

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

(WT/DS291/292/293)

First Oral Statement of the
Argentine Republic

Geneva, June 2-4, 2004

I. INTRODUCTION AND ORDER OF ANALYSIS

1. The Argentine Republic is grateful for the opportunity to argue before the Panel on the inconsistencies with WTO obligations arising from:

i) the “de facto” moratorium -affecting all biotech products- which the European Communities have 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”;

iv) as well as the bans by some EC Member States -Germany, Austria, Italy and Luxembourg- to the detriment of specific biotech agricultural products of particular interest to Argentina.

2. Argentina maintains that the foregoing measures lack scientific support, and therefore infringe the Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement).

II. GENERAL CONSIDERATIONS

3. Argentina respects the right of each State in the International Community to regulate the treatment of products of biotech origin within their territories, and does so by supporting international cooperative efforts and respecting the rights and obligations assumed under the WTO Agreement.

4. Therefore, Argentina also understands that the WTO, and in particular, the Dispute Settlement Understanding, is the appropriate framework for addressing disputes arising in relation to the scope or interpretation of the rules of the *Covered Agreements*.¹

5. For this reason, the Panel is called upon to clarify the provisions of said *Covered Agreements*, on the basis of the rules of interpretation set forth in Article 3.2 of the DSU.

6. The rules of interpretation set forth in Article 3.2 of the DSU do not authorize a broad invocation of the rules of Public International Law beyond the Covered Agreements which would modify -through interpretation, employing methods other than those set forth in the WTO Agreement- the rights and obligations of the Members.

7. Specifically, in the opinion of Argentina, contrary to the allegations of the EC², the fact that the Panel turns to the interpretive support of other rules of International Law, such as the Cartagena Protocol, to interpret the scope of the obligations included within the *Covered Agreements*, is not pertinent.

III. THE “DE FACTO” MORATORIUM IS NOT BASED ON SCIENTIFIC EVIDENCE, AND THEREFORE INFRINGES THE SPS AGREEMENT

¹ Appendix 1 of the DSU.

² First Presentation of the EC, paragraph 453.

III.1 The measure addressed in these proceedings

8. The EC is applying a measure -the “de facto” moratorium- that violates the SPS Agreement, carefully negotiated in the Uruguay Round, by straying from the basic obligation to base the restriction it is applying on scientific evidence.

9. In this regard, Argentina disagrees with the EC regarding the fact that the petitioners have chosen to turn to the WTO dispute settlement procedures rather than attempting to instigate international cooperation³. Argentina reaffirms that the natural venue for the resolution of trade disputes involving measures related to rules considered in the Covered Agreements is the WTO; the logic behind creating the dispute settlement system is a response to this very type of dispute.

10. Focusing on the specifics of the case, Argentina considers it fundamental to note that, in its First Written Presentation, it brought and developed a claim that the “de facto” moratorium *per se* constitutes a violation of WTO obligations.

11. This claim has been developed separately from the allegation on the “suspension of consideration and failure to process specific applications for products of particular interest to Argentina,” and from the claim regarding “undue delay.” This is evident in the structure of Argentina’s presentation, though the EC attempts to misrepresent, in particular, the first claim -on the “de facto” moratorium- as well as the second -on the individual applications for products of particular interest to Argentina- and to resume them all in some type of procedural violation⁴.

12. The EC has expressly acknowledged the existence of the “de facto” moratorium, as indicted in the abundant documentary evidence supporting this affirmation⁵. Therefore, the Panel should reject the allegations of the EC, which attempt to deny the existence of said “de facto” moratorium.

13. Furthermore, the EC has not responded to the evidence that Argentina has presented pointing out the existence of the moratorium, but rather has limited itself to affirming⁶ that it has not adopted any “moratorium,” nor has it suspended the application of its own community legislation on biotech products. The EC even exacerbates the confusion when it erroneously cites the period, which, according to its presentation, would have been necessary to complete its legislative procedures⁷ and eventually lift the moratorium.

