

## VIII. CONCLUSIONS AND RECOMMENDATIONS

8.1 Before concluding, the Panel wishes to make clear the issues on which it made a decision, and those which it did not address.

### A. OVERVIEW OF THE ISSUES ADDRESSED AND DECIDED BY THE PANEL

8.2 The issues before the Panel concerned the alleged failure of the European Communities to reach final decisions regarding the approval of biotech products from October 1998 to the time of establishment of the Panel on 29 August 2003, and the WTO-consistency of prohibitions imposed by certain EC member States with regard to specific biotech products after these products had been approved by the European Communities for Community-wide marketing.

8.3 In light of this, the Panel did *not* examine:

- whether biotech products in general are safe or not.
- whether the biotech products at issue in this dispute are "like" their conventional counterparts. Although this claim was made by the Complaining Parties (*i.e.*, the United States, Canada and Argentina) in relation to some aspects of their complaints, the Panel did not find it necessary to address those aspects of the complaints.
- whether the European Communities has a right to require the pre-marketing approval of biotech products. This was not raised by the Complaining Parties.
- whether the European Communities' approval procedures as established by Directive 90/220, Directive 2001/18 and Regulation 258/97, which provide for a product-by-product assessment requiring scientific consideration of various potential risks, are consistent with the European Communities' obligations under the WTO agreements. This was not raised by the Complaining Parties.
- the conclusions of the relevant EC scientific committees regarding the safety evaluation of specific biotech products. These were not challenged by the Complaining Parties, although they did challenge the scientific basis for some of the questions and objections made by various EC member States. In light of this, the Panel, in consultation with the Parties, sought advice from a number of scientific experts.

8.4 Turning to the issues the Panel *did* examine, the Panel first considered whether the EC approval legislation under which the European Communities allegedly did not reach final decisions is properly assessed under the *SPS Agreement*. The Panel has found that the European Communities' procedures for the approval of GMOs set out in Directives 90/220 and 2001/18 are SPS measures within the meaning of the *SPS Agreement*. The potential risks to be examined in the context of these directives, particularly as described in the annexes to Directive 2001/18, are the types of risk covered by the *SPS Agreement*. Regarding the European Communities' procedures for the approval of novel foods and food ingredients set out in Regulation 258/97, the Panel has found that these are, in part, SPS measures within the scope of the *SPS Agreement*.

8.5 The Panel notes, however, that both the evidence provided by the European Communities and the advice provided to the Panel by the experts advising it indicate that many of the identified

concerns are highly unlikely to occur in practice (*e.g.*, the transfer of antibiotic resistance from marker genes used in the production of some biotech plants to bacteria in the human gut). On the other hand, other identified concerns, such as those relating to the development of pesticide-resistance in target insects through exposure to pesticides (including those incorporated into biotech plants) have indeed been documented to occur, including with respect to non-biotech crops. We reiterate, however, that the right of the European Communities to consider these possible risks prior to giving approval for the consumption or planting of biotech plants has not been questioned by any of the Complaining Parties.

8.6 The Complaining Parties asserted that a moratorium on approvals was in effect in the European Communities between October 1998 and August 2003. Based on the evidence before it, the Panel has found that the European Communities applied a general *de facto* moratorium on approvals of biotech products between June 1999 and 29 August 2003, the date of establishment of this Panel. The Panel determined that the moratorium was not itself an SPS measure within the meaning of the *SPS Agreement*, but rather affected the operation and application of the EC approval procedures, which are set out in the relevant EC approval legislation and which we had found to be SPS measures. With respect to Directives 90/220 and 2001/18, the Panel has concluded that the general *de facto* moratorium resulted in a failure to complete individual approval procedures without undue delay, and hence gave rise to an inconsistency with Article 8 and Annex C of the *SPS Agreement*. With respect to Regulation 258/97, the Panel found that, to the extent the approval procedure addressed safety aspects within the scope of the *SPS Agreement*, the general *de facto* moratorium resulted in a failure to complete individual approval procedures without undue delay, and hence also gave rise to an inconsistency with Article 8 and Annex C of the *SPS Agreement*.

8.7 The Complaining Parties also claimed that, contrary to its WTO obligations, the European Communities failed to consider for final approval applications concerning certain specified biotech products for which the European Communities had commenced approval procedures. We examined the record of consideration of 27 applications identified by the Complaining Parties. We have found that there was undue delay in the completion of the approval procedure with respect to 24 of the 27 relevant products. We therefore concluded that, in relation to the approval procedures concerning these 24 products, the European Communities has breached its obligations under Article 8 and Annex C of the *SPS Agreement*.

8.8 The Complaining Parties furthermore brought complaints against nine safeguard measures taken by certain EC member States. These safeguard measures are in the form of prohibitions imposed by an individual EC member State on a particular biotech product that has been formally approved for use within the European Communities. The safeguard measures challenged by the Complaining Parties have been taken by Austria, Belgium, France, Germany, Italy and Luxembourg. The Complaining Parties did not challenge the EC approval legislation, which provides for the conditional right of individual EC member States to impose SPS measures which differ from those of the European Communities as a whole. Instead, what the Complaining Parties challenged were the prohibitions imposed by the relevant member States on the basis of the aforementioned EC approval legislation. According to the Complaining Parties, the safeguard measures imposed by the relevant member States were inconsistent with the European Communities' WTO obligations.

