communities' own scientific bodies.

(i) *The moratorium is in effect*

4.419 The European Communities gives effect to the moratorium through concerted acts and omissions that stall applications at key decision-making stages in the approval process. This converts the pre-marketing approval requirement into an across-the-board marketing ban on new biotech products.

4.420 The key stages at which the blockage occurs are highlighted by the following acts and omissions:

- EC member State competent authorities have failed to ensure that the approval procedures are completed without undue delay;
- Certain EC member States routinely object to favourable assessments by the competent authority of another member State;
- Where an application is supported by favourable risk assessments, the Commission has failed in all but four cases to submit a draft measure approving a biotech application to the Regulatory Committee;

- EC member States routinely block the adoption of a favourable opinion by the Regulatory Committee, regardless of the scientific merits of the application;
- Where there has been an impasse at the Regulatory Committee, the Commission has failed to refer the matter to the Council of Ministers; and finally,
- When the Commission has approved a product, the responsible member State has failed to issue the consent letter necessary to be able to market the product.

(ii) *The European Communities denies the ample evidence of the moratorium*

4.421 The European Communities denies that the moratorium exists. It says that the lack of decisions is a coincidence, caused by a series of unrelated delays in individual applications for biotech products arising from the insufficiency of scientific evidence, the on-going changes in the European Communities' regulatory regime, and requests for information. This is at odds with the facts and the opinions of the European Communities' own scientists, and with how the European Communities' own officials and documents have characterized the situation. The European Communities also says that Canada cannot point to any law or other formal act on the part of the European Communities that supports the existence of a moratorium.

4.422 Canada has six points in response. **First**, the June 1999 declaration undermines the "coincidence" argument. **Second**, the Commission's own officials have described the situation as a moratorium; EC documents continue to refer to a moratorium. **Third**, although it is true that there is no law or other formal act that Canada can point to, the European Communities cannot use its own lack of transparency as a shield in this dispute. **Fourth**, the moratorium does not arise from the failure to approve a particular application; it is the general suspension of the approval process, resulting in the failure to consider for approval all applications. The European Communities' attempt to treat delays in individual applications as isolated events ignores the surrounding circumstances. **Fifth**, the simplified procedure under Regulation 258/97 does not constitute an approval process; it does not require the Commission to take a decision, and other member States cannot block or stall this process. **Lastly**, Canada does not argue that the moratorium involves a complete shutdown of the approval process; rather it is at the critical decision-making junctures, or key stages, of the approval process where applications have been blocked.

(b) The moratorium is a "measure"

4.423 Whether one calls the moratorium a "requirement", "administrative guidance" or "practice" is immaterial. It is still a measure. A measure may be any act of a Member, whether or not legally binding, and it can include even non-binding administrative guidance by a government. In this case, the moratorium converts the pre-marketing approval requirement of the legislation into an across-the-board marketing ban on new biotech products just as effectively as an amendment to the approval legislation.

4.424 The list of measures in Annex A is not exhaustive. This is supported by the use of the word "include" in Paragraph 1. There is no doubt that the underlying approval legislation is a measure. It is stands to reason that the moratorium, should also be interpreted as a measure. To interpret "measure" narrowly would allow WTO Members to circumvent their obligations by neglecting or refusing to adopt transparent, formal, legally binding laws, regulations or procedures; this would undermine the object and purpose of the *SPS Agreement*.

4.425 The European Communities uses two panel reports to argue that "a practice not laid down in any document whether formal or informal in character" is not a measure. Neither case supports the European Communities' sweeping proposition.

(c) The moratorium is an "SPS measure"

4.426 The moratorium is not based on a legal instrument; therefore its purpose must be inferred from the context. The 1999 declaration confirms that the purpose of the moratorium is to protect human health and the environment from risks arising from biotech products. This suggests that the general suspension of the European Communities' approval procedures is based on concerns that those procedures could not adequately assess those risks. Thus, the purpose of the moratorium can be reasonably inferred from the underlying legislation.

4.427 The European Communities has admitted that the purpose of its approval procedures is, at least in part, to protect against risks to human health and the environment that fall within the *SPS Agreement*. It stands to reason that the purpose of the moratorium is the same. Thus, the moratorium was instituted, at least in part, to protect against risks identified in Annex A of the *SPS Agreement*; therefore, it is an SPS measure.

(d) The scope and application of the *SPS Agreement*

4.428 Canada has five points to make with respect to the European Communities' arguments about the scope and application of the *SPS Agreement*. **First**, the European Communities argues that the "*SPS Agreement* was not intended to address the prevention of risks to the environment." The European Communities highlights biodiversity, suggesting that measures taken to protect biodiversity somehow fall outside of the scope of the *SPS Agreement*. The European Communities concedes, however, that one of the risks posed by biotech products is that they may "choke or stunt" other plants. In other words, biotech products may become a pest or a weed. This is both a concern for biodiversity and a risk identified under the *SPS Agreement*. Thus, the suggestion that risks to biodiversity *per se* are not covered by the *SPS Agreement* should be rejected.

4.429 **Second**, the European Communities asserts that the *SPS Agreement* was not drafted with products like GMOs in mind. The *SPS Agreement* is not applied to products, *per se*, but to measures intended to protect against certain identified risks. Moreover, when the *WTO Agreement* was signed, Directive 90/220 had been in existence for several years and the European Communities had by then approved for commercial release several products.

4.430 **Third**, the European Communities insinuates that measures regulating GMOs should be dealt "outside" the *WTO Agreement* because GMOs have their own "special agreement", the Biosafety Protocol. Again, this argument is totally without merit. To the contrary, the Biosafety Protocol has no material bearing on the issues in dispute before this Panel.

4.431 **Fourth**, the European Communities states that there is "no precise match" between the European Communities' approval legislation and the objectives and scope of the *SPS Agreement*. The implication of this is that a SPS measure, in this case an approval procedure, is no longer subject to the obligations of the *SPS Agreement* if it involves the consideration of non-SPS risks or other issues. The panel should reject this argument. The obligations of the *SPS Agreement* do not cease to apply to SPS measures merely because those measures are also applied to protect against non-SPS risks.

4.432 **Lastly**, the European Communities asserts that, with reference to Codex Standard 193, "toxin" as used in the *SPS Agreement* should be limited only to naturally occurring toxicants that are

not intentionally added to food. Codex Standard 193 does not purport to provide a comprehensive definition of "toxin". It simply sets out the types of toxins included in the scope of that Standard. The limited definition of "toxin" in the Standard in no way limits the term as it is used in the *SPS Agreement*.

3. The product-specific marketing bans

4.433 The European Communities claims that the complaint is really about "undue delay", and denies there has been undue delay. It attributes any delay to "requests for additional information". However, the European Communities makes bald assertions unsupported by specifics and carefully avoids any discussion of the scientific opinions rendered by its own scientists.

4.434 The European Communities fails to respond to Canada's claims under Articles 2.2, 2.3, 5.1, 5.5 and 5.6 of the *SPS Agreement*. The European Communities bases this failure on the contention that "alleged behaviour cannot be an SPS measure itself as well as the application of another SPS measure." There is no basis in the *SPS Agreement* for this contention. In fact, there are many instances where an act can be both an SPS measure and an application of another SPS measure.

4. EC member State national measures

4.435 In this section, Canada responds to arguments made by the European Communities in its written submission, relating to the *EC member State national measures*.

(a) Article 5.7

4.436 The European Communities states that the "safeguard" measures are provisional measures, taken pending a full assessment at the Community level. According to the European Communities, this "full assessment" will lead to either a change in the Community-wide authorization or a termination of the national safeguard measures and that "this will now be done in light of the changes in Community legislation". It is not clear what this means.

4.437 The European Communities argues that, because these measures are "provisional", they must be assessed against Article 5.7, and that, because the complaining parties have not alleged violations of this provision in relation to these measures, they have failed to demonstrate that the measures do not fall exclusively under Article 5.7; thus, there is no burden on the European Communities to respond to the complaining parties' claims that the measures are inconsistent with the remaining SPS provisions. This argument is without merit.

4.438 The language in Article 5.7 does not exclude the applicability of all other SPS provisions simply on the basis that the measures in question are provisional. The starting point for an analysis of an SPS measure is Article 2. It establishes basic rights and obligations of the Members with respect to their SPS measures. Such measures must be based on scientific principles and must not be maintained without sufficient scientific evidence. Whether the measures are provisional or not is beside the point.

4.439 In any event, the provisional nature of a given measure does not exclude the remaining provisions of the *SPS Agreement* from applying to it unless those other provisions indicate that they do not apply to provisional measures. For example, Article 2.2 is not expressed in terms that limit its application to "permanent" measures. A Member is free to challenge a provisional measure under Article 2.2 as being maintained without sufficient scientific evidence. The Member must demonstrate that the measure in question is not adequately supported by scientific evidence. Nowhere does the

jurisprudence indicate that the Member must also demonstrate that the measure does not fall within the scope of Article 5.7.

4.440 At the same time, Article 2.2 recognizes that there may be circumstances where measures have to be taken in the face of insufficient scientific evidence. In such circumstances, it is open to the Member defending such a measure to invoke Article 5.7. The panel in *Japan – Apples* recognized this. The key language in Article 5.7 is not the word "provisional", but the words "[I]n cases where relevant scientific evidence is insufficient ...". It is not the provisional nature of the measure that matters; it is the insufficiency of the scientific evidence. Thus, it is not enough for the European Communities to claim that the measure is provisional in order to exempt it from scrutiny under Article 2.2.