14. On this specific point, the EC does not reliably indicate the actual duration of the “de facto” moratorium, but rather attempts to reduce it to the years 1998/2001 -the period in which, according to the EC, it would have taken to replace Directive 90/220/EEC-. This contradicts the very statements of the EC, which, when referring to the various legislative changes, do not cite this limited period, but rather confirm what was indicated in Argentina’s presentation (1998 to the present), based on the need for additional legislative changes⁸.

³ First Presentation of the EC, paragraph 10.

⁴ First Presentation of the EC, paragraph 460.

⁵ See Exhibits ARG-7, ARG-8, ARG-9, ARG-10, ARG-21, ARG-22, ARG-23, ARG-24, ARG-25, ARG-26, ARG-27, ARG-41 and ARG-42.

⁶ First Presentation of the EC, paragraphs 162 et seq.

⁷ First Presentation of the EC, paragraph 4.

⁸ First Presentation of Argentina, paragraph 30, and see Exhibits ARG-10, ARG-11, ARG-12 and ARG-14.

15. The EC starts from the premise that the co-petitioners have been “unable to identify an instrument or other text”⁹ by which the moratorium was established, and that the claims of the co-petitioners “are all in reality complaints about delay.”¹⁰ This -from the EC’s point of view- is because the co-petitioners are addressing “omissions” in their claims, which, in the EC’s opinion, would not be disputable within the scope of the WTO¹¹.

16. In this regard, it is noted that an “omission” is disputable pursuant to WTO rules, as indicated in the presentation of Argentina¹². Furthermore, New Zealand has argued in its presentation that an interpretation of “measure” in a restricted sense of the word would make it possible for WTO rules to be easily avoided, since only those measures set forth in legislative documents could be disputed¹³. This line of argument also gives rise to the EC’s attempt to divert the Panel’s attention toward what it calls issues “of procedure.” Thus, the EC attempts to avoid addressing the substantive issues: the “de facto” moratorium and the lack of scientific evidence supporting the restriction.

17. In its presentation, Argentina provided elements that demonstrate both the existence of the “de facto” moratorium and the period during which it has taken place.

18. These elements begin with statements by relevant EC officials with jurisdiction over the matter addressed in this dispute. These statements, furthermore, confirm the period during which the “de facto” moratorium has been applied. Nevertheless, Argentina wishes to point out that these statements, notwithstanding the fact that they were made by relevant community officials, are not the moratorium *per se* or the instrument establishing it, but rather are provided as facts demonstrating the existence of the “de facto” moratorium.

19. In other words, the statements are evidence of the existence of the “de facto” moratorium.

20. With respect to the EC’s argument that the “de facto” moratorium could not be identified in an instrument, Argentina refers to its presentation in which it specifically addresses this issue and explains the specific characteristics of the “de facto” moratorium measure¹⁴. In doing so, Argentina emphasized the fact that this measure has not been established in the traditional manner that WTO Members use for such purposes (laws, decrees, resolutions, etc).

21. Furthermore, it is precisely in the EC’s process of approval of GMOs that the application of this “de facto moratorium” is reflected¹⁵. Notwithstanding the fact that in some cases there has been some movement through the successive stages of the approval processes, the fact remains that no biotech agricultural products have been approved since 1998. To counter the statements by the EC, Argentina does not question the total lack of movement in the successive stages, but rather the fact that since 1998, this movement has been completely non-conducting towards approval.

⁹ First Presentation of the EC, paragraph 373.

¹⁰ First Presentation of the EC, paragraph 373.

¹¹ First Presentation of the EC, paragraphs 373-375, and 566-571.

¹² First Presentation of Argentina, point II.A.1.a.ii).

¹³ First Presentation of New Zealand, paragraphs 2.06-2.08.

¹⁴ First Presentation of Argentina, point II.A.1.a.ii).

¹⁵ Stages in the First Presentation of Argentina, paragraphs 9-15.

22. The EC itself claims that it applied a moratorium on the approval of new products at least until its legislative process was completed¹⁶; completing said process has no relation whatsoever with the scientific grounds required to approve or reject products.

23. Argentina notes that the EC has not based the “de facto” moratorium on any scientific evidence. On the contrary, the existing scientific evidence, included as evidence in these proceedings and issued by the EC’s own scientific committees, supports the position contrary to the “de facto” moratorium, and thus recommends the approval of the referenced biotech agricultural products¹⁷.

