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

(WT/DS291, 292, and 293)

First Submission of the United States

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TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	PROCEDURAL BACKGROUND	2
III.	STATEMENT OF FACTS	3
A.	Recombinant DNA Technology	3
1.	How the Technology Works	4
2.	Increased Agricultural Output	6
3.	More Nutritious Food	7
4.	Environmental Benefits	8
5.	Other Benefits	9
6.	Proven Safety Record of Recombinant DNA Technology	9
7.	Commercial Applications of Recombinant DNA Technology	11
B.	Overview of Approval Procedures for Placing Biotech Products on the Market in the EC	11
C.	Moratorium on Approvals of Biotech Products	15
1.	Under the Moratorium the EC has Failed to Approve Any Biotech Products Since October 1998	16
2.	Statements by European Commission and Member State Officials Confirm Existence of Moratorium	18
D.	Effect of the Moratorium on Pending Applications for Biotech Products	19
1.	Applications Pending Under Regulation 2001/18	20
2.	Applications Pending under Regulation 258/97	23
F.	Member States' Marketing or Import Bans	24
1.	Austria	24
2.	France	25
3.	Luxembourg	26
4.	Germany	26
5.	Italy	26
6.	Greece	27
G.	Impact on Developing Countries	27
IV.	Legal Discussion	28
A.	Measures at Issue and Order of Analysis of the Claims	28
1.	Measures at Issue	28
2.	Order of Analysis of the Claims	29
B.	The SPS Agreement	29
1.	General Moratorium Violates the SPS Agreement	29
a.	SPS Agreement Applies to the General Moratorium	30
(i)	General Moratorium is an SPS Measure	31
(ii)	General Moratorium Is a "Measure"	33
(iii)	General Moratorium Affects International Trade	34

b.	The General Moratorium Imposes “Undue Delay” in the EC’s Approval Procedures in Violation of Article 8 and Annex C . . .	35
c.	EC Has Violated Article 7 and Annex B by Failing to “Publish Promptly” the General Moratorium	36
d.	The General Moratorium is Inconsistent with the Procedural Requirements of Article 8 and Annex C(1)(B)	37
e.	Sanitary or Phytosanitary Measures Must Have a Basis in Science	38
f.	General Moratorium Is Not Based on a Risk Assessment as Required under Article 5.1	39
(i)	EC Has Not Put Forth a “Risk Assessment” as Defined by Article 5.1 and Annex A, Paragraph 4	39
(ii)	General Moratorium Is Not “Based On” a Risk Assessment	41
g.	General Moratorium Is Not Based on Scientific Principles and Is Maintained without Sufficient Scientific Evidence in Violation of Article 2.2	42
h.	EC Has Applied Arbitrary or Unjustifiable Distinctions in the Levels of Protection Against Risk that Have Resulted in Discrimination or a Disguised Restriction on International Trade in Violation of Article 5.5	43
(i)	EC Applies Different Levels of Protection for “Different Situations”	43
(ii)	“Arbitrary or Unjustifiable” Differences in Levels of Protection Exist in the EC	46
(iii)	Arbitrary or Unjustifiable Differences in Levels of Protection Have Resulted in “Discrimination or a Disguised Restriction on International Trade”	46
i.	General Moratorium Arbitrarily or Unjustifiably Discriminates between Members and Results in a Disguised Restriction on International Trade in Violation of Article 2.3	48
2.	Product-Specific Moratoria Violate the SPS Agreement	49
a.	SPS Agreement Applies to the Product-Specific Moratoria	50
(i)	Product-Specific Moratoria Are Sanitary or Phytosanitary Measures	50
(ii)	Product-Specific Moratoria Affect International Trade . .	50
b.	Product-Specific Moratoria Impose “Undue Delay” in the EC’s Approval Procedures in Violation of Article 8 and Annex C . . .	50
c.	EC Has Violated Article 7 and Annex B by Failing to “Publish Promptly” the Product-Specific Moratoria	51
d.	Product-Specific Moratoria Violate the Transparency Requirements in Article 8 and Annex C	52
e.	Product-Specific Moratoria Are Not Based on Risk Assessments as Required under Article 5.1	53