8.9 We determined that the objectives identified by each member State for its safeguard measure(s) fall within the scope of the *SPS Agreement*. For each of the products at issue, the European Communities' relevant scientific committee had evaluated the potential risks to human health and/or the environment prior to the granting of Community-wide approval, and had provided a positive opinion. The relevant EC scientific committee subsequently also reviewed the arguments and the evidence submitted by the member State to justify the prohibition, and did not consider that such information called into question its earlier conclusions. The Panel thus considered that sufficient

scientific evidence was available to permit a risk assessment as required by the *SPS Agreement*. Hence, in no case was the situation one in which the Panel had been persuaded that the relevant scientific evidence was insufficient to perform a risk assessment, such that the member State might have had recourse to a provisional measure under Article 5.7 of the *SPS Agreement*.

8.10 The Panel also considered whether any risk assessment had been provided by the relevant member States which would reasonably support the prohibition of the biotech products at issue. Although some of the member States did provide scientific studies, in no case did they provide an assessment of the risks to human health and/or the environment meeting the requirements of the *SPS Agreement*. The Panel likewise examined whether the risk assessments undertaken by the EC scientific committees could provide reasonable support for a prohibition of the biotech products at issue, but considered that this was not the case. In the light of this, the Panel has concluded that each of the safeguard measures taken by the relevant member States fails to meet the obligations of the European Communities under the *SPS Agreement*.

## B. STRUCTURE OF THE PANEL'S CONCLUSIONS AND RECOMMENDATIONS

8.11 As we have indicated at the beginning of the Findings section, consistent with the fact that we examined three legally distinct complaints, we have particularized for each of the three Complaining Parties (*i.e.*, the United States, Canada and Argentina) the conclusions we have reached and the recommendations we make, if any, in respect of their respective complaints. Accordingly, we provide three separate sets of conclusions and recommendations.

8.12 We further recall that the Complaining Parties are each challenging three identical categories of EC measures. The categories in question are:

- (a) the alleged general EC moratorium on approvals of biotech products (hereafter the "general EC moratorium");
- (b) various product-specific EC measures affecting the approval of specific biotech products (hereafter the "product-specific EC measures"); and
- (c) various EC member State safeguard measures prohibiting the import and/or marketing of specific biotech products (hereafter the "EC member State safeguard measures").

## C. COMPLAINT BY THE UNITED STATES (DS291): CONCLUSIONS AND RECOMMENDATIONS OF THE PANEL

### 1. General EC moratorium

8.13 For the reasons set forth in this Report, the Panel concludes, as a factual matter, that:

- (a) The European Communities applied a general *de facto* moratorium on the approval of biotech products between June 1999 and August 2003, which is when this Panel was established.

8.14 For the reasons set forth in this Report, the Panel further concludes, as a legal matter, that:

- (a) The European Communities has acted inconsistently with its obligations under Annex C(1)(a), first clause, of the *SPS Agreement* and, consequently, with its

obligations under Article 8 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

- (b) The United States has not established that the European Communities has acted inconsistently with its obligations under Annex C(1)(b) of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.
- (c) The European Communities has not acted inconsistently with its obligations under Annex B(1) and Article 7 of the *SPS Agreement* in respect of the general *de facto* moratorium on approvals.
- (d) The European Communities has not acted inconsistently with its obligations under Article 5.1 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.
- (e) The European Communities has not acted inconsistently with its obligations under Article 5.5 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.
- (f) The United States has not established that the European Communities has acted inconsistently with its obligations under Article 2.2 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.
- (g) The United States has not established that the European Communities has acted inconsistently with its obligations under Article 2.3 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

8.15 Article 3.8 of the DSU provides that "[i]n cases where there is an infringement of the obligations assumed under a covered agreement, the action is considered prima facie to constitute a case of nullification or impairment". The European Communities failed to rebut this presumption. Therefore, to the extent the European Communities has acted inconsistently with its obligations under the *SPS Agreement*, it must be presumed to have nullified or impaired benefits accruing to the United States under that Agreement.

8.16 In the light of these conclusions, the Panel recommends that the Dispute Settlement Body request the European Communities to bring the general *de facto* moratorium on approvals into conformity with its obligations under the *SPS Agreement*, if, and to the extent that, that measure has not already ceased to exist.

## **2. Product-specific EC measures**

8.17 The Panel made findings in relation to twenty-five product-specific EC measures challenged by the United States (hereafter "the relevant product-specific measures").

8.18 For the reasons set forth in this Report, the Panel concludes that:

- (a) The European Communities has breached its obligations under Annex C(1)(a), first clause, of the *SPS Agreement* and, consequently, its obligations under Article 8 of the *SPS Agreement* in respect of the approval procedures concerning:<sup>2185</sup>
- (i) Falcon oilseed rape;
  - (ii) MS8/RF3 oilseed rape;
  - (iii) RR fodder beet;
  - (iv) Bt-531 cotton;
  - (v) RR-1445 cotton;
  - (vi) Liberator oilseed rape;
  - (vii) Bt-11 maize (EC-69);
  - (viii) RR oilseed rape (EC-70);
  - (ix) BXN cotton;
  - (x) Bt-1507 maize (EC-74);
  - (xi) Bt-1507 maize (EC-75);
  - (xii) NK603 maize;
  - (xiii) GA21 maize (EC-78);
  - (xiv) MON810 x GA21 maize;
  - (xv) RR sugar beet;
  - (xvi) GA21 maize (food);
  - (xvii) Bt-11 sweet maize (food);
  - (xviii) MON810 x GA21 maize (food);
  - (xix) Bt-1507 maize (food);
  - (xx) NK603 maize (food); and
  - (xxi) RR sugar beet (food).