24. Thus, for example, four of the five products of particular interest to Argentina received an opinion from the pertinent Scientific Committee favoring authorization¹⁸. The same holds true for other products in the EC approval system.

25. Within the broader framework of the “de facto” moratorium, a persistent pattern of conduct by the EC can be observed: both through actions and fundamentally through omissions, it has created a “de facto” moratorium that manifests itself as follows 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 for the approval of the Regulatory Committee for products that have received a favorable opinion from the scientific committees

iii) Systematic opposition by Member States to approval when a draft is submitted, without scientific grounds to oppose the Commission’s draft

iv) Failure by the EC to refer the proposal to the Council of Ministers when the Regulatory Committee does not render an opinion

26. Although the foregoing combination of actions and omissions within the EC’s regulatory framework does allow movement of applications through the various regulatory stages, this movement, in the opinion of Argentina, is circular in nature and never results in approval.

27. In short, on the one hand, a pattern of behavior is verified determining the failure to approve any biotech agricultural product since 1998 as a function of their being blocked or stagnating in the key stages of the process. On the other hand, statements by the EC itself have been indicated -which the EC does not refute in its presentation, but rather attempts to minimize-. Therefore, Argentina requests that the Panel consider the existence of the “de facto” moratorium as demonstrated, based on the evidence presented¹⁹, and in the sense that:

“a) it has never been set forth in the form of positive legislation -a regulation or directive- but it has been applied and maintained as a practice in the EC since 1998;

¹⁶ First Presentation of the EC, paragraph 562, and First Presentation of Argentina, paragraph 31, and Exhibits ARG-10, ARG-11, ARG-12 and ARG-14.

¹⁷ See Exhibits ARG-21, ARG-22, ARG-23, ARG-24, ARG-25, ARG-26, ARG-27, ARG-41 and ARG-42.

¹⁸ See Exhibits ARG-21, ARG-22, ARG-23, ARG-24, ARG-25, ARG-26, ARG-27, ARG-41 and ARG-42.

¹⁹ See Exhibits ARG-7, ARG-8, ARG-9, ARG-10, ARG-11, ARG-12, ARG-14, ARG-21, ARG-22, ARG-23, ARG-24, ARG-25, ARG-26, ARG-27, ARG-34, ARG-41 and ARG-42.

b) from 1998 to the present, no new biotech agricultural product has been approved for placement on the market, which entails the systematic suspension of the processing 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, while causing an undue delay in the completion of the processing of said applications;

d) it is not supported by scientific evidence;

e) it has manifested itself in a repeated delay of deadlines by the EC since 1998, under the continued pretext of the approval of new legislation: amendment of Directive 90/220/EEC by Directive 2001/18/EC, the need to have additional legislation covering different aspects and new requirements, etc.

f) reveals an arbitrary and unjustified discrimination against biotech agricultural products.”²⁰

III.2 The application of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) to the “de facto” moratorium

28. In the previous section, reference was made to the existence and the form taken by the “de facto” moratorium. Now we will refer to the purpose of the “de facto” moratorium, due to its importance in characterizing it as a measure falling under the SPS Agreement.

29. In this regard, the purpose of the EC regulations for the approval of biotech products is *to determine*, by means of case-by-case assessment, the presence or lack of “additives,” “contaminants” or “toxins” in foods, beverages or foodstuffs and the assessment of the risks to human life and health resulting from the presence thereof. Such regulations constitute a sanitary and phytosanitary measure as defined by the SPS Agreement, regardless of the fact that, in a particular case, their application may result in the conclusion that such elements do not exist in the assessed product. In other words, what defines the nature of a measure as sanitary or phytosanitary is the purpose of identifying and preventing certain risks, and not the characteristics or components of the assessed product.

30. The risk arising from the mass consumption of varieties containing marker genes, which may develop bacteria resistant to antibiotics, falls within the definition of section (b) of Annex A:1 of the SPS Agreement. Such concerns have been characterized as food safety issues. Therefore, a measure based on such concerns is a measure aimed at protecting human and animal health from the risks arising from diseases and disease-carrying organisms in foods, beverages and foodstuffs.