(i)	EC Has Not Put Forth “Risk Assessments” as Defined by Article 5.1 and Annex A, Paragraph 4 for All Pending Applications	53
(ii)	Product-Specific Moratoria Are Not “Based On” Risk Assessments	54
f.	Product-Specific Moratoria Are Not Based on Scientific Principles and Are Maintained without Sufficient Evidence in Violation of Article 2.2	55
g.	EC Has Applied Arbitrary or Unjustifiable Distinctions in the Levels of Protection Against Risk that Have Resulted in “Discrimination or a Disguised Restriction on International Trade” in Violation of Article 5.5	55
3.	EC Member State Marketing or Import Bans Violate the SPS Agreement	56
a.	SPS Agreement Applies to member State Marketing or Import Bans	56
(i)	Member State Bans Are Sanitary or Phytosanitary Measures	56
(ii)	Member State Bans Affect International Trade	60
b.	Member State Bans Are Not Based on a Risk Assessment as Required under Article 5.1	61
(i)	Member States Have Not Put Forth “Risk Assessment[s]” as Defined by Article 5.1 and Annex A, Paragraph 4	61
(ii)	Member State Bans Are Not “Based On” Risk Assessments as Required by Article 5.1	63
c.	Member State Bans Are Not Based on Scientific Principles and Are Maintained without Sufficient Scientific Evidence in Violation of Article 2.2	64
C.	Greek Import Ban Violates Article XI	64
V.	CONCLUSION	64

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 European Communities implemented those procedures, and approved more than ten biotech products. Consumers in the European Communities have been enjoying the benefits of these products, without any adverse health or environmental effects.

2. Starting in October 1998, however, the European Communities suspended its own approval procedures. In particular, the European Communities suspended consideration of applications for, or granting of, approval of biotech products under the 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 European Communities 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 European Communities. 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 European Communities allows its scientific and regulatory procedures to reach their conclusion, it will once again approve new biotech products, benefitting EC consumers and biotech producers around the world.

II. PROCEDURAL BACKGROUND

7. On May 13, 2003, the United States requested formal dispute settlement consultations with the EC. The consultation request explained:

“Since October 1998, the EC has applied a moratorium on the approval of biotech products. The EC has suspended consideration of applications for, or granting of, approval of biotech products under the EC approval system. A number of applications for placing biotech products on the market have been blocked in the approval process under EC legislation^[FN1] and have never been considered for final approval. The approvals moratorium has restricted imports of agricultural and food products from the United States.

“Moreover, the member States maintain a number of national marketing and import bans on biotech products even though those products have already been approved by the EC for import and marketing in the EC. The national marketing and import bans have restricted imports of agricultural and food products from the United States.

“The measures affecting biotech products in the EC include:

- (1) the suspension by the EC of consideration of applications for, or granting of, approval of biotech products;
- (2) the failure by the EC to consider for approval applications for the biotech products mentioned in Annexes IA and IB to this request; and
- (3) national marketing and import bans maintained by member States, as described in Annex II to this request.

“^[FN1] Directive 2001/18, O.J. L 106 17.4.2001, p. 1 (and its predecessor, Directive 90/220, O.J. L 117, 8.5.1990, p. 15, as amended by Directive 94/15, O.J. L 103, 22.4.1994, p. 20 and Directive 97/35, O.J. L 169, 27.6.1997, p. 72); and Regulation 258/97, O.J. L 043, 14.2.1997, p. 1.”¹

The consultation request then noted that these measures appeared to be inconsistent with the EC’s obligations under specified provisions of the *Agreement on the Application of Sanitary and Phytosanitary Measures* (“SPS Agreement”), the *Agreement on Agriculture* (“Agriculture Agreement”), the *Agreement on Technical Barriers to Trade* (“TBT Agreement”) and the *General Agreement on Tariffs and Trade 1994* (“GATT 1994”).

¹ WT/DS291/1.