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<sup>2185</sup> In respect of the approval procedures conducted under Regulation 258/97 – the procedures concerning those biotech products which are identified as "food" – the Panel's conclusions apply to the extent the relevant approval procedure is an SPS measure.

- (b) The United States has not established that the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement* in respect of the approval procedures concerning:
  - (i) the Transgenic potato;
  - (ii) LL soybeans (EC-71);
  - (iii) LL oilseed rape; and
  - (iv) LL soybeans (food).
- (c) The United States has not established that the relevant product-specific measures have resulted in the European Communities acting inconsistently with its obligations under Annex C(1)(b) and Article 8 of the *SPS Agreement*.
- (d) The European Communities has not acted inconsistently with its obligations under Annex B(1) and Article 7 of the *SPS Agreement* in respect of any of the relevant product-specific measures.
- (e) The European Communities has not acted inconsistently with its obligations under Article 5.1 of the *SPS Agreement* in respect of any of the relevant product-specific measures.
- (f) The European Communities has not acted inconsistently with its obligations under Article 5.5 of the *SPS Agreement* in respect of any of the relevant product-specific measures.
- (g) The United States has not established that the European Communities has acted inconsistently with its obligations under Article 2.2 of the *SPS Agreement* in respect of any of the relevant product-specific measures.

8.19 Article 3.8 of the DSU provides that "[i]n cases where there is an infringement of the obligations assumed under a covered agreement, the action is considered prima facie to constitute a case of nullification or impairment". The European Communities failed to rebut this presumption. Therefore, to the extent the European Communities has acted inconsistently with its obligations under the *SPS Agreement* in respect of the relevant product-specific measures, it must be presumed to have nullified or impaired benefits accruing to the United States under that Agreement.

8.20 In the light of these conclusions, the Panel recommends that the Dispute Settlement Body request the European Communities to bring the relevant product-specific measures into conformity with its obligations under the *SPS Agreement*. These recommendations do not apply to those relevant product-specific measures that were withdrawn after the Panel was established or the product-specific measure affecting the approval of Bt-11 sweet maize (food), since the application concerning Bt-11 sweet maize (food) was definitively approved during the course of the Panel proceedings.

### **3. EC member State safeguard measures**

8.21 The Panel made findings in relation to all nine member State safeguard measures challenged by the United States (hereafter "the relevant member State safeguard measures").

(a) Austria – T25 maize

8.22 In relation to the Austrian safeguard measure on T25 maize, and for the reasons set forth in this Report, the Panel concludes that:

- (a) The Austrian safeguard measure on T25 maize is not based on a risk assessment as required by Article 5.1 of the *SPS Agreement*, and it is not consistent with the requirements of Article 5.7 of the *SPS Agreement*. Therefore, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.
- (b) By maintaining, inconsistently with Article 5.1 of the *SPS Agreement*, the Austrian safeguard measure on T25 maize, the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.

(b) Austria - Bt-176 maize

8.23 In relation to the Austrian safeguard measure on Bt-176 maize, and for the reasons set forth in this Report, the Panel concludes that:

- (a) The Austrian safeguard measure on Bt-176 maize is not based on a risk assessment as required by Article 5.1 of the *SPS Agreement*, and it is not consistent with the requirements of Article 5.7 of the *SPS Agreement*. Therefore, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.
- (b) By maintaining, inconsistently with Article 5.1 of the *SPS Agreement*, the Austrian safeguard measure on Bt-176 maize, the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.

(c) Austria - MON810 maize

8.24 In relation to the Austrian safeguard measure on MON810 maize, and for the reasons set forth in this Report, the Panel concludes that:

- (a) The Austrian safeguard measure on MON810 maize is not based on a risk assessment as required by Article 5.1 of the *SPS Agreement*, and it is not consistent with the requirements of Article 5.7 of the *SPS Agreement*. Therefore, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.
- (b) By maintaining, inconsistently with Article 5.1 of the *SPS Agreement*, the Austrian safeguard measure on MON810 maize, the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.

(d) France - MS1/RF1 oilseed rape (EC-161)

8.25 In relation to the French safeguard measure on MS1/RF1 oilseed rape (EC-161), and for the reasons set forth in this Report, the Panel concludes that:

- (a) The French safeguard measure on MS1/RF1 oilseed rape (EC-161) is not based on a risk assessment as required by Article 5.1 of the *SPS Agreement*, and it is not consistent with the requirements of Article 5.7 of the *SPS Agreement*. Therefore, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.
- (b) By maintaining, inconsistently with Article 5.1 of the *SPS Agreement*, the French safeguard measure on MS1/RF1 oilseed rape (EC-161), the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.

(e) France - Topas oilseed rape

8.26 In relation to the French safeguard measure on Topas oilseed rape, and for the reasons set forth in this Report, the Panel concludes that:

- (a) The French safeguard measure on Topas oilseed rape is not based on a risk assessment as required by Article 5.1 of the *SPS Agreement*, and it is not consistent with the requirements of Article 5.7 of the *SPS Agreement*. Therefore, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.
- (b) By maintaining, inconsistently with Article 5.1 of the *SPS Agreement*, the French safeguard measure on Topas oilseed rape, the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.