4.441 The European Communities claims that certain statements by the Appellate Body in *Japan – Apples* support its argument with respect to the objective scope of application of Article 5.7, and the proper allocation of the burden of proof. However, the statements to which the European Communities refers do not explicitly address this matter.

4.442 Furthermore, the European Communities refers to the application of provisional measures in the *Anti-Dumping Agreement* and the *Subsidies Agreement* as support for its interpretation of Article 5.7. However, these provisions do not concern themselves with the allocation of the burden of proof, and are therefore irrelevant to the European Communities' argument concerning the proper scope to be given to Article 5.7. In short, they have no bearing whatsoever on the issues before this Panel.

4.443 The European Communities appears to base its arguments with respect to Article 5.7 solely in relation to what it terms the "threshold" argument. It claims that it is for Canada to demonstrate inconsistency with Article 5.7, and that Canada has failed to discharge this burden. The European Communities is mistaken on this point. There is no burden on Canada until the European Communities invokes Article 5.7 and makes out a *prima facie* case for its application.

4.444 Even if the European Communities were correct that the departure point for an analysis of these measures is Article 5.7, these measures do not meet the requirements of that provision. Even a cursory review of the measures and the factual and scientific circumstances surrounding their adoption and maintenance reveals that they fail to satisfy even one of the four required elements under Article 5.7.

4.445 Under the **first** element, based on the opinions adopted by the European Communities' own scientific experts, there is no indication that there was insufficient scientific evidence to allow them to come to unambiguous conclusions. Equally importantly, those conclusions were uniformly favourable as regards the safety of the products in question. Under the **second** element, a measure that bans the commercialization or marketing of a product that has repeatedly been found to be safe by the competent scientific authorities cannot be said to be based on the "available pertinent information". The **third** element becomes irrelevant as a criterion, given the sufficiency of the scientific evidence available from the European Communities' own sources. In any event, the European Communities has failed to demonstrate that the member States sought to obtain any additional information to support their measures, even in the face of the opinions of the European Communities' scientific experts that the information initially provided did not alter the original favourable risk assessments. Finally, under the **fourth** element, to Canada's knowledge, no review has taken place at all, let alone "within a reasonable period of time".

4.446 Because the *EC member State national measures* do not satisfy any of the four required elements, they cannot fall within the scope of Article 5.7.

(b) Article 5.1

4.447 The European Communities claims that even if Article 5.1 applies, the use of the words "appropriate to the circumstances" ... gives the WTO Members "a certain degree of flexibility in meeting the requirements of Article 5.1". Canada agrees that, in principle, Article 5.1 offers "a certain flexibility", but it is not of the kind identified by the European Communities. The European Communities claims that the "circumstances" in the present case are that "relevant scientific evidence was or is insufficient". Canada has already responded to this argument.

4.448 Article 5.1 sets out a clear standard. A risk assessment must meet that standard and the measures must be "based on" that risk assessment. If the scientific evidence is insufficient, it is for the WTO Member concerned to make its case under Article 5.7. In this case, the risk assessments of the competent authorities of the sponsoring EC member States, and the scientific opinions rendered by the relevant scientific committees conclude that these products are safe. These risk assessments and scientific opinions do not indicate that the available scientific evidence was insufficient to support those conclusions.

4.449 The European Communities does present arguments for why it considers that the *EC member State national measures* are consistent with Article 5.1. While it states that the measures are based on risk assessments, it does not identify those risk assessments. The only risk assessments that Canada is aware of are the European Communities' own risk assessments, which found no evidence that the products in question are unsafe. These do not bear a rational relationship to a ban. Even if Canada accepted the European Communities' contention that the same risk assessment, as a matter of WTO law, might 'sufficiently warrant – that is to say, reasonably support' – more than one possible SPS measure, depending, *inter alia*, on the specific legislator", the European Communities does not make it clear to which legislators or to which circumstances it is referring. In any event, publicly available risk assessments, which uniformly concluded that there was no evidence of a risk to human health or the environment, cannot be said to "reasonably support" a complete ban on such products.

(c) Article 5.6

4.450 The European Communities' arguments with respect to Article 5.6 are difficult to follow. It is true that Canada bases its arguments with respect to Article 5.6 on an assumption as to the European Communities' appropriate level of protection. The European Communities' legislation seems to indicate that the level of protection sought by the European Communities with respect to biotech products is a high level of protection, but not zero risk. Canada asks the European Communities to state clearly whether its appropriate level of protection is the level of protection that is set out in the relevant EC legislation, or the level of protection – that is, zero risk – implied by the *EC member State national measures*. In any event, the European Communities has not refuted Canada's arguments under Article 5.6 and it remains open to the Panel to conclude that the *EC member State national measures* are inconsistent with that provision.

(d) Article 5.5

4.451 The European Communities makes a number of assertions and statements in its written submission, none of which refute the *prima facie* case that Canada has made.

4.452 Canada agrees with the European Communities that there is no inconsistency in the absence of arbitrary or unjustifiable distinctions. However, the European Communities has failed to address, much less refute, the arbitrary or unjustifiable distinctions that Canada has demonstrated exist with respect to the appropriate levels of protection applied by the European Communities to the comparable situations outlined in Canada's written submission.

4.453 When the European Communities' own experts unambiguously find that there is no evidence to show that these products are unsafe, and the member States nevertheless ban the products and maintain those bans in the face of further scientific advice that such bans are groundless, this cannot be characterized as anything other than a complete disregard or determination to ignore such opinions and advice. When this is done on a selective basis that bears no relationship to the actual risks involved, the conclusion is inescapable that the resulting measures give rise to a violation of Article 5.5.

K. FIRST ORAL STATEMENT OF ARGENTINA

1. Introduction

4.454 This case concerns inconsistencies with WTO obligations, arising from: (i) the *de facto* moratorium which the European Communities has maintained from 1998 to the present; (ii) the "suspension of processing and failure to consider individual applications for specific products of particular interest to Argentina"; (iii) the "undue delay"; and (iv) the bans imposed by some EC member States to the detriment of specific biotech agricultural products of particular interest to Argentina. Argentina maintains that the foregoing measures infringe the *SPS Agreement*.

4.455 Article 3.2 of the DSU does not authorize any broad reliance on rules of public international law beyond the *Covered Agreements* which would modify the rights and obligations of Members. Specifically, Argentina is of the view that it would not be proper for the Panel to look for additional endorsement from other rules of international law, such as the Cartagena Protocol, in interpreting the scope of the obligations included within the *Covered Agreements*.

2. The *de facto* moratorium is not based on scientific evidence and therefore infringes the *SPS Agreement*

(a) The measure at issue in these proceedings

4.456 The "de-facto" moratorium violates the *SPS Agreement*. Argentina disagrees with the assertion of the European Communities that the complaining parties have chosen to turn to the WTO dispute settlement procedures rather than to promote international cooperation.

4.457 Argentina claims that the *de facto* moratorium constitutes *per se* a breach of WTO obligations. This claim is separate from the claim concerning the "suspension of consideration and failure to process specific applications for products of particular interest to Argentina", and from the claim regarding "undue delay".

4.458 The European Communities has expressly acknowledged the existence of a *de facto* moratorium, as indicated in the abundant documentary evidence supporting this affirmation. Furthermore, the European Communities has not responded to the evidence that Argentina has produced to show the existence of the moratorium.

4.459 The European Communities does not faithfully report the actual duration of the *de facto* moratorium, but attempts to reduce it to the period from 1998 to 2001. This contradicts the European Communities' own statements which confirm what Argentina indicated in its submission (1998 to the present), on the basis of the need for further legislative changes.

4.460 The European Communities starts from the premise that the complaining parties have been "unable to identify an instrument or other text" by which the moratorium was established, and that the complaining parties' claims "are all in reality complaints about delay". This is because the complaining parties are addressing "omissions", which, in the European Communities' opinion, would not be challengeable under the WTO. We note that an "omission" is actionable under WTO rules. The European Communities' intent in so arguing is to divert the Panel's attention to what it calls issues "of procedure". The European Communities is thus attempting to evade the substantive issues: the *de facto* moratorium and the lack of scientific evidence supporting the restriction.

4.461 One of the elements that demonstrate both the existence of the *de facto* moratorium and the period during which it has been applied comprises statements by EC officials having competence in the matter at issue. Argentina nevertheless wishes to point out that the statements do not constitute the moratorium itself or the instrument embodying it, but are provided as facts demonstrating the existence of a *de facto* moratorium.

4.462 With regard to the European Communities' argument that the *de facto* moratorium could not be identified in any instrument, Argentina in its submission specifically explains the specific characteristics of the *de facto* moratorium measure. Furthermore, the fact remains that no biotech agricultural products have been approved since 1998. The European Communities concedes that it applied a moratorium on the approval of new products at least until its legislative process was completed.

4.463 Argentina notes that the European Communities has not based the *de facto* moratorium on any scientific evidence. On the contrary, the existing scientific evidence supports the position contrary to the *de facto* moratorium, since it recommends approval of the biotech agricultural products at issue.

4.464 Within the broader framework of the *de facto* moratorium, a persistent pattern of conduct by the European Communities can be observed. Through actions and, essentially, through omissions, a *de facto* moratorium has taken shape that is visible in the various stages of the procedures under EC regulations: (i) Undue delay in completing the procedures; (ii) lack of action by the Commission in presenting the draft measure to the Regulatory Committee for approval of products that have received a favourable opinion from the scientific committees; (iii) systematic opposition by member States to approval when a draft is submitted, with no scientific grounds for opposing the Commission's draft; and (iv) failure by the European Communities to refer a proposal to the Council of Ministers when the Regulatory Committee issues no opinion. Although in the foregoing combination of actions and omissions within the European Communities' regulatory system some movement of applications through the various regulatory stages is visible, in the opinion of Argentina the movement is circular in nature and never results in approval.