31. The risk arising from the cross-contamination of biotech products with other undesired organisms falls within the scope of section (d) of Annex A:1 of the SPS Agreement, which considers the measures applied “to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests” and paragraph (c) of the same text, as the EC itself seems to concede implicitly²¹. Annex A:1 of the SPS Agreement defines “pests,” which include “weeds”.

²⁰ First Presentation of Argentina, paragraph 34.

²¹ First Presentation of the EC, paragraph 419.

32. The EC acknowledges that part of the objective sought by the community system governing the approval of GMOs falls under the SPS Agreement²². With respect to those issues allegedly excluded from the scope of the SPS Agreement, the EC has not been sufficiently precise.

33. On this point, Argentina considers it appropriate to reiterate that the purpose of the SPS Agreement is to address measures aimed at protecting against certain risks. In other words, the SPS Agreement does not refer to products, but rather to risks. The EC seems to acknowledge this in its presentation²³.

34. In turn, with respect to the applicable WTO Agreement, Argentina would like to point out that the “de facto” moratorium, as indicated in its presentation²⁴, not only has the purpose required for a measure to be included under the SPS Agreement, but also meets the formal requirement of a sanitary or phytosanitary measure.

35. In short, the EC’s arguments that the SPS Agreement does not apply should be rejected as groundless.

III.3 Conclusions with respect to the “de facto” moratorium

36. In short, Argentina considers that the EC has clearly violated the rules of the SPS Agreement. Furthermore, the EC itself has admitted the existence of the measure in dispute²⁵ -the “de facto” moratorium-, even when its own scientific committees have ruled in favor of the approval of various biotech agricultural products²⁶.

37. For this reason, Argentina respectfully requests that the Panel first confirm the inconsistency of the “de facto” moratorium with Article 5.1 of the SPS Agreement, in order to subsequently rule on the violation of Article 2.2 of the SPS Agreement.

38. In this regard, Argentina notes that, in the event the Panel confirms the violations of Articles 5.1 and 2.2 of the SPS Agreement related to this claim, it would not be necessary to further confirm the “de facto” moratorium’s violations of the other invoked Articles of the SPS Agreement, without prejudice to the fact that, according to the Panel’s assessment, Argentina reaffirms its other arguments with respect to the Articles of the SPS Agreement violated by the EC, as set forth in its First Presentation.

IV. THE “SUSPENSION AND FAILURE TO CONSIDER” IS NOT BASED ON SCIENTIFIC EVIDENCE, AND THEREFORE VIOLATES WTO OBLIGATIONS

39. 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. In turn, Article 1.4 of the SPS Agreement reaffirms the rights of the Members under the TBT Agreement with respect to those measures not within the scope of the SPS Agreement. Therefore, a measure may only be examined under one agreement or the other when these two agreements are in play. Otherwise, we would stray from the textual base that considers them mutually exclusive.

²² First Presentation of Argentina, paragraphs 44-50.

²³ First Presentation of the EC, paragraph 384.

²⁴ First Presentation of Argentina, point II.A.1a.i).

²⁵ See Exhibits ARG-7, ARG-8, ARG-9, ARG-10, ARG-11, ARG-12 and ARG-14.

²⁶ See Exhibits ARG-21, ARG-22, ARG-23, ARG-24, ARG-25, ARG-26, ARG-27, ARG-34, ARG-41, and ARG-42.

40. The applicability of the SPS Agreement is indicated first, since the EC's measures were established with the purpose of protecting life and health.

41. Argentina considers that, in this case, the purpose of protecting life and health places the measure within the scope of the SPS Agreement, regardless of the form in which said measure is embodied. This also rules out the applicability of the Agreement on Technical Barriers to Trade -TBT Agreement-, which does have a specific requirement regarding the form of the measure. In fact, the TBT Agreement requires the existence of at least one document which embodies a "technical regulation" or which sets forth a procedure for conformity assessment.