(f) Germany – Bt-176 maize

8.27 In relation to the German safeguard measure on Bt-176 maize, and for the reasons set forth in this Report, the Panel concludes that:

- (a) The German safeguard measure on Bt-176 maize is not based on a risk assessment as required by Article 5.1 of the *SPS Agreement*, and it is not consistent with the requirements of Article 5.7 of the *SPS Agreement*. Therefore, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.
- (b) By maintaining, inconsistently with Article 5.1 of the *SPS Agreement*, the German safeguard measure on Bt-176 maize, the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.



(g) Greece - Topas oilseed rape

8.28 In relation to the Greek safeguard measure on Topas oilseed rape, and for the reasons set forth in this Report, the Panel concludes that:

- (a) The Greek safeguard measure on Topas oilseed rape is not based on a risk assessment as required by Article 5.1 of the *SPS Agreement*, and it is not consistent with the requirements of Article 5.7 of the *SPS Agreement*. Therefore, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.
- (b) By maintaining, inconsistently with Article 5.1 of the *SPS Agreement*, the Greek safeguard measure on Topas oilseed rape, the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.
- (c) There is no need to rule on the United States' claim under Article XI:1 of the GATT 1994.

(h) Italy - Bt-11 maize (EC-163), MON810 maize, MON809 maize and T25 maize

8.29 In relation to the Italian safeguard measure on Bt-11 maize (EC-163), MON810 maize, MON809 maize and T25 maize, and for the reasons set forth in this Report, the Panel concludes that:

- (a) The Italian safeguard measure on Bt-11 maize (EC-163), MON810 maize, MON809 maize and T25 maize is not based on a risk assessment as required by Article 5.1 of the *SPS Agreement*, and it is not consistent with the requirements of Article 5.7 of the *SPS Agreement*. Therefore, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.
- (b) By maintaining, inconsistently with Article 5.1 of the *SPS Agreement*, the Italian safeguard measure on Bt-11 maize (EC-163), MON810 maize, MON809 maize and T25 maize, the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.

(i) Luxembourg – Bt-176 maize

8.30 In relation to Luxembourg's safeguard measure on Bt-176 maize, and for the reasons set forth in this Report, the Panel concludes that:

- (a) Luxembourg's safeguard measure on Bt-176 maize is not based on a risk assessment as required by Article 5.1 of the *SPS Agreement*, and it is not consistent with the requirements of Article 5.7 of the *SPS Agreement*. Therefore, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.
- (b) By maintaining, inconsistently with Article 5.1 of the *SPS Agreement*, Luxembourg's safeguard measure on Bt-176 maize, the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.

(j) Nullification or impairment of benefits and recommendations

8.31 Article 3.8 of the DSU provides that "[i]n cases where there is an infringement of the obligations assumed under a covered agreement, the action is considered prima facie to constitute a case of nullification or impairment". The European Communities failed to rebut this presumption. Therefore, to the extent the European Communities has acted inconsistently with its obligations under the *SPS Agreement* in respect of the relevant member State safeguard measures, it must be presumed to have nullified or impaired benefits accruing to the United States under that Agreement.

8.32 In the light of these conclusions, the Panel recommends that the Dispute Settlement Body request the European Communities to bring the relevant member State safeguard measures into conformity with its obligations under the *SPS Agreement*.

D. COMPLAINT BY CANADA (DS292): CONCLUSIONS AND RECOMMENDATIONS OF THE PANEL

**1. General EC moratorium**

8.33 For the reasons set forth in this Report, the Panel concludes, as a factual matter, that:

- (a) The European Communities applied a general *de facto* moratorium on the approval of biotech products between June 1999 and August 2003, which is when this Panel was established.

8.34 The Panel further concludes, as a legal matter, that:

- (a) The European Communities has acted inconsistently with its obligations under Annex C(1)(a), first clause, of the *SPS Agreement* and, consequently, with its obligations under Article 8 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.
- (b) The European Communities has not acted inconsistently with its obligations under Annex B(1) and Article 7 of the *SPS Agreement* in respect of the general *de facto* moratorium on approvals.
- (c) The European Communities has not acted inconsistently with its obligations under Article 5.1 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.
- (d) The European Communities has not acted inconsistently with its obligations under Article 5.6 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.
- (e) The European Communities has not acted inconsistently with its obligations under Article 5.5 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.
- (f) Canada has not established that the European Communities has acted inconsistently with its obligations under Article 2.2 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

- (g) Canada has not established that the European Communities acted inconsistently with its obligations under Article 2.3 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

8.35 Article 3.8 of the DSU provides that "[i]n cases where there is an infringement of the obligations assumed under a covered agreement, the action is considered prima facie to constitute a case of nullification or impairment". The European Communities failed to rebut this presumption. Therefore, to the extent the European Communities has acted inconsistently with its obligations under the *SPS Agreement*, it must be presumed to have nullified or impaired benefits accruing to Canada under that Agreement.

8.36 In the light of these conclusions, the Panel recommends that the Dispute Settlement Body request the European Communities to bring the general *de facto* moratorium on approvals into conformity with its obligations under the *SPS Agreement*, if, and to the extent that, that measure has not already ceased to exist.