4.465 Argentina requests the Panel, on the basis of the evidence submitted, to consider the existence of the *de facto* moratorium as having been demonstrated above.

(b) Application of *SPS Agreement* to the *de facto* moratorium

4.466 We will now address the purpose of the *de facto* moratorium. The purpose of the European Communities' regulations for the approval of biotech products is *to determine*, by means of case-by-case assessment, the presence or absence of "additives", "contaminants" or "toxins" in foods, beverages or feedstuffs and the risks to human life and health resulting from their presence. Such regulations constitute a sanitary and phytosanitary measure within the meaning of the *SPS Agreement*.

4.467 The risk arising from the mass consumption of varieties containing marker genes falls within the definition given in paragraph 1(b) of Annex A of the *SPS Agreement*. The risk arising from the cross-contamination of biotech products with other, undesired organisms falls within the scope of paragraph 1(d) of Annex A of the *SPS Agreement* and of paragraph 1(c). Paragraph 1 of Annex A defines "pests", which include "weeds".

(c) Conclusions with respect to the *de facto* moratorium

4.468 To sum up, Argentina considers that the European Communities is in obvious breach of the rules of the *SPS Agreement*. Furthermore, the European Communities has itself admitted the existence of the *de facto* moratorium, even when its own scientific committees have ruled in favour of the approval of various biotech agricultural products. For this reason, Argentina respectfully requests the Panel first to find the *de facto* moratorium inconsistent with Article 5.1, and then with Article 2.2 of the *SPS Agreement*.

4.469 Argentina notes that, should the Panel find in respect of this claim that there is breach of Articles 5.1 and 2.2 of the *SPS Agreement*, it need not rule as to the inconsistency of the *de facto* moratorium with the other Articles of the *SPS Agreement* cited, without prejudice to Argentina's reaffirming, in the light of the Panel's finding, the other arguments concerning the Articles of the *SPS Agreement* violated by the European Communities that it adduced in its first written submission.

3. The "suspension and failure to consider" is not based on scientific evidence and therefore violates WTO obligations

4.470 Article 1.5 of the *TBT Agreement* indicates that its provisions are not applicable to the sanitary and phytosanitary measures defined in Annex A of the *SPS Agreement*. Article 1.4 of the *SPS Agreement* reaffirms the rights of the Members under the *TBT Agreement* in respect of those measures not within the scope of the *SPS Agreement*. Therefore, a measure may be examined – under one or other of the two Agreements – only when both are in play. The contrary would be a departure from the textual basis, which treats them as mutually exclusive.

4.471 Argentina considers that, in this case, the object of life and health protection places the measure within the scope of the *SPS Agreement*, regardless of the form the measure takes. This also rules out the applicability of *TBT Agreement* which requires the existence of at least one document embodying a "technical regulation" or setting forth a procedure for conformity assessment. The "suspension of processing and failure to consider" are not set forth in a document. This in itself rules out application of the *TBT Agreement* as a Covered Agreement against which the measures at issue are assessed for consistency.

4.472 As to the biotech agricultural products considered individually, Argentina notes, for example, that the "suspension of processing" affected four of them, which had reached the stage of receiving favourable scientific opinions.

4.473 With regard to Cotton Bt-531, the application was filed in 1996 under Directive 90/220. It obtained a favourable opinion from the competent body's biosafety committee in 1997. In 1998, the Scientific Committee on Plants issued a positive opinion. In 1999, the Regulatory Committee failed to obtain a qualified majority and so did not issue an opinion. According to Directive 90/220, the Commission should have referred a proposal to the Council without delay. The Commission never made such a referral. The application was suspended until it had to be refiled under Directive 2001/18. Although the product has had a favourable scientific opinion since 1998, as at June 2004 its marketing has not been authorized.

4.474 With regard to Cotton RRC-1445, the application was filed in 1997 under Directive 90/220. In 1998 the Scientific Committee on Plants issued a positive opinion. In 1999, the Regulatory Committee failed to obtain a qualified majority and so did not issue an opinion. According to Directive 90/220, the Commission should have referred a proposal to the Council without delay. The Commission never made such a referral. The application was suspended until it had to be refiled under Directive 2001/18. Although the product has had a favourable scientific opinion since 1998, as at June 2004, its marketing has not been authorized.

4.475 With regard to Maize NK-603, the application was filed under Directive 90/220 in 2000 and was refiled under Directive 2001/18 in 2003. The new European Food Safety Authority (EFSA) issued a favourable opinion. The European Communities indicates that the requisite majority was not obtained in the Regulatory Committee and consequently, the Commission sent a draft proposal to the Council. Argentina trusts that after the favourable scientific opinion Maize NK-603 will be approved this June as indicated by the European Communities. Unfortunately, notwithstanding the favourable opinion of the EFSA, processing the same product under Regulation 258/97 offers no alternative since there are no plans in the Council to address the application in question.

4.476 With regard to Maize GA-21, the application under Directive 90/220 dates back to 1998 and obtained a favourable opinion from the Scientific Committee in 2000. In 2003 the application for approval of this product was withdrawn. Argentina mentions this because the product is one of interest which, for nearly three years did not obtain authorization despite favourable scientific evidence. Under Regulation 258/97 the application was filed in 1998 and obtained a favourable opinion in 2002. Despite the favourable opinion, no authorization has been obtained, placing this product in the category of those which, despite scientific analysis, never obtained authorization.

4.477 The European Communities has not refuted the scientific evidence of its own committees, which recommended the approval of the products in question, clearly depriving of scientific backing the measures affecting the approval procedures of at least four of these products. Therefore, Argentina's first claim is to a finding of inconsistency of the "suspension of processing and failure to consider" with the *SPS Agreement*, specifically with Article 5.1. This would automatically imply inconsistency with Article 2.2 of the *SPS Agreement*.

4.478 Furthermore, should the "suspension of processing and failure to consider" be found to be inconsistent with Articles 5.1 and 2.2 of the *SPS Agreement*, Argentina considers that the Panel need not address the inconsistency of the other legal provisions cited in respect of these measures, without prejudice to Argentina's reaffirming, in the light of the Panel's assessment, the other arguments related to provisions violated by the European Communities that it adduced in its first written submission.

4. The "undue delay"

4.479 In Argentina's view, "undue delay" implies a violation of the provisions of Article 8 and Annex C of the *SPS Agreement*.

4.480 Both Directive 2001/18 and Regulation 258/97 set time limits for each stage in the control, assessment and approval of new biotech agricultural products. It is possible to estimate an approximate average length of time within which the procedures can reasonably be completed. The procedures established in EC regulations should not, on average, exceed 240 days.

4.481 The European Communities has simply failed to explain why new biotech agricultural products receive less favourable treatment under the same regulatory system – i.e. Regulation 258/97 – than new "non-biotech" products. For new biotech agricultural products, the same procedures are applied in a way that results in an "undue delay", while new "non-biotech" products subject to the same regulations are not delayed at all and have been approved.

5. The state bans are not based on scientific evidence and therefore violate the SPS Agreement

4.482 First, with regard to the European Communities' argument concerning Article 5.7 of the *SPS Agreement*, Argentina reserves the right to develop this point at a later stage of the proceedings.

4.483 With regard to the measures applied by Germany, Austria, Italy and Luxembourg against certain biotech agricultural products, all of the affected products had the prior approval of the European Communities, based on scientific opinions issued by the European Communities' own committees.

4.484 Furthermore, some of these countries have resorted to safeguard procedures in an attempt to justify their measures. This has resulted in new scientific opinions from EC committees, which have specifically refuted the grounds for the EC member State measures.

4.485 Consequently, our first claim is again to a finding of inconsistency with Article 5.1 of the *SPS Agreement*. Furthermore, that violation implies inconsistency with Article 2.2 of the *SPS Agreement*, according to WTO jurisprudence.

4.486 Notwithstanding the foregoing, in the interests of procedural economy a finding of inconsistency of the state bans with Articles 5.1 and 2.2 of the SPS will obviate the need for a further finding that the bans by some EC member States violate the other legal provisions cited, without prejudice to Argentina's reaffirming, in the light of the Panel's assessment, the other arguments concerning provisions violated by the European Communities that it adduced in its first written submission.

6. Article XX of the GATT 1994

4.487 Nowhere in their submissions have the complaining parties indicated the possibility that the European Communities' conduct and breaches were justified under Article XX of the GATT 1994. In this regard, the European Communities has the burden of proof, which cannot be deemed to be discharged by a mere assertion. The European Communities has not put forward a single argument justifying the first test needed to invoke a provisional exception under one of the subparagraphs of Article XX of the GATT 1994, nor has it made any case whatsoever regarding the "chapeau". Argentina requests that the Panel reject this attempt by the European Communities to mount a defence based on an exception under Article XX of the GATT 1994.

7. Special and differential treatment

(a) In the framework of the *SPS Agreement*

4.488 Argentina does not agree with the European Communities as to the scope and interpretation of the special and differential treatment for developing countries as set forth in Article 10.1 of the *SPS Agreement*.