8. The United States consulted with the EC on June 19, 2003. The consultations failed to resolve the dispute.

9. Consequently, on August 7, 2003, the United States requested the establishment of a panel. The Dispute Settlement Body (“DSB”) considered the U.S. panel request, along with similar requests from Canada and Argentina, at its meetings held on August 18 and August 29, 2003. This panel was established at the August 29, 2003 meeting of the DSB, with the following terms of reference:

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

III. STATEMENT OF FACTS

A. Recombinant DNA Technology

10. This dispute concerns the European Communities’ suspension of consideration of applications for, or granting of, approval of biotech products since 1998 (“moratorium”). The phrase “biotech products,” as used in this submission, refers to plant cultivars that have been developed through recombinant deoxyribonucleic acid (“recombinant DNA”) technology, the most advanced technique of genetic modification. In this section, the United States will provide background information, placing modern biotechnology² techniques in their historical and scientific context, as well as the benefits of the technology, its proven safety record, and commercial applications.

11. Modern biotechnology continues the trend in developing ever more precise and effective methods for improving the productivity and functionality of plants, animals and microorganisms. Over the centuries, plants have been genetically engineered through, among other methods,

² In this submission, the phrase “modern biotechnology” is used to refer to “recombinant DNA” technology.

selective breeding,³ grafting,⁴ crossbreeding,⁵ induced mutation,⁶ and tissue culture.⁷ Modern biotechnology, or recombinant DNA technology, is the latest technique in genetic modification to have been developed and applied to crop plants.⁸

1. How the Technology Works

12. As scientists obtained greater understanding of the principles of genetics, they began to identify the specific biochemical and molecular mechanisms that operated within living organisms to give them their particular traits. Scientists learned that within the nucleus of every cell of all organisms there are molecular structures, which they called “genes,” that are packaged in long chains called chromosomes on which all of the biochemical instructions that determine the organism’s characteristics are encoded. Although there are thousands of unique genes on the chromosomes of each organism (a simple plant has approximately 20,000 genes, complex plants

³ Genetic modification of plants began with the invention by early farmers of selective breeding techniques to obtain plants with improved traits and qualities. Selective breeding represents human’s first successful modification, for the benefit of all succeeding generations, of the process of natural selection in plants. See Trevor V. Suslow, et al., “Biotechnology Provides New Tools for Plant Breeding,” Agricultural Biotechnology in California Series, University of California, Davis, March 2001 Suslow, at 1-5 (Exhibit US-3).

⁴ Early agriculturalists also learned to use, in addition to selective breeding, the technique of grafting to improve genetically certain plants. Grafting was the first technique by which man inserted genes from one organism directly into another to achieve an improvement in plant performance. *Id.*

⁵ A number of technological advances in the genetic modification of crop plants have occurred since the end of the nineteenth century as the science of genetics developed based on the pioneering work of Gregor Mendel. In particular, the basic understanding of genetics that Mendel provided paved the way for the development of more powerful and more precise methods to improve plants. One such tool was the development of plant “hybridization,” or “combination breeding.” Plant hybridization involves crossing two plants of the same species in an effort to improve plant performance. This important method of genetic modification has permitted modern agriculturalists to create new cultivars that are more disease resistant, more uniform and higher yielding. Virtually all modern crop plants incorporate characteristics – e.g., disease resistance – that were acquired from wild species by virtue of such inter-species genetic transfers. *Id.*

⁶ In the late 1920s, researchers found that they could induce mutation by exposing plants or their embryos to radiation or chemical mutagens. These mutagens produce genetic changes that occasionally produce useful traits. However, researchers have no control over the number or kind of genetic changes made when they employ these techniques; the mutations are random and unpredictable. Its non-specific nature results in a low frequency of useful mutations. *Id.*

⁷ The last major type of genetic modification technique introduced prior to recombinant DNA technology was a tissue culture technique developed beginning in the 1940s. This technique involves culturing cells, embryos or parts of plants in growth media in the laboratory until they can be moved to the field. The technique can speed the development cycle for new crops and greatly expand the number of plant cultivars that can be screened for useful traits. *Id.*

⁸ The phrase “genetically modified organism” or the acronym “GMO” are often used in reference to products of modern biotechnology. As is evident from this discussion, such usage is misleading, since virtually all modern crops are the product of genetic modification. See Suslow, at 14. Therefore, as stated above, this submission uses the term “biotech products” when referring to products of modern biotechnology.

approximately 30,000), researchers learned that particular characteristics are determined by a discrete number – one or several – of those thousands of genes.