## **2. Product-specific EC measures**

8.37 The Panel made findings in relation to four product-specific EC measures challenged by Canada (hereafter "the relevant product-specific measures").

8.38 For the reasons set forth in this Report, the Panel concludes that:

- (a) The European Communities has breached its obligations under Annex C(1)(a), first clause, of the *SPS Agreement* and, consequently, its obligations under Article 8 of the *SPS Agreement* in respect of the approval procedures concerning:
- (i) MS8/RF3 oilseed rape;
  - (ii) RR oilseed rape (EC-70);
  - (iii) MS1/RF1 oilseed rape (EC-89); and
  - (iv) MS1/RF2 oilseed rape.
- (b) The European Communities has not acted inconsistently with its obligations under Article 5.1 of the *SPS Agreement* in respect of any of the relevant product-specific measures.
- (c) The European Communities has not acted inconsistently with its obligations under Article 5.6 of the *SPS Agreement* in respect of any of the relevant product-specific measures.
- (d) The European Communities has not acted inconsistently with its obligations under Article 5.5 of the *SPS Agreement* in respect of any of the relevant product-specific measures.
- (e) Canada has not established that the European Communities has acted inconsistently with its obligations under Article 2.2 of the *SPS Agreement* in respect of any of the relevant product-specific measures.

- (f) Canada has not established that the European Communities has acted inconsistently with its obligations under Article 2.3 of the *SPS Agreement* in respect of any of the relevant product-specific measures.
- (g) There is no need to rule on Canada's claim under Article III:4 of the GATT 1994 in respect of any of the relevant product-specific measures.
- (h) There is no need to rule on Canada's claims under Articles 5.1.2, 5.2.1, first part, 2.1 and 2.2 of the *TBT Agreement* in respect of any of the relevant product-specific measures.

8.39 Article 3.8 of the DSU provides that "[i]n cases where there is an infringement of the obligations assumed under a covered agreement, the action is considered prima facie to constitute a case of nullification or impairment". The European Communities failed to rebut this presumption. Therefore, to the extent the European Communities has acted inconsistently with its obligations under the *SPS Agreement* in respect of the relevant product-specific measures, it must be presumed to have nullified or impaired benefits accruing to Canada under that Agreement.

8.40 In the light of these conclusions, the Panel recommends that the Dispute Settlement Body request the European Communities to bring the relevant product-specific measures into conformity with its obligations under the *SPS Agreement*.

### **3. EC member State safeguard measures**

8.41 The Panel made findings in relation to all five member State safeguard measures challenged by Canada (hereafter "the relevant member State safeguard measures").

- (a) Austria – T25 maize

8.42 In relation to the Austrian safeguard measure on T25 maize, and for the reasons set forth in this Report, the Panel concludes that:

- (a) The Austrian safeguard measure on T25 maize is not based on a risk assessment as required by Article 5.1 of the *SPS Agreement*, and it is not consistent with the requirements of Article 5.7 of the *SPS Agreement*. Therefore, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.
- (b) By maintaining, inconsistently with Article 5.1 of the *SPS Agreement*, the Austrian safeguard measure on T25 maize, the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.
- (c) There is no need to rule on Canada's claim under the first requirement of Article 2.2 and under Article 2.3 of the *SPS Agreement*.
- (d) There is no need to rule on Canada's claims under Articles 5.5 and 5.6 of the *SPS Agreement*.
- (e) There is no need to rule on Canada's alternative claims under Articles 2.1, 2.2 and 2.9 of the *TBT Agreement*.

(f) There is no need to rule on Canada's claim under Article III:4 of the GATT 1994.

(b) France - MS1/RF1 oilseed rape (EC-161)

8.43 In relation to the French safeguard measure on MS1/RF1 oilseed rape (EC-161), and for the reasons set forth in this Report, the Panel concludes that:

(a) The French safeguard measure on MS1/RF1 oilseed rape is not based on a risk assessment as required by Article 5.1 of the *SPS Agreement*, and it is not consistent with the requirements of Article 5.7 of the *SPS Agreement*. Therefore, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(b) By maintaining, inconsistently with Article 5.1 of the *SPS Agreement*, the French safeguard measure on MS1/RF1 oilseed rape, the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.

(c) There is no need to rule on Canada's claim under the first requirement of Article 2.2 and under Article 2.3 of the *SPS Agreement*.

(d) There is no need to rule on Canada's claims under Articles 5.5 and 5.6 of the *SPS Agreement*.

(e) There is no need to rule on Canada's alternative claims under Articles 2.1, 2.2 and 2.9 of the *TBT Agreement*.

(f) There is no need to rule on Canada's claim under Article III:4 of the GATT 1994.

(c) France - Topas oilseed rape

8.44 In relation to the French safeguard measure on Topas oilseed rape, and for the reasons set forth in this Report, the Panel concludes that:

(a) The French safeguard measure on Topas oilseed rape is not based on a risk assessment as required by Article 5.1 of the *SPS Agreement*, and it is not consistent with the requirements of Article 5.7 of the *SPS Agreement*. Therefore, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(b) By maintaining, inconsistently with Article 5.1 of the *SPS Agreement*, the French safeguard measure on Topas oilseed rape, the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.

(c) There is no need to rule on Canada's claim under the first requirement of Article 2.2 and under Article 2.3 of the *SPS Agreement*.

(d) There is no need to rule on Canada's claims under Articles 5.5 and 5.6 of the *SPS Agreement*.