4.489 In the opinion of Argentina, the European Communities has failed to respond and to demonstrate that it took into account and engaged in positive actions of the kind envisaged in Article 10.1 of the *SPS Agreement*, in deciding on and applying the *de facto* moratorium to, suspending consideration of, not approving or unduly delaying approval of the biotech products of particular interest to Argentina. The ban on all access for biotech agricultural products of particular interest to Argentina arising from the European Communities' failure to consider, suspension, non-approval or undue delay in the approval of those products has, as argued, affected and continues to affect Argentina.

4.490 In this regard, the European Communities is wrong in asserting that the claim is consequential. To construe Article 10.1 of the *SPS Agreement* as containing only a consequential obligation is to devoid the provision on special and differential treatment of substance.

(b) In the framework of the *TBT Agreement*

4.491 Argentina has already made its alternative claims regarding the *TBT Agreement* in its first written submission, and will not bring them up here other than to make the following comments relating to Article 12 of the *TBT Agreement*.

4.492 The European Communities has limited its response to the argument that Argentina infers violation of Article 12.3 in the event of a finding of breach of Article 5.2.1; and since the European Communities does not accept the existence of any violation, it concludes that there is no violation of this obligation. Argentina points out that the arguments concerning the obligations laid down in Article 12.3 are much more extensive and are based on a detailed analysis of the logic of Article 12 as a whole.

4.493 Argentina also emphasizes that the European Communities has ignored the special trade, financial and development needs of developing countries. The European Communities has not responded to this argument.

4.494 Furthermore, Argentina puts forward arguments about the absolute ban on imports, whose main effect of the ban has been to prevent the access of biotech agricultural products of particular interest to Argentina not approved prior to 1998. The European Communities has failed to take into account the special needs of a developing country, in this case Argentina. The European Communities has not responded to this argument.

4.495 The European Communities submits that imports of biotech agricultural products from developing countries have not declined and, on the contrary, have increased since 1995/96 in the case of Argentina and Brazil.

4.496 Argentina considers it necessary to clarify certain aspects of this claim. First, Argentina has made no reference to any increase or decrease in imports. The GATT/WTO system protects not volumes of trade but competitive expectations. Secondly, while the European Communities' claim

mentions in particular "commodities likely to contain GMOs", what Argentina is referring to is an absolute ban on imports in respect to biotech agricultural products of particular interest to Argentina which have not been considered, or approved and have been subjected to suspension or undue delays since 1998. Thirdly, Argentina disagrees with the European Communities as to the period during which the increase has occurred "since 1995/1996" in the European Communities' submission. Argentina argued that the absolute ban on imports into the European Communities of biotech agricultural products of particular interest to Argentina started in 1998.

(c) Conclusions regarding special and differential treatment for developing countries

4.497 Argentina is of the view that, through the arguments in its first written submission the European Communities has not refuted Argentina's argument in that it has not addressed the special needs of developing countries, in this case, Argentina, by according the mandatory treatment envisaged in Article 10.1 of the *SPS Agreement*. Furthermore, the European Communities has not argued that in applying EC legislation to biotech agricultural products of particular interest to Argentina, it has observed the special needs of Argentina as a developing country, as the relevant provisions of Article 12 of the *TBT Agreement* require. Lastly, Argentina wishes to note that the special and differential treatment obligations set forth in the Agreements are not supplementary or lesser obligations.

8. Conclusion

4.498 Argentina reiterates the claims of inconsistency it put forward in its first written submission, and requests that they be analysed with a view to procedural economy as proposed earlier in this Oral Statement, so that a prompt settlement of this dispute can be reached in accordance with the provisions of the DSU.

L. FIRST ORAL STATEMENT OF THE EUROPEAN COMMUNITIES

1. Introduction

4.499 The European Communities would like to express its thanks to all three panellists for having accepted to serve on this Panel and to assist in the resolution of this difficult dispute. The complex and controversial issues before the Panel are not only about science and societal values – they also raise some very difficult issues of legal interpretation.

4.500 Despite the complaining parties' occasional attempts to suggest the contrary, this dispute is not about protectionism, nor is it about discrimination. This is, in the view of the European Communities, a case about regulators' choices of the appropriate level of protection of public health and the environment in the face of scientific complexity and uncertainty and in respect of which there is great public interest. It is a case essentially about time. The time allowed to a prudent government to set up and apply a process for effective risk assessment of products which are novel for its territory and ecosystems, and that have the potential of causing irreversible harm to public health and the environment. In these matters there cannot be a "one size fits all" kind of solution and the Panel should resist the temptation to use simplistic approaches, as suggested by the complaining parties.

2. GMOs are still in their infancy

4.501 For more than a decade, the world has witnessed extraordinary advances in the field of genetic modification. We have found ourselves at a crossroads with many paths open in front of

us, as new opportunities are created by tremendous technological advances while, at the same time, the need is felt to harness technological progress in a context of still limited scientific knowledge.

4.502 Over that period, the international Community has been busy considering what may be the appropriate roads to take to exploit the full potential of new biotechnologies while minimising any risks to human health and the environment. The international Community has agreed that special rules are needed to address GMOs, since GMOs are inherently of a character which requires particular scrutiny, and that, in the face of scientific uncertainty, states' actions should be based on precaution. That conclusion is notably enshrined in the Convention on Biological Diversity and the Cartagena Protocol on Biosafety.

3. GMOs are characterised by scientific complexity

4.503 As early as the end of the 1970s, the need was identified to address the potential risks of genetically modified organisms for human health and the environment differently compared to non-GM organisms, because of the extraordinary new potential of genetic engineering. The new technology has brought to us the ability to theoretically introduce within any living organism, as quickly as it takes to go from one generation to the next, any trait from any other organism, and more importantly, totally new properties to that organism, as yet inexistent in nature.

4.504 The science necessary to assess the risks of these new combinations, and in particular any long term, indirect, or delayed effects, has had and is having a hard time to catch up with the rapid development of new GM products. The science traditionally used in risk assessment can hardly apprehend all the properties of highly complex individual organisms, the interaction between organisms, and the full picture of the ecosystems or the agroecosystems that might be affected, taking also into account that the consequences of the introduction of GMOs into the open environment can be highly variable between different ecosystems.

4.505 Furthermore, GMOs are living organisms, and they are able to reproduce autonomously. Any measure bringing a GMO into the environment has therefore a character of irreversibility. Another element to be considered is that the experience we have today of GMOs is still very limited both in time and in quality, as the acquisition of this technology has happened at a pace which is unprecedented in the history of agriculture. However, only an extremely limited number of inserted genes are widely used in agriculture and very few systematic studies exist or have been planned on this limited set of GMOs. As a consequence, many questions remain as yet unanswered.

4.506 The debate on the uses of modern biotechnology and its potential impact on public health, sustainability and biodiversity should be seen against this growing awareness of the fragility of human conditions and natural systems. On all of this, the complaining parties are silent.

4. GMOs raise the need for targeted regulatory approaches

4.507 In the face of the fast evolution of science, the European Communities, as well as many other governments, have chosen to act prudently, setting up effective processes for risk assessment to be performed before any of these new products is accepted for production, importation or commercialisation. In a context of growing awareness over possible effects of agriculture on health and the environment, countries that had developed early-on a regulatory framework for GMOs had to revise it in recent years and to adapt it to take account of new scientific and economic issues. Both Canada and the United States are examples of countries which are in the process of developing more stringent regulatory frameworks.

4.508 Scientific evolution is not, however, the only factor to take into account. As the joint EU/US Biotechnology Consultative Forum concluded in December 2000,

"judgements about risk cannot be reduced to scientific assessment alone. There are legitimate concerns for which science, at least natural science, cannot provide answers. Such concerns may cover issues of distribution of power and influence, risks of concentration of knowledge and expertise to a few very large corporations, relations between different social groups and classes, between ethics and social values, between large corporations and small companies, between small-scale subsistence farmers and family farmers and the agroindustrial complex, between developed and developing countries. As is true of all technologies with the potential for far-reaching benefits, the societal consequences are far reaching as well".

4.509 The move towards a strong regulatory process has not been limited to the national dimension. The international Community has been working through the last two decades in order to develop a proper framework to address the specificities of GMOs, and by now, international consensus exists on a number of issues related to GMOs, such as the need for a tailor-made regulatory regime for GMOs, including pre-marketing authorization; the right of each country to make its own decisions on each and every GMO on the basis of its legitimate policy goals; the right to adopt a precautionary approach when dealing with GMOs; the need for labelling and post-marketing surveillance.

5. The regulatory choices of the European Communities are those of a prudent, responsible government

4.510 Against this background, the European Communities believes that its actions have been and are those of a prudent government. Over the years, far from having "stalled the process", as is being alleged, the European Communities has worked diligently to design and put in place a regulatory environment for GMOs which takes into account health and environmental concerns while allowing their production, importation and marketing.

4.511 In parallel, and as demonstrated by the forty-nine detailed chronologies that the European Communities has submitted in its first written submission, the European Communities has continued the assessment of each individual application on a case-by-case basis, anticipating, to the extent possible, the application of the standards of review of the upcoming legislation to pending applications. This has always been done in a constant and continued dialogue between the various levels of the EC administration and the applicants.

6. The case of Bt 11 Maize

4.512 Bt 11 Maize – the product that was granted a market authorization two weeks ago – is a perfect illustration of the fact that the approval process, far from being stalled, has been steadily proceeding over the past years.