13. During the past century, scientists also discovered that the basic genetic material in all living organisms is chemically similar. All DNA (deoxyribonucleic acid, the molecule that genes are made of) is a combination of just four chemical compounds – adenine, thymine, cytosine and guanine. The sequence in which these compounds appear on a particular gene is a biological code – instructions that the cell machinery follows in order to manufacture different proteins. The particular set of proteins produced in an organism – whether a plant, animal or microorganism – direct the functions necessary for life and for the expression of specific traits. Because DNA is chemically similar in all living things, different organisms can read and interpret the information encoded on any gene.

14. Improved understanding of the biochemistry underlying the laws of genetics has allowed scientists to operate on a the molecular level and to develop new “transgenic” techniques – *i.e.*, techniques in which a discrete number of genes (usually one or several) are transferred to an organism. The major difference between the traditional forms of genetic modification described above and recombinant DNA technology is not in the basic strategy but the much improved efficiency and precision of the genetic transfer. In both cases, the goal is to improve a plant by introducing a particular trait or set of traits through the transfer of genes. Recombinant DNA technology permits scientists to accomplish this goal by transferring only those genes that are needed, without transferring unnecessary and potentially problematic genes.

15. In theory, any gene from any living organism can be transferred into another organism giving that organism the ability to do something that it could not previously have done – *e.g.*, resist a particular disease or produce a vitamin it had not previously been able to produce. Some of the early applications of this knowledge and of transgenic technology have been dramatic and profound. For example, before the enhancement of this technology, humans suffering from diabetes had to obtain insulin from the pancreases of pigs. Now, most insulin used in human therapy for diabetes can be produced using human genes responsible for the production of insulin.

16. The following sections will describe the benefits of modern biotechnology 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. As Nobel Laureate Norman Borlaug said, the requirement to double the current level of food production by 2025 (to meet world food demand) “cannot be accomplished unless farmers across the world have access to current high-yielding crop production methods as well as new biotechnological breakthroughs that can increase the yields, dependability, and nutritional quality of our basic food crops.”⁹

⁹ Norman E. Borlaug, “Ending World Hunger. The Promise of Biotechnology and the Threat of Antiscience Zealotry,” 124 *PLANT PHYSIOLOGY* 487, 490 (October 2000) (Exhibit US-4).

2. Increased Agricultural Output

17. Modern biotechnology can significantly increase agricultural output by protecting plants from factors that reduce yields, such as pests, diseases, spoilage and extreme weather conditions.¹⁰ Indeed, nearly 40 percent of global food production is lost to pests, diseases and spoilage. Losses are particularly great in the developing world. Biotechnology is the most cost-effective and environmentally sound method of addressing this problem.¹¹ 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.¹²

18. One recent study found that, in the United States in 2001, cultivation of eight types of biotech crops – insect-resistant corn (maize) and cotton, herbicide-tolerant soybeans, corn, cotton and canola (oilseed rape), and virus-resistant papaya and squash – increased production by 1.8 million metric tons (“MT”) and lowered production costs by \$1.2 billion. The same study estimated that thirty-two additional products under development could increase production in the United States by 4.5 million MT per year and reduce costs by \$400 million per year, for a total net value to farmers of \$1 billion per year.¹³

19. Other scientific reports have similarly found that modern biotechnology can play an important role in increasing food production throughout the world. For example, in its Statement on Biotechnology, the Food and Agriculture Organization of the United Nations (“FAO”) said,

¹⁰ See, e.g., Report of the National Academy of Medicine and National Academy of Pharmacology (l’Académie Nationale de Médecine et de l’Académie Nationale de Pharmacie), “How can genetic engineering contribute to the improvement of human health and food, and what are the obstacles to its applications in this area?” November 26, 2002, at 1 available in the original French at <http://www.academie-medicine.fr> (Exhibit US-5); see also Borlaug (Exhibit US-4).