- (e) There is no need to rule on Canada's alternative claims under Articles 2.1, 2.2 and 2.9 of the *TBT Agreement*.
- (f) There is no need to rule on Canada's' claim under Article III:4 of the GATT 1994.
- (d) Greece - Topas oilseed rape

8.45 In relation to the Greek safeguard measure on Topas oilseed rape, and for the reasons set forth in this Report, the Panel concludes that:

- (a) The Greek safeguard measure on Topas oilseed rape is not based on a risk assessment as required by Article 5.1 of the *SPS Agreement*, and it is not consistent with the requirements of Article 5.7 of the *SPS Agreement*. Therefore, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.
- (b) By maintaining, inconsistently with Article 5.1 of the *SPS Agreement*, the Greek safeguard measure on Topas oilseed rape, the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.
- (c) There is no need to rule on Canada's claim under the first requirement of Article 2.2 and under Article 2.3 of the *SPS Agreement*.
- (d) There is no need to rule on Canada's claims under Articles 5.5 and 5.6 of the *SPS Agreement*.
- (e) There is no need to rule on Canada's alternative claims under Articles 2.1, 2.2 and 2.9 of the *TBT Agreement*.
- (f) There is no need to rule on Canada's claim under Article XI:1 of the GATT 1994.
- (e) Italy - Bt-11 maize (EC-163), MON810 maize, MON809 maize and T25 maize

8.46 In relation to the Italian safeguard measure on Bt-11 maize (EC-163), MON810 maize, MON809 maize and T25 maize, and for the reasons set forth in this Report, the Panel concludes that:

- (a) The Italian safeguard measure on Bt-11 maize (EC-163), MON810 maize, MON809 maize and T25 maize is not based on a risk assessment as required by Article 5.1 of the *SPS Agreement*, and it is not consistent with the requirements of Article 5.7 of the *SPS Agreement*. Therefore, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.
- (b) By maintaining, inconsistently with Article 5.1 of the *SPS Agreement*, the Italian safeguard measure on Bt-11 maize (EC-163), MON810 maize, MON809 maize and T25 maize, the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.
- (c) There is no need to rule on Canada's claim under the first requirement of Article 2.2 and under Article 2.3 of the *SPS Agreement*.

- (d) There is no need to rule on Canada's claims under Articles 5.5 and 5.6 of the *SPS Agreement*.
  - (e) There is no need to rule on Canada's alternative claims under Articles 2.1, 2.2 and 2.9 of the *TBT Agreement*.
  - (f) There is no need to rule on Canada's claim under Article III:4 of the GATT 1994.
- (f) Nullification or impairment of benefits and recommendations

8.47 Article 3.8 of the DSU provides that "[i]n cases where there is an infringement of the obligations assumed under a covered agreement, the action is considered prima facie to constitute a case of nullification or impairment". The European Communities failed to rebut this presumption. Therefore, to the extent the European Communities has acted inconsistently with its obligations under the *SPS Agreement* in respect of the relevant member State safeguard measures, it must be presumed to have nullified or impaired benefits accruing to Canada under that Agreement.

8.48 In the light of these conclusions, the Panel recommends that the Dispute Settlement Body request the European Communities to bring the relevant member State safeguard measures into conformity with its obligations under the *SPS Agreement*.

#### E. COMPLAINT BY ARGENTINA (DS293): CONCLUSIONS AND RECOMMENDATIONS OF THE PANEL

##### 1. General EC moratorium

8.49 For the reasons set forth in this Report, the Panel concludes, as a factual matter, that:

- (a) The European Communities applied a general *de facto* moratorium on the approval of biotech products between June 1999 and August 2003, which is when this Panel was established.

8.50 The Panel further concludes, as a legal matter, that:

- (a) The European Communities has not acted inconsistently with its obligations under Annex B(1) and Article 7 of the *SPS Agreement* in respect of the general *de facto* moratorium on approvals.
- (b) The European Communities has not acted inconsistently with its obligations under Article 5.1 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.
- (c) The European Communities has not acted inconsistently with its obligations under Article 5.5 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.
- (d) Argentina has not established that the European Communities has acted inconsistently with its obligations under Article 2.2 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

- (e) Argentina has not established that the European Communities has acted inconsistently with its obligations under Article 2.3 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.
- (f) Argentina has not established that the European Communities has acted inconsistently with its obligations under Article 10.1 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

8.51 In view of the above conclusions, the Panel makes no recommendations pursuant to Article 19.1 of the DSU.

## 2. Product-specific EC measures

8.52 The Panel made findings in relation to ten product-specific EC measures challenged by Argentina (hereafter "the relevant product-specific measures"). However, Argentina made various claims under Article 8 and Annex C(1) of the *SPS Agreement* with regard to only eight of the ten "relevant product-specific measures". Therefore, for the purposes of the Panel's conclusions concerning the claims under Article 8 and Annex C(1), the term "relevant product-specific measures" refers to the eight product-specific measures in question. The two excluded measures are those affecting the approval of Bt-531 cotton and RR-1445 cotton under Regulation 258/97. In relation to these two measures, the Panel concludes that their existence has not been demonstrated by Argentina.