4.513 Bt11 maize was notified in 2000 and moved up to the Community level quite quickly. The European Commission asked its scientific committee for advice on this dossier in December 2002 and, as soon as the applicant provided the necessary data (this took him more than two years), the Committee issued its opinion. In line with the new legislation that was being prepared, the applicant, on a voluntary basis, agreed to provide the necessary materials to develop validation and detection methods, but it took more than a year to obtain the necessary material from the applicant. The detection and validation method was then rapidly finalized and the decision-making process launched immediately. The proposal for the decision has made its way through the decision-making procedures

exactly as provided for in the legislation and, thus, the decision was adopted by the Commission two weeks ago.

4.514 This marketing authorization has not happened overnight because of a sudden change in the European Communities' policy on GMOs. It is simply the result of a normal process of assessment. How else can you prove the absence of a moratorium if not through demonstrating that the approval process moves on and results in decisions?

7. Legal issues

(a) Preliminary legal remarks

4.515 First, the European Communities is struck by the fact that all the complaining parties, who have the burden of proof, are requesting the Panel NOT to have recourse to scientific and technical advice. It is interesting to note that it is only the defendant who is open to a clarification of the facts in this case on the basis of expert advice. It is definitely not the case that there are no scientific facts in dispute. For instance, the European Communities does contest that the risks involved in GMOs are no different from those presented by conventional products. Most importantly, the views of the European Communities' scientific committees, now regrouped under the European Food Safety Authority, have no formal overriding effect on the opinions of the corresponding national committees, and they are only part of the evidence that EC authorities may use as a risk assessment within the meaning of the *SPS Agreement*.

4.516 Second, as explained in the European Communities' first written submission, it is simply not tenable to examine the facts of this dispute in the light of the *SPS Agreement* only. The complaining parties' approach is too simplistic.

4.517 In fact, both these features of the way in which the complaining parties are conducting their case are illustrative of one fact. That the complaining parties want to avoid that the Panel enters into any detailed factual or legal analysis of the European Communities' actions, which they intentionally misrepresent. They want this Panel to rule on certain issues of general concern for all WTO Members, but in a biased way and in the light of only limited information. It is the defendant that is prepared to confront these complexities fairly and squarely and seek to resolve them, in order to show the true simplicity of the case: there is no moratorium and no suspension to rule on. There is only a series of prudent actions in response to concerns shared by responsible governments around the world.

(b) The correct approach to interpretation

4.518 A correct interpretation of the balance of rights and obligations contained in the WTO agreements has to ensure a close and careful reading of the text of the individual agreement in question, and a reading of the relevant WTO provisions in accordance with other international law instruments and the Appellate Body's findings on the need to take into account the "contemporary concerns of the community of nations about the protection and conservation of the environment"⁸⁰. Thus, the provisions at stake in this case will have to be interpreted not in clinical isolation from, but rather in the light of, the other existing instruments of international law referred to in the European Communities' first written submission.

⁸⁰ Appellate Body Report, *US – Shrimp*, para. 129.

(c) The *SPS Agreement* alone cannot dispose of all the issues linked to GMOs

4.519 The scope of the *SPS Agreement* is identified in the text of Annex A, point 1, as relating exclusively to measures to protect animal or plant life or health within the territory of the Member from precise risks such as "the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms"; "additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs"; or "diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests". The text of this provision was carefully negotiated, is very clearly phrased and has to be strictly interpreted and applied. In particular, contrary to the complaining parties' approach, it cannot be read as applying to all products and all risks in all circumstances. Following such an approach amounts to reducing the whole of point 1 of Annex A to inutility.

4.520 The Panel will thus have to assess under the *SPS Agreement* only those measures adopted for reasons that fall within the scope of that Agreement. A same measure can pursue multiple objectives which fall within the scope of different WTO agreements. This possibility is not only inherent in the text of the agreements but it is also recognized, as noted above, by the current practice of other Members of the WTO, as is evident from the notifications of draft measures to the SPS and TBT Committees.

(d) The issue of delay

4.521 The European Communities does not contest that the WTO agreements apply to delays, or more generally to omissions or failures to act, and it has shown its readiness to answer to the Panel for each and every instance of such alleged delays under the WTO agreements. However, it is obvious that only WTO provisions that address such failures to act within a given timeframe can be relevant. The *SPS Agreement* contains such obligations in its Article 8 and Annex C. Other provisions listed by the complaining parties do not address delays but the very opposite, namely actions or acts. They address the development and content of SPS measures, not their application.

(e) Article 5.7 *SPS Agreement*

4.522 The European Communities considers that to the extent that the national safeguard measures come under the *SPS Agreement* they are regulated by Article 5.7 of the *SPS Agreement*. and not by the other provisions of the agreement invoked by the complaining parties. The burden of proving that the conditions of Article 5.7 are met is on the complaining parties, as the United States has formally acknowledged at the meeting of the DSB held on 10 December 2003. Thus, the European Communities sees the relationship between Article 5.7 and the rest of the agreement in the same way as the Appellate Body saw the relationship between Articles 3.3 and 3.1 of the *SPS Agreement* – as an autonomous right.⁸¹

(f) The precautionary principle is a general principle of international law

4.523 Article 5.7 of the *SPS Agreement* is of course one expression of the precautionary principle – Article 3.3 is another. This principle has by now become a fully-fledged and general principle of international law. This is another reason why Article 5.7 is an autonomous right, an autonomous right that is also recognized in the Biosafety Protocol.

⁸¹ Appellate Body Report, *EC – Hormones*, paras. 169-172.

4.524 The precautionary principle was first recognized in the World Charter for Nature, adopted by the UN General Assembly in 1982. The 1992 Rio Declaration codified an application of this principle in its Principle 15. Since then, the United Nations Framework Convention on Climate Change and the Convention of Biological Diversity both refer to the precautionary principle. More recently, and in the specific field of GMOs, the Biosafety Protocol has confirmed the key function of the precautionary principle in the decision to restrict or prohibit imports of GMOs in the face of scientific uncertainty.

8. Conclusion

4.525 In conclusion, the Panel has been called upon to decide what the reasonable attitude of a prudent government should be faced with scientific complexity and uncertainty of a kind and on a scale unique and unprecedented in the history of trade in agricultural products. It is an important and delicate task and it will have consequences far beyond this case. GMOs are not an issue which is confined to the WTO and the close attention of states, other international organisations, civil society, industry and others, rests on the work of this Panel.

4.526 The European Communities is confident that, apart from the absence of any moratorium, the Panel will also find that in applying a regulatory process for effective and forward-looking governance, based on a precautionary approach, the European Communities has acted in accordance with its obligations under the WTO agreements.

M. SECOND WRITTEN SUBMISSION OF THE UNITED STATES

1. Introduction

4.527 The United States in its first written submission showed that the European Communities' moratorium on biotech approvals (both across-the-board, and with respect to individual pending product applications), as well as the member State product-specific bans, are inconsistent with the European Communities' fundamental obligations under the WTO Agreement. The European Communities' response to these clear showings of breaches of its WTO obligations have been remarkable: the European Communities has failed to address the central issues. With regard to the moratoria, the European Communities' only defence is that no such measures ever existed. In taking this position, the European Communities asks the Panel to ignore the statements, and indeed actions, of the EC political-level decision-makers. The European Communities makes this argument even though it has informed the Panel that there indeed is a key political component in the European Communities' approval system. By asking the Panel to find that the moratoria never existed, the European Communities is requesting that the Panel adopt – solely for the purpose of this dispute and based only on the assertions of the EC representative in this dispute – a factual finding that is directly contrary to reality as understood throughout the European Communities and the worldwide agricultural trade community. In so requesting, the European Communities would seek to undermine the credibility of the WTO dispute settlement system.

4.528 Instead of acknowledging the reality of the moratorium and then attempting to justify it under the legal standards set out in the *SPS Agreement*, the European Communities has submitted a substantial volume of communications between member States and applicants for biotech approvals. None of this information, however, is inconsistent with the fundamental reality that the European Communities had adopted moratoria on biotech approvals. To the contrary, staff-level information exchanges regarding product applications are entirely consistent with a moratorium adopted on a political level, under which no product was allowed to reach final approval. Moreover, the very

information that the European Communities has submitted confirms that certain member States simply were not going to allow final approvals, regardless of the underlying science.

4.529 With regard to the member States measures, the European Communities has asserted that there "may" be scientific bases for the product bans, but to date the European Communities has failed to identify any of them. This is understandable, since the European Communities' own scientific committees have reviewed the products and have found that they meet the requirements of the European Communities' biotech approval system.

2. The European Communities' statement of facts is misleading

(a) The European Communities' statement on the purported risks of biotech products is misleading

4.530 Even though the European Communities' factual presentation on biotechnology is not tied to the legal issues in this dispute, the United States would like to note that the European Communities' statements regarding the purported risks of biotechnology are fundamentally misleading. Contrary to the European Communities' assertion, there has, in fact, been consensus over the types of risks potentially posed by agricultural biotechnology products since the late 1980's. The consensus among international experts is that, qualitatively, the types of risks potentially posed by products of modern biotechnology are essentially the same as those posed by similar products produced through other, more traditional technologies.

4.531 In other words, the types of risks that regulators assess for foods produced through biotechnology are qualitatively the same as for foods produced through other methodologies—for example, the production of toxins, significant changes in composition, and the presence of food allergens. Similarly, the types of environmental risks – for example, the production of plant pests, and effects on beneficial non-target organisms – are not qualitatively different between biotechnology and non-biotechnology agricultural products.

