

**European Communities – Measures Affecting the Approval and Marketing of Biotech
Products**

(WT/DS291, 292, and 293)

**Executive Summary of the
First Submission of the United States**

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I. INTRODUCTION

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

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

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

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

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

6. In challenging the EC's moratorium under the *Understanding on Rules and Procedures Governing the Settlement of Disputes* (“DSU”), the United States is simply calling on the EC to allow its own approval procedures to run their course. The United States is confident that once the EC allows its scientific and regulatory procedures to reach their conclusion, it will once again approve new biotech products, benefitting EC consumers and biotech producers around the world.

II. STATEMENT OF FACTS

A. Biotechnology

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

8. Modern biotechnology can significantly increase agricultural output by protecting plants from factors that reduce yields, such as pests, diseases, spoilage and extreme weather conditions. A report issued by seven national and international academies of science (“Multinational Science Academies Report”) concluded that modern biotechnology must play a role in addressing the shortage of food in the developing world, where 800 million people currently do not have access to sufficient food and malnutrition is a

contributing factor in the deaths of six million children under the age of five each year. In its Statement on Biotechnology, the Food and Agriculture Organization of the United Nations (“FAO”) said, “genetic engineering has the potential to help increase production and productivity in agriculture, forestry and fisheries. It could lead to higher yields on marginal lands in countries that today cannot grow enough food to feed their people.” A Joint FAO/World Health Organization (“WHO”) report of scientific experts recognized that “developing countries look on [recombinant DNA] technology as a means of addressing the need to produce sufficient quantities of nutritionally adequate and safe food for their growing populations.”

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

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

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

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

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

B. Moratorium on Approvals of Biotech Products

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

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

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

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

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

19. Commission documents also confirm the existence of the moratorium. A Commission Working Document dated November 2000 states “the current authorization procedure for commercial release of GMOs, including those that may end up in the food chain, has ground to a standstill. A Commission Press Release dated July 2001 states that the adoption of new legislative proposals “will contribute towards the lifting of the de facto moratorium on the commercial release of GMOs.” An October 2001 internal Commission working paper states that “[t]his reluctance to go forward with authorizations of GMOs has resulted in a de facto moratorium on the marketing of new GMOs and impacted on product approvals under the sector-based legislation.” In July 2003, a Commission fact sheet on GMO regulation stated that “[t]he revised Directive [2001/18] and the two proposals for Regulations are expected to pave the way for a resumption of GM authorizations in the European Union,” implying that authorizations had been suspended. A document issued by the General Secretariat of the Council of the European Union stated that the proposed rules on traceability and labeling of biotech products could “possibly lead to the lifting of the current moratorium.” More recently, in a January 2004, Communication to the Commission, Commission officials

admitted that “no authorizations have been granted since October 1998” despite the adoption of an “interim approach” to biotech product approvals allegedly adopted in July 2000.

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

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

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

C. Member States’ Marketing or Import Bans

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

24. In particular, Austria issued three measures prohibiting the “placing on the market” of three corn biotech products: Bt-176, MON 810 and T25; France issued two Orders on November 16, 1998, prohibiting the “placing on the market” of two rapeseed biotech products: MS1/RF1 and Topas 19/2; Luxembourg issued a Ministerial Order on February 7, 1997, prohibiting the “use and sale” of biotech corn Bt-176; Germany issued a Ruling March 31, 2000, “suspending the approval” and the placing on the market of Bt-176; Italy issued a Decree on August 4, 2000, suspending the “commercialization and use” of the following corn products: Bt-11, MON 810, MON 809 and T25; and Greece issued a Decree September 8, 1998, prohibiting the importation of Agrevo oilseed rape (Topas 19/2).

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

IV. Legal Discussion

A. General Moratorium Violates the SPS Agreement

26. The general moratorium is one component of the EC’s biotech approval regime; in particular, the general moratorium is a moratorium on approvals under the novel foods and deliberate release legislation. The EC’s biotech approval regime is unquestionably an SPS measure. Directive 2001/18 states that one of the objectives of the Directive is “to protect human health and the environment” when, among other things,

“placing on the market genetically modified organisms as or in products within the Community.” Similarly, its predecessor legislation, Directive 90/220, states that one of its objectives is “to protect human health and the environment” from, among other things, “placing on the market products containing, or consisting of, genetically modified organisms intended for subsequent deliberate release into the environment.” Finally, Regulation 258/97 states that “[f]oods and food ingredients falling within the scope of the Regulation must not present a danger for the consumer” or be “nutritionally disadvantageous.”

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

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

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

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

31. Moreover, the SPS Agreement includes in its definition of “measure” the terms “requirement” and “procedure”, which are not necessarily in written form. For example, the *New Shorter Oxford English Dictionary* defines the term “procedure” as a “particular mode or course of action” or a “set of instructions

for performing a specific task which may be invoked in the course of a program.” Under the ordinary meaning of the term “procedure,” a suspension by the EC of the consideration of applications for, or granting of, approval of biotech products is an unwritten procedure covered under the SPS Agreement.