42. Of course, the "suspension of processing and failure to consider" -substantive matters- are not set forth in a document. This *per se* already rules out application of the TBT Agreement as a Covered Agreement with respect to the assessment of the consistency of the measures in dispute.

43. With respect to the biotech agricultural products considered individually, Argentina notes, for example, that the "suspension of processing" affected four of them²⁷, which received favorable scientific opinions.

44. Allow me to make detailed reference to the specific applications:

➤ **Cotton Bt-531**

45. The application was filed in 1996 under Directive 90/220/EEC. It obtained a favorable opinion from the competent body's Biosafety Commission in November 1997, the Commission requested the scientific opinion of the Scientific Committee on Plants, and in 1998, six years ago, the Committee issued a positive opinion, stating "*there is no evidence to indicate that the placing on the market of line IPC 531 with the purpose to be used as any other cotton is likely to pose adverse effects on human health and the environment.*"²⁸

46. In February 1999, according to the EC²⁹, the Regulatory Committee failed to attain the qualified majority and did not issue an opinion. According to the procedure set forth in Directive 90/220/EEC³⁰, the Commission should have referred a proposal to the Council without delay. The Commission never made such a referral. The procedure was suspended due to the inaction of the Regulatory Committee. The application was suspended until it had to be refiled under Directive 2001/18/EC. Consequently the EC has acknowledged that the application for approval of Cotton Bt 531 had its processing suspended and was not considered.

47. Although the product has had the favorable scientific opinion since 1998, as of June 2004 -six years after the scientific opinion- its marketing has not been authorized.

➤ **Cotton RRC-1445**

48. The application was filed in 1997 under Directive 90/220/EEC. The Commission requested the scientific opinion of the Scientific Committee on Plants and in 1998, six years ago, the Committee issued a positive opinion, stating

²⁷ Maize GA21, Cotton RRC 1445, Cotton Bt-531 and Maize NK-603.

²⁸ First Submission of the EC, paragraph 224.

²⁹ First Submission of the EC, paragraphs 222-228; see also Exhibit EC-65.

³⁰ Article 21 of Directive 90/220/EEC.

“there is no evidence to indicate that the placing on the market of line RRC-1445 with the purpose to be used as any other cotton is likely to pose adverse effects on human health and the environment.”³¹

49. In February 1999, according to the EC³², the Regulatory Committee failed to attain the qualified majority and did not issue an opinion. According to the procedure set forth in Directive 90/220/EEC³³, the Commission should have referred a proposal to the Council without delay. The Commission never made such a referral. The procedure was suspended due to the inaction of the Regulatory Committee. The application was suspended until it had to be refiled under Directive 2001/18/EC. Consequently the EC has acknowledged that the application for approval of Cotton RRC-1445 had its processing suspended and was not considered.

50. Although the product has had the favorable scientific opinion since 1998, as of June 2004 -six years after the scientific opinion- its marketing has not been authorized.

➤ **Maize NK-603**

51. The application was filed under Directive 90/220/EEC in the year 2000 and was refiled under Directive 2001/18 in 2003. The new European Food Safety Authority (EFSA) issued a favorable opinion stating: *“Having considered the evidence, the ... Panel is of the opinion that Maize NK-603 is as safe as conventional maize and therefore the placing on the market of Maize NK-603 for food or feed or processing is unlikely to have an adverse effect on human and animal health and, in that context, the environment...”³⁴*

52. The EC indicates that it did not obtain the majority necessary in the Regulatory Committee and consequently, the Commission sent a draft proposal to the Council. Argentina trusts that, as indicated by the EC, after the favorable scientific opinion, four years after beginning the procedure, Maize NK-603 will be approved this month of June as indicated by the EC.

53. Unfortunately, the processing of the same product under Regulation (EC) 258/97, notwithstanding the favorable opinion of the European authority (EFSA)³⁵, has no alternative since there are no plans in the Council to address the respective application.

➤ **Maize GA-21**

54. The application under Directive 90/220/EEC dates back to 1998 and obtained the favorable opinion of the Scientific Committee in September 2000. In September 2003 the application for approval of this product was withdrawn. Argentina mentions this, considering it a product of interest, which, for nearly three years did not obtain

³¹ See Exhibit ARG-23.