4.532 In 1986, the OECD Ad Hoc Group on Safety and Regulations in Biotechnology concluded that any potential environmental impacts of recombinant DNA organisms are "expected to be similar to effects that have been observed with introductions of naturally occurring species or selected species used for agricultural applications." In 1987 the US National Academy of Sciences (NAS) published a white paper that stated that the risks posed by biotech organisms are the "same in kind" as those associated with organisms that have been modified through other techniques.

4.533 In 1993, the OECD, through work commissioned by the Group of National Experts on Safety in Biotechnology, concluded that the risks potentially posed by plants produced through modern biotechnology should be approached within the context of the potential risks of plants produced through traditional plant breeding. While the OECD and NAS may have been the earliest scientific bodies to come to these conclusions, the same conclusion has been reached by other international scientific organizations and national scientific advisory bodies. In 1996, a joint FAO/WHO expert consultation on biotechnology and food safety concluded that "Food safety considerations regarding organisms produced by techniques that change the heritable traits of an organism, such as rDNA technology, are basically of the same nature as those that might arise from other ways of altering the genome of an organism, such as conventional breeding." The Royal Society of the United Kingdom came to essentially the same conclusion that "as with genetic modification, conventional plant breeding technology (which can involve chemical or radiation-induced mutagenesis or cross-species hybridization) might also cause rearrangements of the genome, and therefore might also cause the activation of previously unknown toxins, anti-nutrients or allergens."

4.534 The scientific advisory bodies of the European Union have also confirmed the conclusion that, for both food and environmental risks, plants produced through modern biotechnology do not present new or novel risks. In 2003, the Scientific Steering Committee of the European Commission acknowledged that both the Scientific Committee on Plants and the Scientific Committee on Food have concluded in their published risk assessment that for the "GM crops" reviewed no new safety issues to humans or the environment have been presented. The Scientific Steering Committee also stated that the "published review of data do not indicate the GM crops presently in cultivation pose any more risks for humans, animals and the environment than do their conventional counterparts."

4.535 The level of scientific uncertainty claimed by the European Communities to exist around the risks posed by biotechnology products is both inconsistent with the history of the international discussion of this issue and with the actions of individual government regulatory authorities. In its 2003 report, the International Council for Science (ICSU) concluded after a synthesis of more than 50 independent scientific reviews that there is "convergence of science" that "Presently available genetically modified foods are safe to eat. GM foods presently on the market have been assessed for any risks of increased allergenicity, toxicity, or other risks to human health, using internationally agreed food safety standards. ... This is the consensus view of several reports by national and international agencies."

4.536 In addition, government regulatory authorities with experience in regulating plants produced through modern biotechnology routinely use a case-by-case approach. For example, the United States, Canada, the European Communities, Japan, Australia, and South Africa have completed risk assessments on plants produced through biotechnology – essentially addressing the same types of risk assessment end points on a case-by-case basis. The foundation for this case-by-case approach to the regulation of biotechnology plants is the widely held scientific consensus that: 1) the risks potentially associated with biotech plants are essentially the same as those of plants produced by other techniques and 2) the assessment of risk should not focus on the methodology used in the breeding process but rather on the results of that process; *i.e.*, on the characteristics of the product itself.

4.537 To further illustrate the scientific consensus surrounding the types of risks potentially posed by biotech plants, both the Codex Alimentarius and the International Plant Protection Convention have adopted guidances that provide recommendations on the type of data that should be considered when conducting safety assessments for biotech plants. Both of these standard setting bodies were able to conclude these guidelines because of the already existing consensus on the types of risk issues that should be addressed in the risk assessment for biotech plants.

4.538 If scientific uncertainty concerning the risks of biotech plants had been as great as claimed by the European Communities, it is unlikely that any of these products would have successfully completed the regulatory process in any country. The assertion that the complexities – and uncertainties – of assessing the risks of the biotech plants currently in the EC system are far greater than non-biotech products is not born out by experience.

(b) Neither the biosafety protocol nor the precautionary approach serves as a defence to the European Communities in this dispute

4.539 The only way other sources of international law could be pertinent to this dispute is if, under Article 3.2 of the DSU, those other sources of law would assist the Panel in "clarifying the existing provisions of the [covered] agreements in accordance with customary rules of interpretation of public international law." But the European Communities has not identified how the Biosafety Protocol or a "precautionary principle" would be of relevance to interpreting any particular provision of the WTO Agreement.

4.540 Moreover, in the *EC – Hormones* dispute, the Appellate Body examined at length nearly identical arguments presented by the European Communities regarding the relationship between a purported "precautionary principle" and the *SPS Agreement*. The European Communities has not presented, and cannot argue, that any different results should apply here. Thus, even if a precautionary principle were considered a relevant rule of international law under Article 31(3) of the Vienna Convention, it would be useful only for interpreting particular treaty terms, and could not override any part of the *SPS Agreement*. So, for example, the notion of precaution could not excuse the European Communities from complying with the requirement under Article 5.1 that SPS measures be based on risk assessments. In addition, Article 5.7 of the *SPS Agreement* already allows for the European Communities to adopt a precautionary approach to regulating biotech products.

4.541 Just as the Appellate Body found it unnecessary and imprudent to make a finding on the status of the precautionary principle in international law, this Panel also should have no need to address this theoretical issue. Nonetheless, the United States notes that it strongly disagrees that "precaution" has become a rule of international law. In particular, the "precautionary principle" cannot be considered a general principle or norm of international law because it does not have a single, agreed formulation. In fact, quite the opposite is true: the concept of precaution has many permutations across a number of different factors. Thus, the United States considers precaution to be an "approach," rather than a "principle" of international law.

4.542 Moreover, if – as the United States submits – precaution is not a principle of international law, then it is *a fortiori* not a rule of customary international law. Customary international law is a binding rule that results from: (1) a general, consistent, extensive, virtually uniform practice of States; (2) followed by them from a sense of legal obligation. Precaution does not fulfil any of these requirements. Precaution cannot be considered a "rule" because it has no clear content and therefore cannot be said to provide any authoritative guide for a State's conduct. Second, it cannot be said to reflect the practice of States, as it cannot even be uniformly defined by those who espouse it. Third, given that precaution cannot even be defined and, therefore, could not possibly be a legal norm, one could not argue that States follow it from a sense of legal obligation.

4.543 For the purposes of interpreting the WTO Agreement in accordance with the principles in Article 31(3) of the Vienna Convention, the United States also strongly disagrees with any notion that the Biosafety Protocol is a rule of international law. To be relevant under Article 31(3), the international rule must be "applicable in the relations between the parties." In this case, however, the Biosafety Protocol is not applicable to relations between the United States and the European Communities, because the United States is not a party to the Biosafety Protocol.

4.544 Finally, the United States would not agree that the Panel would need to look to the Biosafety Protocol in interpreting the WTO Agreement even in a dispute between WTO Members that were both parties to the Protocol. The Protocol has a clear and unequivocal statement that it does not change the rights and obligations under any existing international agreement. In addition, the European Communities does not argue that any provision of the Protocol is in any way inconsistent with the European Communities' full compliance with its WTO obligations.

(c) The European Communities' description of its biotech approval regime is inaccurate

4.545 In describing the "European Communities' regulatory Framework," the European Communities conveniently leaves out a number of mandatory procedural steps, omits several deadlines by which specific action is required, and implies that the Commission has discretion – which the legislation does not grant – not to act on product notifications. But an accurate presentation of the EC system is important, because this serves as the baseline for understanding that the European

Communities' delays under the moratorium are inconsistent with the European Communities' own laws. The inconsistency of the European Communities' moratorium with the underlying biotech approval legislation further highlights that the delays resulting from the moratorium are undue.

3. The *SPS Agreement* applies to all measures in this dispute

4.546 In its first written submission, the European Communities argues at length, and in the hypothetical, that the European Communities might adopt measures with respect to one or more biotech products that are not covered within the scope of the *SPS Agreement*. But, once again, the European Communities' discussion is not linked to any of the legal issues in this dispute.

4.547 The pertinent question is whether the measures that the European Communities has actually adopted, and that are covered in this dispute's terms of reference, are within the scope of the *SPS Agreement*. But the European Communities does not even appear to contest this fundamental point. First, the European Communities has not disputed that both its Novel Foods regulation and Deliberate Release directive are covered within the scope of the *SPS Agreement*. Furthermore, with respect to the member State measures, the European Communities acknowledges that each of the member State measures was adopted for "some reasons" that fall within the scope of the *SPS Agreement*.

4.548 The European Communities' agreement that its measures were adopted for "some reasons" covered within the scope of the *SPS Agreement* is more than sufficient to bring those measures within the scope of that Agreement. Annex A to the *SPS Agreement* makes clear that "any measure" applied to protect against one of the enumerated risks falls within the scope the *SPS Agreement*. The Annex does not state that the measure needs to be exclusively applied to protect against only the enumerated risks. In fact, in the *EC – Hormones* dispute, the EC directive was not solely adopted to address alleged affects on human health. To the contrary, as the Appellate Body explained, the European Communities was also motivated to adopt its Hormones Directive by the perceived need to harmonize beef regulations in order to prevent distortions in the conditions of competition between producers in various EC member States. The harmonization of product standards is a goal expressed in the *TBT Agreement*. Yet, despite the variety of rationales, all parties in the *EC – Hormones* dispute agreed that the Hormones Directive fell within the scope of the *SPS Agreement*.

4.549 The detailed European Communities' discussion purporting to classify various alleged risks of biotech products as within or without the scope of the *SPS Agreement* is not tied to the legal issues in this dispute and is thus hypothetical. Nonetheless, the United States has responded to these arguments in an attachment to its second written submission, and notes that the European Communities' analysis would result in an overly narrow scope of the measures intended to be covered by the *SPS Agreement*.