¹¹ Martina McGloughlin, “Why Safe and Effective Food Biotechnology is in the Public Interest,” PUBLICATION November 2000 (Exhibit US-6).

¹² See National Academy of Sciences, *Transgenic Plants and World Agriculture 3* (July 2000) available at <http://www.nap.edu/openbook/N1000227/html/R1.html> (citing a study by UNICEF on the shortage of food) (Exhibit US-7). This report was jointly prepared on behalf of the Royal Society of London, the Brazilian Academy of Sciences, the Chinese Academy of Sciences, the Indian National Science Academy, the Mexican Academy of Sciences, the National Academy of Sciences of the United States, and the Third World Academy of Sciences; see also Pontifical Academy of Sciences, *Study Document on the Use of Genetically Modified Food Plants to Combat Hunger in the World 526* (2001) available at [http://www.vatican.va/roman_curia/pontifical_academies/acdscien/documents/sv%2099\(5of5\).pdf](http://www.vatican.va/roman_curia/pontifical_academies/acdscien/documents/sv%2099(5of5).pdf) (stating that the developments of biotechnology “clearly offer substantial benefits for the improvement of the human condition worldwide”) (Exhibit US-8).

¹³ Leonard P. Gianessi, et al., “Plant Biotechnology: Current and Potential Impact for Improving Pest Management in U.S. Agriculture” June 2002, at 1 available at <http://www.ncfap.org/40CaseStudies.htm> (Exhibit US-9).

“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.”¹⁴ 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.”¹⁵

3. More Nutritious Food

20. In addition to increasing agricultural output, biotechnology is helping to increase the nutritional value of foods. As Nobel Laureate Norman Borlaug wrote, “[t]he power of genetic engineering to improve the nutritional quality of our food crop species is [] immense.”¹⁶ The multinational science academies report also 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.”¹⁷ 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.”¹⁸

21. An excellent example of the nutritional benefits of modern biotechnology is the development of so-called “golden rice,” a transgenic rice that could help address two of the most critical nutritional needs in the developing world: deficiencies in vitamin A and iron.¹⁹

22. The health advantages of biotechnology are already apparent in the current generation of biotech products. Insect-damaged corn is commonly infected by fungi that produce highly

¹⁴ Food and Agriculture Organization of the United Nations, “FAO Statement on Biotechnology” (March 2000) available at <http://www.fao.org/biotech/stat.asp> (Exhibit US-10). Noted Kenyan scientist Dr. Florence Wambugu has asserted that plant biotechnology presents the greatest opportunity for increasing agricultural productivity in Africa because the use of transgenic cultivars of currently-used crops that were developed to address the specific problems faced by African farmers would not require changes in local farming practices. See Florence Wambugu, “Modifying Africa: How Biotechnology Can Benefit the Poor and the Hungry” (2001) available at www.modifyingafrica.com (Exhibit US-11).

¹⁵ *Report of Joint FAO/WHO Expert Consultation on Biotechnology and Food Safety*, at 18 (held in Rome, Italy on September 30 to October 4, 1996) (Exhibit US-10).

¹⁶ See Borlaug, at 487 (Exhibit US-4).

¹⁷ National Academy of Sciences, at 1 (Exhibit US-7). The nutritional improvement of biotech crops “have rarely been achieved previously by traditional methods of plant breed.” *Id.* at 5. See also Pontifical Academy of Sciences, at 518 (stating, “[g]enetically modified food plants can play an important role in improving nutrition and agriculture products, especially in the developing world”) (Exhibit US-8).

¹⁸ Pontifical Academy of Sciences, at 522 (Exhibit US-8).