³² First Submission of the EC, paragraphs 229-234; see also Exhibit EC-66.

³³ Article 21 of Directive 90/220/EEC.

³⁴ See Exhibit ARG-25.

³⁵ See Exhibit ARG-26.

authorization for marketing despite favorable scientific evidence³⁶. This illustrates the impact and consequences of the moratorium.

55. Under Regulation (EC) 258/97 it was filed in July 1998 and obtained a favorable opinion in February 2002, indicating that Maize GA-21 is a product *“as safe as grain and derived products from conventional maize lines.”*³⁷ Despite the favorable opinion, no marketing authorization has been obtained, placing this product in the category with those, which, despite scientific analysis, never obtained authorization.

Conclusions with respect to the “suspension and failure to consider”

56. The EC has not refuted the scientific evidence of its own Committees, which recommended the approval of the referenced products³⁸, clearly leaving without scientific support the measures affecting the approval procedures for at least four of these products.

57. For this reason, Argentina requests that first, the inconsistency of the “suspension of processing and failure to consider” with the SPS Agreement be confirmed, specifically with Article 5.1. This would automatically imply inconsistency with Article 2.2 of the SPS Agreement.

58. Furthermore, in the event that the inconsistency of the “suspension of processing and failure to consider” with Articles 5.1 and 2.2 of the SPS Agreement is confirmed, Argentina considers that the Panel will not need to analyze the inconsistency with respect to the remaining legal standards invoked with respect to these measures, without prejudice to the fact that, according to the Panel’s assessment, Argentina reaffirms its other arguments related to regulations violated by the EC, as set forth in its First Presentation.

V. THE “UNDUE DELAY”

59. In the opinion of Argentina, and as arises from the First Presentation³⁹, despite the degree of detail and complexity contemplated in Directive 2001/18/EC and in Regulation (EC) 258/97 for the approval of biotech agricultural products for release or marketing, the “undue delay” implies a violation of the provisions of Article 8 and Annex C of the SPS Agreement.

60. Both Directive 2001/18/EC and Regulation (EC) 258/97 establish terms for each of the stages provided for the control, assessment and approval of new biotech agricultural products. As held by Argentina and not refuted by the EC, an approximate average time during which it would seem reasonable to complete these procedures can be estimated⁴⁰.

61. The procedures regulated by EC regulations should not, on average, exceed 240 days⁴¹.

³⁶ See Exhibit ARG-41.

³⁷ See Exhibit ARG-42.

³⁸ See Exhibits ARG-21, ARG-22, ARG-23, ARG-24, ARG-25, ARG-26, ARG-27, ARG-41 and ARG-42.

³⁹ First Presentation of Argentina, paragraphs 324-334.

⁴⁰ First Presentation of Argentina, paragraphs 306-314.

⁴¹ First Presentation of Argentina, paragraphs 307 and 308.

62. The EC simply has not stated why new biotech agricultural products receive less favorable treatment within the same regulatory framework -i.e., Regulation (EC) 258/97- as new “non-biotech” products.

63. 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 approved⁴².

64. The Argentine Republic reiterates that elements exist demonstrating that the EC has caused an “undue delay” in the approval of new biotech products since 1998. The EC has approved new “non-biotech” products, but has not approved new biotech products within the scope, e.g., of Regulation (EC) 258/97, that the EC considers appropriate for purposes of comparison.

VI. THE STATE BANS ARE NOT BASED ON SCIENTIFIC EVIDENCE, AND THEREFORE VIOLATE THE SPS AGREEMENT

65. First, Argentina wishes to note that, with respect to the EC’s argument on Article 5.7 of the SPS Agreement, we reserve the right to develop this point at another stage in the proceedings.

66. So, according to the substantive arguments put forward by Argentina in its First Presentation⁴³ with respect to the measures applied by Germany, Austria, Italy and Luxembourg against specific biotech agricultural products, all of the affected products had prior approval by the EC⁴⁴, based on scientific opinions issued by the EC’s own committees⁴⁵.