4. General moratorium violates the *SPS Agreement*

4.550 The European Communities' discussion of the general moratorium is remarkable in that it is concerned solely with whether or not the general moratorium qualifies as a "measure" under the *SPS Agreement*. Should the Panel find, as the complaining parties all submit, that the general moratorium is indeed a measure under the *SPS Agreement*, the European Communities has not contested that the general moratorium is inconsistent with the European Communities' obligations under the WTO Agreement. Indeed, in its answers to Panel's questions, the European Communities concedes that there was no overall risk assessment for biotech products that could serve as a basis for the general moratorium.

4.551 The evidence that the general moratorium exists is overwhelming. In addition to the evidence that the United States cited in its first written submission and opening statement, official documents of the European Parliament also confirm the existence of the moratorium. For example, a February 2001 parliamentary Report: "Observes that the existing *de facto* moratorium particularly harms small and medium sized enterprises which, unlike multinational corporations, are often unable to perform their research work in countries outside the EU"; "Welcomes the agreement reached between Council and Parliament in the conciliation committee on the amendment of the directive on the release of genetically modified organisms and the assurances given by the Commission in that connection with regard to labelling and traceability, and considers that a clear framework now exists for the release of genetically modified organisms in Europe which will ensure maximum consumer protection and environmental protection, and that it would therefore not be justified to continue the *de facto* moratorium on the release of GMOs"; and notes that "Under this system approval takes an unacceptably long time. ... [N]o authorizations have been approved under this directive since October 1998. This demonstrates a lack of mutual recognition between member States and a *de facto* moratorium on all development. It calls into question the political will in Europe to support this industry."

4.552 More recently, a March 2003 resolution introduced in the European Parliament acknowledges the moratorium: "whereas, in view of the risks which GMOs represent, there are no grounds for lifting the *de facto* moratorium on GMO authorization, especially since no labelling and tracing system has been introduced and no assessment has been carried out of the impact which GMOs may have on organic/conventional farming." The same resolution then goes on to urge the continuance of the moratorium pending the launch of "a broad public debate."

4.553 The European Communities presents three arguments in its first written submission as to why this Panel should nonetheless find that there is no general moratorium. First, the European Communities argues that it cannot be "legally affected" by "casual statements of any of its numerous representatives." But the complaining parties are not relying on "casual statements of numerous representatives"; the statement cited by complaining parties are statements made by the European Communities' highest officials, by its member States, and by its official bodies. Moreover, the European Communities itself concedes, as it must, that such statements can be considered as evidence of the existence of a measure.

4.554 Second, the European Communities argues that even if the European Communities did adopt a general moratorium on approvals of biotech products, such a moratorium is legally precluded from qualifying as a "measure" under the *SPS Agreement*. The European Communities' argument, however, is based on two panel reports that are inapposite to this dispute. The United States does not contend that the European Communities' suspension of its approval process constituted a "practice" as described in the *US – Steel Plate* and *US – Export Restraints* reports cited by the European Communities. Although the European Communities' measure was not adopted in a transparent manner and officially published as a formal law, decree or regulation, the European Communities' decision to indefinitely suspend its approval procedures falls within the SPS definition of a measure and blocks biotech approvals just as effectively as would a written amendment to EC legislation.

4.555 Third, the European Communities claims that the application histories for certain products covered in the US panel request disprove the existence of the moratorium. To the contrary, the information submitted by the European Communities is entirely consistent with the European Communities' imposition of a general moratorium. First, the information submitted by the European Communities confirms that there were in fact no approvals of biotech products between October 1998 and the establishment of the Panel's terms of reference in August 2003. Second, not only do the

product histories confirm that no product was submitted for final approval, many of the product histories – as described below – illustrate just how the moratorium operated.

5. Product-specific moratoria violate the SPS Agreement

4.556 The primary basis for the European Communities' denial of the product-specific moratoria is the vague statement that "what has happened in many of these applications is that, at different stages of the procedure, requests for additional information have been put to applicants." The European Communities ignores, however, that product histories exhibiting requests for information are entirely consistent with the existence of a general and product-specific moratoria. The United States has not claimed that each and every application stopped all progress beginning in 1998. To the contrary, the moratorium was a decision by the European Communities not to move products to a final decision in the approval process. Certain progress in the process, short of final decision, is not the least bit inconsistent with a moratorium on final approvals.

4.557 Moreover, the European Communities' product histories provide further, compelling evidence of the existence of both a general and product-specific moratoria. First, a number of applications – particularly those nearing the final stage of approval – exhibit lengthy, unwarranted delays, unrelated to any requests for additional information. Second, a number of product histories contain statements from member States acknowledging – in writing – that regardless of any scientific issues regarding the particular application at issue, the member State simply was not going to vote for approval unless and until the European Communities had adopted new forms of legislation. Such statements illustrate that, contrary to the European Communities' assertions, the moratorium applied to each and every application, regardless of whether or not particular regulators had particular questions about individual applications.

(a) Examples of applications which faced lengthy delays, without any pending requests for information

4.558 *Oil-Seed Rape MS1, RF1 and Oil-Seed Rape, MS1, RF2*: In these two cases, France never allowed the product to be placed on the market, and thus these products in fact were never approved for cultivation, import, and marketing in the European Communities. In Question 99, the Panel asked the European Communities to confirm that France withheld its consent. The European Communities responded "Yes." The European Communities then goes on to argue that, nonetheless, an individual "can directly assert his or her right by directly relying on the Community law in question." This excuse is entirely unpersuasive. The European Communities does not assert that either of these products is in fact on the market in the European Communities; that EC Customs officials – in France or elsewhere – would admit either of these oil-seed products without the final step (the French consent) in the approval process; or that any biotech applicant has ever successfully asserted this right. Nor does the European Communities even attempt to explain what mechanism – such as a legal challenge – might be used to assert this right, or explain how a product can be considered approved if additional legal proceedings are required to allow the product to be placed on the market.

4.559 *BT-Cotton*: In February 1999 the regulatory committee did not approve the application by a qualified majority vote. Under the European Communities' own rules, an application that fails to achieve a qualified majority of votes in the regulatory committee must be submitted to the EC Council for an additional vote, and such submission must be made, to quote Article 21 of the EC Directive, "without delay." But, the European Communities' own chronology states that the next action is nearly three months later, in May 1999. And the action taken is not, as required under EC legislation, the submission of the application to the EC Council. Instead, the chronology states: "Launching of Inter-

Service Consultation on draft Council Decision." This term, and this step, is not provided for under the European Communities' regulations. The chronology is then blank until July of 2001.

4.560 *Roundup Ready Cotton*: In February 1999, the Roundup Ready cotton application, like Bt cotton, did not receive a qualified majority vote in the regulatory committee. Like for Bt cotton, the next step in the European Communities' chronology is the "Launching of Inter-Service Consultation on draft Council Decision" in May 1999. There is no further entry in the chronology until January 2003, which is more than two and one-half years later. Again, this is another example of a major delay that was not caused, as the European Communities' claims, by a pending request to the applicant for additional information.

4.561 *Oilseed rape tolerant for glufosinate-ammonium*: According to the European Communities' chronology, this product received a favourable opinion from the scientific committee on plants in November 2000. Under the European Communities' approval system, the next step should have been to submit the application for approval by the European Communities' Regulatory Committee. But the European Communities' chronology shows that no action was taken on the application until November 2002, a full 2-year delay. This 2-year gap belies the European Communities' assertions that under its supposed "interim approach," it was moving ahead on processing applications in advance of the entry-into-force of 2001/18.

4.562 *Maize BT-11*: In the chronology of BT-11, there is no action on the application for 2 years after a favourable opinion of the Scientific Committee on Plants in November 2000. The next entry, an "evaluation of updates by the lead CA" in October 2002, is unexplained and unsupported by any exhibit or attachment.

(b) Product histories in which member States acknowledge opposition to approval regardless of the merits of the individual application

4.563 The exhibits accompanying the product histories provide numerous examples in which member States noted in writing that they would oppose approvals until some type of new legislation was adopted, even though under EC law any objection had to be based on the merits of the application. These statements by member States stand in stark contrast to the European Communities' argument that it had adopted an "interim approach" under which final approvals were to be granted prior to the adoption of new legislation. They also directly contradict the European Communities' arguments that the delays with respect to individual products were justified by fact-specific considerations unique to the individual products, such as conflicting science, or delays on the part of applicants.

4.564 *Novel Food and Feed Regulation*. Some member States have used the implementation of new food and feed regulations (which did not become effective until April 2004) as an excuse for halting this process. Pioneer/Dow's Bt corn application: The Austrian Federal Ministry of Health and Women notes in its letter to the EU's DG XI, dated 24 October 2003, that any registration of Pioneer/Dow's product "should also take into consideration the two new EU regulations concerning traceability and genetically modified food and feed which will enter into force in April 2004." Roundup Ready corn (NK603): In a letter from the Austrian Federal Ministry for Social Affairs and Generations to the EU's DG XI regarding Monsanto's application for Roundup Ready corn (NK603), the Ministry cites several scientific concerns, but states that "Irrespective of the above mentioned scientific objections raised, Austria is of the opinion, that products shall not be placed on the market before the new regulations concerning genetically modified food and feed as well as on traceability and labelling of GMOs will enter into force." Syngenta's Bt11 biotech sweet corn: On 10 August 2000, the French authorities cited the yet to be implemented food and feed regulations as a reason for

withholding support for Bt11, choosing to disregard comprehensive scientific findings and instead continue the moratorium on biotech reviews.