8.53 For the reasons set forth in this Report, the Panel concludes that:

- (a) The European Communities has breached its obligations under Annex C(1)(a), first clause, of the *SPS Agreement* and, consequently, its obligations under Article 8 of the *SPS Agreement* in respect of the approval procedures concerning:<sup>2186</sup>
  - (i) Bt-531 cotton;
  - (ii) RR-1445 cotton;
  - (iii) LL soybeans (EC-71);
  - (iv) NK603 maize;
  - (v) GA21 maize (EC-78);
  - (vi) GA21 maize (food); and
  - (vii) NK603 maize (food).
- (b) Argentina has not established that the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement* in respect of the approval procedures concerning:

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<sup>2186</sup> In respect of the approval procedures conducted under Regulation 258/97 – the procedures concerning those biotech products which are identified as "food" – the Panel's conclusions apply to the extent the relevant approval procedure is an SPS measure.



- (i) LL soybeans (food).
- (c) Argentina has not established that the relevant product-specific measures have resulted in the European Communities acting inconsistently with its obligations under Annex C(1)(a), second clause, and Article 8 of the *SPS Agreement*.
- (d) Argentina has not established that the relevant product-specific measures have resulted in the European Communities acting inconsistently with its obligations under Annex C(1)(b) and Article 8 of the *SPS Agreement*.
- (e) Argentina has not established that the relevant product-specific measures have resulted in the European Communities acting inconsistently with its obligations under Annex C(1)(c) and Article 8 of the *SPS Agreement*.
- (f) Argentina has not established that the relevant product-specific measures have resulted in the European Communities acting inconsistently with its obligations under Annex C(1)(e) and Article 8 of the *SPS Agreement*.
- (g) The European Communities has not acted inconsistently with its obligations under Article 5.1 of the *SPS Agreement* in respect of any of the relevant product-specific measures.
- (h) The European Communities has not acted inconsistently with its obligations under Article 5.6 of the *SPS Agreement* in respect of any of the relevant product-specific measures.
- (i) The European Communities has not acted inconsistently with its obligations under Article 5.5 of the *SPS Agreement* in respect of any of the relevant product-specific measures.
- (j) Argentina has not established that the European Communities has acted inconsistently with its obligations under Article 2.2 of the *SPS Agreement* in respect of any of the relevant product-specific measures.
- (k) Argentina has not established that the European Communities has acted inconsistently with its obligations under Article III:4 of the GATT 1994 in respect of any of the relevant product-specific measures.
- (l) There is no need to rule on Argentina's alternative claims under Articles 5.1.1, 5.1.2, 5.2.1, first part, 5.2.2, 2.1, 2.2 and 12 of the *TBT Agreement* in respect of any of the relevant product-specific measures.

8.54 Article 3.8 of the DSU provides that "[i]n cases where there is an infringement of the obligations assumed under a covered agreement, the action is considered prima facie to constitute a case of nullification or impairment". The European Communities failed to rebut this presumption. Therefore, to the extent the European Communities has acted inconsistently with its obligations under the *SPS Agreement* in respect of the relevant product-specific measures, it must be presumed to have nullified or impaired benefits accruing to Argentina under that Agreement.

8.55 In the light of these conclusions, the Panel recommends that the Dispute Settlement Body request the European Communities to bring the relevant product-specific measures into conformity

with its obligations under the *SPS Agreement*. These recommendations do not apply to those of the relevant product-specific measures which were withdrawn after the Panel was established.

### 3. EC member State safeguard measures

8.56 The Panel made findings in relation to all six member State safeguard measures challenged by Argentina (hereafter "the relevant member State safeguard measures").

(a) Austria – T25 maize

8.57 In relation to the Austrian safeguard measure on T25 maize, and for the reasons set forth in this Report, the Panel concludes that:

- (a) The Austrian safeguard measure on T25 maize is not based on a risk assessment as required by Article 5.1 of the *SPS Agreement*, and it is not consistent with the requirements of Article 5.7 of the *SPS Agreement*. Therefore, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.
- (b) By maintaining, inconsistently with Article 5.1 of the *SPS Agreement*, the Austrian safeguard measure on T25 maize, the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.
- (c) There is no need to rule on Argentina's claim under the first requirement of Article 2.2 and under Article 2.3 of the *SPS Agreement*.
- (d) There is no need to rule on Argentina's claims under Articles 5.5 and 5.6 of the *SPS Agreement*.
- (e) There is no need to rule on Argentina's alternative claims under Articles 2.1, 2.2 and 2.9 of the *TBT Agreement*.
- (f) There is no need to rule on Argentina's claim under Article III:4 of the GATT 1994.

(b) Austria - Bt-176 maize

8.58 In relation to the Austrian safeguard measure on Bt-176 maize, and for the reasons set forth in this Report, the Panel concludes that:

- (a) The Austrian safeguard measure on Bt-176 maize is not based on a risk assessment as required by Article 5.1 of the *SPS Agreement*, and it is not consistent with the requirements of Article 5.7 of the *SPS Agreement*. Therefore, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.
- (b) By maintaining, inconsistently with Article 5.1 of the *SPS Agreement*, the Austrian safeguard measure on Bt-176 maize, the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.