67. Despite this, the state bans have ignored this scientific evidence and maintain restrictions on the entry of these products into their territories.

68. Furthermore, some of these countries have attempted to seek protection under safeguard procedures to try to justify their measures, which has resulted in new scientific opinions issued by EC committees, which not only reaffirmed support for the biotech agricultural products in question, but also specifically refuted the grounds for the state measures⁴⁶, which consequently become unlawful within the EC’s regulatory system.

69. In other words, the same biotech product that has a positive opinion from the respective scientific committee at the community level, may then be banned at the state level and in fact, the ban by some EC Member States has been verified.

70. All of this demonstrates the lack of scientific evidence supporting the measures currently maintained by Germany, Austria, Italy and Luxembourg, and confirms the arbitrary and unjustified distinction made with respect to these products. For this reason, as in the foregoing sections, we request that the Panel first confirm inconsistency with Article 5.1 of the SPS Agreement.

⁴² See Exhibit ARG-34.

⁴³ First Presentation of Argentina, point V.

⁴⁴ See Exhibits ARG-6, ARG-35, ARG-36, ARG-37 and ARG-38.

⁴⁵ See Exhibits ARG-30, ARG-31, ARG-32 and ARG-33.

⁴⁶ See Exhibits ARG-43, ARG-44, ARG-45, ARG-46 and ARG-47.

71. Furthermore, said violation implies inconsistency with Article 2.2 of the SPS Agreement, in accordance with WTO jurisprudence.

72. Without bias to the previous argument, Argentina also raises the issue of judicial economy, indicating that once the inconsistency of the state bans with Articles 5.1 and 2.2 of the SPS Agreement is confirmed, it will not be necessary to further confirm the violations of the bans by some EC Member States with the other legal standards invoked, without bias to the fact that, according to the Panel's assessment, Argentina reaffirms its other arguments with respect to the regulations violated by the EC, as set forth in its First Presentation.

VII. ARTICLE XX OF THE 1994 GATT AGREEMENT

73. Nowhere in their presentations have the co-petitioners indicated the possibility that the conduct and violations by the EC were justified pursuant to Article XX of GATT 1994⁴⁷. In this regard, the EC has the burden of proof, which cannot be considered fulfilled with a simple assertion.

74. The EC has not put forward a single argument justifying the first test necessary to invoke the provisional exemption of one of the subparagraphs of Article XX of GATT 1994, nor has it made any argument whatsoever regarding the "chapeau."

75. Argentina requests that the Panel reject this defense claimed by the EC based on the exception provided for under Article XX of GATT.

VIII. SPECIAL AND DIFFERENTIAL TREATMENT

VIII.1 In the framework of the SPS Agreement

76. Argentina does not share the EC's scope and interpretation of the special and differential treatment accorded to developing countries as set forth in Article 10.1 of the SPS Agreement⁴⁸.

77. In the opinion of Argentina, the EC has failed to respond and has not demonstrated that they have taken account of and undertaken positive actions, such as those considered in Article 10.1 of the SPS Agreement, in deciding and applying the "de facto" moratorium, suspending consideration, not approving or unduly delaying approval of biotech products of particular interest to Argentina.

78. The absolute ban on access for the biotech agricultural products of particular interest to Argentina arising from the failure of consideration, suspension, non-approval or undue delay in the approval thereof by the EC, as argued⁴⁹, has affected and continues to affect Argentina.

79. In this regard, the EC is incorrect in holding that it is a consequential claim. To construe Article 10.1 of the SPS Agreement as only containing a consequential obligation is to strip the provision on special and differential treatment of its content.

⁴⁷ First Presentation of the EC, paragraphs 673 and 674.

⁴⁸ First Presentation of the EC, paragraph 665 et seq.

⁴⁹ First Presentation of Argentina, paragraph 183.

VIII.2 In the framework of the TBT Agreement

80. Argentina has already presented its alternative allegations with respect to the TBT Agreement in its First Submission, and will not reiterate them here, with the exception of the following comments relating to Article 12 of the TBT Agreement⁵⁰.