4.565 *Traceability and Labeling Legislation.* Member States opposed to re-starting the review process for biotech crops also used the proposed new traceability and labelling regulations (which also did not become effective until April 2004) as a reason for continuing the moratorium. Syngenta's Bt-11 biotech sweet corn: several member State competent authorities statements clearly require that the new traceability and labelling regulations be in place prior to the lifting of the moratorium on biotech reviews and approvals. The German competent authority's objections, dated September 26, 2003, provided that "In accordance with the French position, the German CA is of the opinion that no consent should be given until both regulations are in force. In particular, the regulation on traceability and labelling of GMOs will provide for additional transparency and the possibility of choice for consumers." Likewise, Denmark, in late September 2003 stated that its support for Bt-11 was contingent on the implementation of the new traceability and labelling regulations. In doing so, it reminded the EC authority of the March 2001 declaration of six member States (the "March 2001 declaration") reaffirming the moratorium until traceability and labelling rules, as well as a system for environmental liability, are adopted. Again in February 2004, the Danish competent authority writes: "Furthermore, Denmark finds that approval for placing on the market cannot take place before the regulation on traceability and labelling is fully into force." Oilseed rape (GT-73): The Danish, Italian, Austrian and Belgian competent authorities all cite the need for traceability and labelling regulations to be in place before they will support the approval of any biotech crops. The Austrian competent authority wrote: "As a matter of principle, this product should not be placed on the market before the entry into force of the Regulation of the European Parliament and of the Council concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC." Roundup Ready corn (GA21): Denmark acknowledged that "the assessment of the health and nutritional aspects of this application gives Denmark no reason to object to the approval of the GA21 maize nor to products derived from the maize." However, "in spite of the favourable assessment ... , Denmark will submit a reasoned objection to the approval of the genetically modified GA21 maize, reference being made to the statement submitted by this country and four other member states at the Environmental Council on 24 and 25 June 1999 [declaring a suspension of new GMO authorizations until labelling and traceability rules are adopted]." Bt-11 sweet corn: Denmark states that "[w]ith regard to the issue of food safety as such, Denmark sees no problem in allowing the Bt11 maize for food purposes ... Apart from this however, Denmark will refer to the Declaration concerning the suspension of new GMO authorizations made by five member States (France, Greece, Italy, Luxembourg, and Denmark) at the Environmental Council of 24 and 25 June 1999. With reference to this Declaration, Denmark therefore wishes to submit a reasoned objection concerning the Bt11 maize."

4.566 *Co-Existence and Environmental Liability Legislation.* Several member States have used the lack of coexistence and environmental liability laws as a reason to continue the moratorium. Such rules have no bearing on decisions or assessments regarding the environment or human or animal health or safety, and a desire for such rules cannot justify delay. Otherwise, a Member could always say it would like a better regulatory regime in other aspects and delay approvals indefinitely, rendering the SPS "undue delay" discipline meaningless. Glufosinate tolerant and Bt resistant (Bt-11) corn: The Austrian competent authority states: "As this product is in particular destined for cultivation in all countries of the European Union, Austria – apart from the need for further information – raises an objection against the putting of this product on the market, as long as all conditions for coexistence with GMO-free cultivation methods are not cleared in a sound legal way." Belgium makes the same objection for the same product: "Belgium is of the opinion that the placing on the market of this product should not be granted before a coexistence regulation is not yet entered

into force." Denmark once again cites the March 2001 declaration of six member States reaffirming the moratorium until traceability and labelling rules, as well as a system for environmental liability, are adopted. Roundup Ready oilseed rape GT73: Austria objected to Roundup Ready oilseed rape GT73, as a "matter of principle," requiring that "further issues concerning liability and the coexistence of genetically modified, conventional and organic crops remain to be resolved." Also, on 24 March 2003, Denmark objected, citing the March 2001 declaration. Pioneer/Dow AgroSciences Bt corn (Cry1F 1507): The Austrian CA, as late as 17 October 2003, objected to the placing on the market of Pioneer/Dow AgroSciences Bt corn (Cry1F 1507), citing coexistence. The specific reasons cited by the CA are generally economic in nature, rather than issues of environmental safety: "Import, processing and cultivation of GM 1507 maize will result in the presence of adventitious and/or technically unavoidable GMO traces in non GMO maize. Although maize has limited capabilities to survive, disseminate or outcross, this may lead to effects on the implementation of co-existence of different agricultural systems (with or without GMO). As long as the conditions for co-existence are not clarified on the EU level, Austria holds the opinion that no consent for the placing on the market of 1507 maize should be given." Roundup Ready corn (NK603): Austria states that not only should biotech product approvals continue to be suspended until feed and traceability and labelling legislation becomes effective, but also, that no biotech products may be placed on the market without coexistence rules: "In addition the issue of co-existence of genetically modified, conventional and organic farming is at the moment under discussion and has to be resolved." Denmark also objects, again citing to the March 2001 declaration.

(c) The European Communities' product histories are incomplete

4.567 The European Communities relies almost exclusively on its product histories to support its claim that – despite the statements and actions of EC officials – there were in fact no general or product-specific moratoria. But the European Communities' product histories are incomplete in three important ways. First, the product histories do not cover any products that were withdrawn prior to establishment of the Panel. These failed product applications are direct, compelling evidence of the existence of a general moratorium. In its first written submission, the United States noted that applications under both the environmental release and novel food legislations had been indefinitely delayed by the general moratorium and consequently withdrawn, and gave nine specific examples. The European Communities has failed to provide any chronologies for these products.

4.568 The European Communities' product histories are also incomplete in that the European Communities has not provided the underlying documentation for each step in the process. Instead, in selecting what exhibits to provide to the Panel, the European Communities has picked and chosen among the various chronological entries.

4.569 Finally, the product histories are incomplete in that they do not include every step in the product histories. Although only the applicants and the European Communities have access to all correspondence, the United States has learned that at least some of the product histories are missing significant entries. For example, the application history for Fodder Beet A5/15 excludes a reference to at least one significant document. In particular, at a point in the process where the applicant believed that it had complied with all outstanding information requests, the chronology omits a letter from the lead competent authority to the applicant, stating that: "Since we met the new directive [2001/18] has been adopted and as you probably already know Denmark and five other member states have confirmed their opinion on suspending new authorizations for cultivation and marketing until effective provisions concerning complete traceability which guarantees reliable labelling has been adopted."

6. Member State measures violate the SPS Agreement

4.570 The nine measures imposed by six member States are sanitary or phytosanitary measures which are not "based on" "risk assessment[s]" as required by Article 5.1 of the *SPS Agreement*. Although each of the six member States that have imposed bans on approved biotech products offered reasons for their measures – though unjustified according to the scientific committees – none of the member States put forth a "risk assessment" as defined in Annex A, paragraph 4. In response to the Panel's Question (No. 107) on this issue, the European Communities claimed that "the member States have made their own assessments and further risk assessments may be forthcoming" (emphasis added). The United States submits that, in fact, no such risk assessments supporting the member State measures have been provided.

4.571 In particular, the European Communities has provided on their second CD-ROM a folder titled "Safeguard Measures," in which the European Communities purports to provide EC member State justifications for the member State measures. A review of the documents confirms that none of the member State bans is based on a risk assessment.

4.572 In fact, the only risk assessments put forth for the banned products are the positive scientific assessments rendered by member States to which the products were submitted, and then by the European Communities' own scientific committees. In the case of each member State ban, these favourable assessments were reaffirmed when the scientific committees considered and rejected the information provided by the member States. Thus, the member State measures do not bear a "rational relationship" to the European Communities' positive risk assessments, and are not "based on" a risk assessment, in violation of Articles 5.1 and 2.2 of the *SPS Agreement*.

4.573 The European Communities' argument in defence is that each of the member State measures falls within the scope of Article 5.7 of the *SPS Agreement*. But the European Communities does not specify how Article 5.7 might apply. Its only argument is that under the terms of the EC legislation, the member State measures are labeled as "provisional." The mere label of a measure, however, is most certainly not sufficient to bring it within the scope of Article 5.7.

4.574 Before turning to the specific criteria of Article 5.7, the United States would note that the European Communities is incorrect in claiming that the United States was obliged to include an explicit Article 5.7 argument in its first written submission. This argument fundamentally misunderstands the structure of the *SPS Agreement*. The United States in its first written submission most certainly did explain that the member State measures are inconsistent with Article 2.2 of the *SPS Agreement*, and this necessarily means that the United States submits that Article 5.7 does not apply. In other words, Article 5.7 provides not the basis for a claim of an alleged breach of a WTO obligation, but acts as a defence to shield measures that would otherwise violate Articles 2.2 and 5.1. As explained by the Appellate Body in *Japan – Agricultural Products II*, "Article 5.7 operates as a qualified exemption from the obligation under Article 2.2 not to maintain SPS measures without sufficient scientific evidence."

4.575 In *Japan – Agricultural Products II*, as well as in *Japan – Apples*, another dispute in which Article 5.7 was considered, the Respondent invoked the provision to defend the challenged measure against alleged violations of Articles 2.2 and 5.1. The Complainant (the United States in both cases) did not assert Article 5.7 as an independent claim in either dispute, nor did the Panels suggest that the Complainant should have invoked Article 5.7. Indeed, the United States is not aware of any dispute in which the Complainant has based a claim on the Respondent's violation of Article 5.7.