- (c) There is no need to rule on Argentina's claim under the first requirement of Article 2.2 and under Article 2.3 of the *SPS Agreement*.
  - (d) There is no need to rule on Argentina's claims under Articles 5.5 and 5.6 of the *SPS Agreement*.
  - (e) There is no need to rule on Argentina's alternative claims under Articles 2.1, 2.2 and 2.9 of the *TBT Agreement*.
  - (f) There is no need to rule on Argentina's claim under Article III:4 of the GATT 1994.
- (c) Austria - MON810 maize

8.59 In relation to the Austrian safeguard measure on MON810 maize, and for the reasons set forth in this Report, the Panel concludes that:

- (a) The Austrian safeguard measure on MON810 maize is not based on a risk assessment as required by Article 5.1 of the *SPS Agreement*, and it is not consistent with the requirements of Article 5.7 of the *SPS Agreement*. Therefore, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.
  - (b) By maintaining, inconsistently with Article 5.1 of the *SPS Agreement*, the Austrian safeguard measure on MON810 maize, the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.
  - (c) There is no need to rule on Argentina's claim under the first requirement of Article 2.2 and under Article 2.3 of the *SPS Agreement*.
  - (d) There is no need to rule on Argentina's claims under Articles 5.5 and 5.6 of the *SPS Agreement*.
  - (e) There is no need to rule on Argentina's alternative claims under Articles 2.1, 2.2 and 2.9 of the *TBT Agreement*.
  - (f) There is no need to rule on Argentina's claim under Article III:4 of the GATT 1994.
- (d) Germany – Bt-176 maize

8.60 In relation to the German safeguard measure on Bt-176 maize, and for the reasons set forth in this Report, the Panel concludes that:

- (a) The German safeguard measure on Bt-176 maize is not based on a risk assessment as required by Article 5.1 of the *SPS Agreement*, and it is not consistent with the requirements of Article 5.7 of the *SPS Agreement*. Therefore, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.
- (b) By maintaining, inconsistently with Article 5.1 of the *SPS Agreement*, the German safeguard measure on Bt-176 maize, the European Communities has, by implication,

also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.

- (c) There is no need to rule on Argentina's claim under the first requirement of Article 2.2 and under Article 2.3 of the *SPS Agreement*.
  - (d) There is no need to rule on Argentina's claims under Articles 5.5 and 5.6 of the *SPS Agreement*.
  - (e) There is no need to rule on Argentina's alternative claims under Articles 2.1, 2.2 and 2.9 of the *TBT Agreement*.
  - (f) There is no need to rule on Argentina's claim under Article III:4 of the GATT 1994.
- (e) Italy - Bt-11 maize (EC-163), MON810 maize and T25 maize<sup>2187</sup>

8.61 In relation to the Italian safeguard measure on Bt-11 maize (EC-163), MON810 maize and T25 maize, and for the reasons set forth in this Report, the Panel concludes that:

- (a) The Italian safeguard measure on Bt-11 maize (EC-163), MON810 maize and T25 maize is not based on a risk assessment as required by Article 5.1 of the *SPS Agreement*, and it is not consistent with the requirements of Article 5.7 of the *SPS Agreement*. Therefore, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.
  - (b) By maintaining, inconsistently with Article 5.1 of the *SPS Agreement*, the Italian safeguard measure on Bt-11 maize (EC-163), MON810 maize and T25 maize, the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.
  - (c) There is no need to rule on Argentina's claim under the first requirement of Article 2.2 and under Article 2.3 of the *SPS Agreement*.
  - (d) There is no need to rule on Argentina's claims under Articles 5.5 and 5.6 of the *SPS Agreement*.
  - (e) There is no need to rule on Argentina's alternative claims under Articles 2.1, 2.2 and 2.9 of the *TBT Agreement*.
  - (f) There is no need to rule on Argentina's claim under Article III:4 of the GATT 1994.
- (f) Luxembourg – Bt-176 maize

8.62 In relation to Luxembourg's safeguard measure on Bt-176 maize, and for the reasons set forth in this Report, the Panel concludes that:

- (a) Luxembourg's safeguard measure on Bt-176 maize is not based on a risk assessment as required by Article 5.1 of the *SPS Agreement*, and it is not consistent with the

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<sup>2187</sup> Unlike the United States and Canada, Argentina did not challenge the Italian safeguard measure on MON809 maize.

requirements of Article 5.7 of the *SPS Agreement*. Therefore, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

- (b) By maintaining, inconsistently with Article 5.1 of the *SPS Agreement*, Luxembourg's safeguard measure on Bt-176 maize, the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.
- (c) There is no need to rule on Argentina's claim under the first requirement of Article 2.2 and under Article 2.3 of the *SPS Agreement*.
- (d) There is no need to rule on Argentina's claims under Articles 5.5 and 5.6 of the *SPS Agreement*.
- (e) There is no need to rule on Argentina's alternative claims under Articles 2.1, 2.2 and 2.9 of the *TBT Agreement*.
- (f) There is no need to rule on Argentina's claim under Article III:4 of the GATT 1994.
- (g) Nullification or impairment of benefits and recommendations

8.63 Article 3.8 of the DSU provides that "[i]n cases where there is an infringement of the obligations assumed under a covered agreement, the action is considered prima facie to constitute a case of nullification or impairment". The European Communities failed to rebut this presumption. Therefore, to the extent the European Communities has acted inconsistently with its obligations under the *SPS Agreement* in respect of the relevant member State safeguard measures, it must be presumed to have nullified or impaired benefits accruing to Argentina under that Agreement.

8.64 In the light of these conclusions, the Panel recommends that the Dispute Settlement Body request the European Communities to bring the relevant member State safeguard measures into conformity with its obligations under the *SPS Agreement*.

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