82. The EC has limited its response⁵¹ to holding that Argentina infers the violation of Article 12.3 in the case by confirming a violation of Article 5.2.1 and consequently, since the EC does not accept the existence of any violation, it concludes that there is no violation of the obligation of special and differential treatment.

83. Argentina notes that the arguments surrounding the obligations prescribed in Article 12.3 are much more extensive and are based on a detailed analysis⁵² of the logic of Article 12 in its entirety.

84. Thus, Argentina accurately indicates violations⁵³ of Article 12.3 and further highlights that the EC has ignored the special trade, financial and development needs of developing countries⁵⁴. The EC has not responded to this argument.

85. Furthermore, Argentina argues on the absolute ban on imports in paragraph 448 of its First Written Presentation. Due to the primary effect of preventing the access of biotech agricultural products of particular interest to Argentina not approved prior to 1998, this ban demonstrates that the EC has failed to take into account the special needs of a developing country such as Argentina. The EC has not responded to this argument.

86. The EC holds⁵⁵ that imports of biotech agricultural products from developing countries have not been reduced, and to the contrary, have increased for Argentina and Brazil since 1995/96.

87. Argentina considers it necessary to clarify certain aspects of this claim.

88. First, Argentina has argued⁵⁶ that there was no access to the EC market and has not made reference to an increase or decrease of imports as the EC has. In this regard, it must be noted that the GATT/WTO system does not protect volumes of trade, but rather expectations of competition. Consequently, the increase in trade mentioned by the EC refers to biotech agricultural products that were already approved, which does not release it from the obligation to ensure conditions of access, taking into account the special and differential treatment provisions for other products from developing countries that cannot currently be marketed in the EC.

89. Secondly, the EC's claim takes account of biotech agricultural products, and in particular, mentions the "commodities likely to contain GMOs." In its assessment, Argentina is referring to an absolute ban on imports with

⁵⁰ First Presentation of Argentina, paragraphs 439-449.

⁵¹ First Presentation of the EC, paragraph 668.

⁵² First Presentation of Argentina, paragraphs 439-444.

⁵³ First Presentation of Argentina, paragraph 445.

⁵⁴ First Presentation of Argentina, paragraph 446.

⁵⁵ First Presentation of the EC, paragraph 671.

⁵⁶ First Presentation of Argentina, paragraph 448.

respect to biotech agricultural products of particular interest to Argentina, which have not been considered, not approved, suspended or subject to undue delays since 1998.

90. Thirdly, Argentina disagrees with the period during which the EC considers that the increase has taken place, beginning "since 1995/1996". Argentina argued that the absolute ban on imports of biotech agricultural products of particular interest to Argentina into the EC was verified beginning in 1998. And on this point, Argentina reminds the Panel that in their presentations, all of the co-petitioners have completely agreed on the start of the time period considered, that is, the year 1998.

VIII.3 Conclusions with respect to special and differential treatment for developing countries

91. In the opinion of Argentina, with respect to the claims contained in its First Written Presentation, the EC has not refuted the arguments of Argentina in the sense that it has not addressed the special needs of developing countries, *in this case*, Argentina, by according the mandatory treatment⁵⁷ considered in Article 10.1 of the SPS Agreement.

92. Furthermore, on the grounds set forth above, the EC has not argued, much less managed to demonstrate that, in the application of community legislation to the biotech agricultural products of particular interest to Argentina, it has observed the special needs of Argentina as a developing country as provided in the pertinent sections of Article 12 of the TBT Agreement.

93. Finally, Argentina wishes to note that the obligations of special and differential treatment set forth in the Agreements are not complementary or lesser obligations: in fact, the Covered Agreements and in particular the SPS or TBT Agreements, do not differentiate between primary and auxiliary provisions and much less can a complementary nature be attributed to the Articles on special and differential treatment.

IX. CONCLUSION

94. Argentina reiterates the claims of inconsistency of its First Written Presentation, and requests that they be analyzed in light of the considerations of judicial economy mentioned in this Oral Statement, in order to reach a prompt settlement of this dispute pursuant to the provisions of the DSU.

⁵⁷ For example, in any of the forms in the non-exhaustive list in paragraph 176 of the First Presentation of Argentina.