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

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

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

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

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

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

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

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

40. Where the EC’s own legislation provides procedures and timelines for the approval of biotech products, an indefinite suspension of that approval procedure, without any scientific justification, must be considered “undue delay” under Annex C.

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

42. The general moratorium is also inconsistent with each of the related procedural obligations in Annex C(1)(b) of the SPS Agreement.

43. (1) “*the standard processing period of each procedure is published or that the anticipated processing period is communicated to the applicant upon request*”: Although the EC novel food and deliberate release directives contain processing periods, under the general moratorium those processing periods are not followed. Instead, the EC has imposed an indefinite delay. However, since the EC does not acknowledge the moratorium, the standard processing period is not published, and the anticipated processing period is not communicated to the applicant.

44. (2) “*when receiving an application, the competent body promptly examines the completeness of the documentation and informs the applicant in a precise and complete manner of all deficiencies*”: Under the general moratorium, the EC does not promptly examine documentation and inform the applicant of all deficiencies. To the contrary, applications under the EC directives are stalled, without explanation.

45. (3) “*the competent body transmits as soon as possible the results of the procedure in a precise and complete manner to the applicant so that corrective action may be taken if necessary*”: Under the general moratorium, results of procedures are not promptly communicated to applicants so that corrective action may be taken. Instead, applications are stalled in the approval process without explanation.

46. (4): “*even when the application has deficiencies the competent body proceeds as far as practicable with the procedure if the applicant so requests*”: Under the general moratorium, the EC does not proceed as far as practicable in the approval process. Instead, one again, application are stalled in the approval process.

47. (5) “*and that upon request, the applicant is informed of the stage of the procedure, with any delay being explained*”: Under the general moratorium, delays are not explained. To the contrary, the EC does not even inform applicants of the existence of the moratorium.

48. To the extent the EC’s suspension of consideration of applications for, or granting of, approval of biotech products (the general moratorium) is preventing the sale or marketing of biotech products, the general moratorium violates Article 5.1 of the SPS Agreement. In order for a measure to be based on a risk

assessment in accordance with Article 5.1, the following two criteria must be met: (1) “the study put forward as a risk assessment [must] meet the requirements of a risk assessment set forth in Article 5.1 and Annex A of the SPS Agreement”; and (2) “the sanitary measures . . . selected [must be] *based on* this risk assessment . . .” The EC has not met either requirement. Each is analyzed separately below.

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

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

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

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

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

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

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

56. Third, the EC has applied the general moratorium in a manner that results in “discrimination or a disguised restriction on international trade.” The EC’s application of the general moratorium exhibits all three “warning signals” and an “additional factor” which indicate that the measure discriminates or provides a disguised restriction on international trade.

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

58. Finally, the “additional factor” is a disproportionate effect of the general moratorium on producers outside the EC as compared to producers within the EC. In 2001, the EC accounted for less than four-tenths of one percent of the worldwide land area devoted to growing biotech products. In contrast, the United States, Argentina, Canada, and China accounted for ninety-nine percent of the total land area devoted to biotech products in 2001. For producers in these countries, the moratorium on approvals of biotech products has had a substantial negative effect.

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

B. Product-Specific Moratoria Violate the SPS Agreement

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

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

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

63. Although the EC has put forth risk assessments for fourteen of the twenty-seven pending applications for approval of biotech products, the product-specific moratoria are not “based on” these risks assessments as required by Article 5.1. Specifically, there is no “rational relationship” between the EC’s risk assessments and the product-specific moratoria. To the contrary, there is an irrational relationship between the opinions of the scientific committees, which found no evidence that these products pose a risk to human or animal health or the environment, and the product-specific moratoria, which, in effect, ban

these products from the EC market. Because the product-specific moratoria are not “based on” the EC’s risk assessments, the measures are inconsistent with Article 5.1 of the SPS Agreement.

C. EC Member State Marketing or Import Bans Violate the SPS Agreement

64. Like the moratoria (general and product-specific), the member State measures are (1) sanitary or phytosanitary measures, which (2) affect international trade. The general purpose of the member State measures can be inferred from the text of the EC legislation that the member States invoked when they enacted their import or marketing bans. In particular, Article 16 of Directive 90/220 allows member States provisionally to “restrict or prohibit the use and/or sale of [an approved] product” if the “Member State has justifiable reasons to consider that [the] product . . . constitutes a risk to *human health or the environment*.” Similarly, Article 12 of Regulation 258/97 allows Members to “temporarily restrict or suspend the trade in and use of” an approved product if it has information that the approved product “endangers *human health or the environment*.” As each of the member States enacted their measures pursuant to Article 16 of Directive 90/220 or Article 12 of Regulation 258/97, all of the measures were enacted for the purpose of protecting human health or the environment. Second, and more importantly, the sanitary or phytosanitary purpose of the member State measures can be found in the measures themselves, as well as in the justifications offered by the member States at the time the measures were adopted.

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

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

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

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

D. Greek Import Ban Violates Article XI

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