¹⁹ See McGloughlin (Exhibit US-6).

carcinogenic mycotoxins. Insect-resistant biotech crops reduce mycotoxin contamination by as much as 92 percent.²⁰

4. Environmental Benefits

23. Modern biotechnology can also provide numerous environmental benefits, including, as stated by the Research Directorate-General of the European Commission, “cleaner” agriculture.”²¹ 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.²² In this regard, the multinational science academies report noted that “[t]ransgenic crops containing insect-resistance genes from *Bacillus thuringiensis* have made it possible to reduce significantly the amount of insecticide applied on cotton in the United States.”²³ Additionally, products that are genetically resistant to herbicides can increase the precision with which herbicides can be applied, thus reducing the amount of herbicide used.²⁴ A recent study found that cultivation of biotech crops in the United States reduced pesticide (insecticides and herbicides) use by 21,000 MT in 2001. The same study estimated that the adoption of thirty-two new products currently under development would result in a further reduction in pesticide use of 53,000 MT annually.

24. The use of biotech crops also permits farmers to employ conservation tillage techniques that reduce soil disturbance and erosion and increase carbon sequestration.²⁵ 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.²⁶ 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.²⁷ In summary, by reducing the use of pesticides, fertilizers, water, and soil tillage, modern biotechnology can significantly lessen the environmental effects of commercial farming.

²⁰ See McGloughlin (Exhibit US-6).

²¹ “Will clean agriculture be transgenic?” October 2, 2001 available at <<http://europa.eu.int/comm/research/news-centre/en/agr/01-09-agr03d.html>> (Exhibit US-12).

²² See, e.g., National Academy of Sciences, at 6 (stating that “[t]he benefits from transgenic plants under study include decreased dependency on chemical insecticides”) (Exhibit US-7); see also Borlaug, at 487 (Exhibit US-4).

²³ National Academy of Sciences, at 8 (citing a study showing that the use of “Bt-cotton” reduced the application of insecticides by one million kilograms) (Exhibit US-7).

²⁴ See Borlaug, at 487 (Exhibit US-4).

²⁵ National Academy of Science, at 6 (Exhibit US-7).

²⁶ See “Will clean agriculture be transgenic?” (Exhibit US-12).

²⁷ See, e.g., “Will clean agriculture be transgenic?” (Exhibit US-12).

5. Other Benefits

25. Transgenic techniques offer other important advantages as well. Perhaps the most important is the ability of scientists to have access to additional sources of germplasm²⁸ that have not been available to plant breeders using more traditional cross breeding techniques. Plant breeders had previously been limited to trying to achieve specific genetic variations using the germplasm available within each crop species and the few closely related wild relatives that were capable of cross breeding. With the development of transgenic technologies, scientists now have access to a broad range of genetic material from other plant species.

26. As a result, transgenic techniques can be used to overcome some other serious limitations inherent in traditional cross breeding. First, scientists can now respond much more quickly when farmers face crop production problems associated with particularly virulent diseases or pests. Some examples have included the use of marker-assisted plant breeding to develop commercial tomato cultivars resistant to the root knot nematode (a serious worldwide pest) and the development of a virus-resistant papaya plant that has prevented the extinction of the papaya-growing industry in Hawaii. Scientists are currently working on developing a transgenic cassava that would be resistant to the cassava mosaic virus that destroyed nearly half of Africa's cassava crop in 2000.²⁹

6. Proven Safety Record of Recombinant DNA Technology

27. 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,³⁰ seven national and international academies of science,³¹ and the Organization for Economic Co-operation and Development,³² as well as independent scientists in the United States,³³ Africa³⁴ and Europe.³⁵ In

²⁸ “Germplasm” is the living matter used by plant breeders and biotechnology researchers to develop and enhance desirable traits in crops. Modern germplasm includes genetic material in cultivars used by farmers, “breeder lines” developed by plant breeders for use in creating new cultivars, and now, with the advent of modern biotechnology, other plants and micro-organisms possessing desirable traits.

²⁹ “Monsanto to Share Technologies with Danforth Center to Support Global Cassava Research,” Donald Danforth Plant Science Center Press Release, April 16, 2002 (Exhibit US-13).

³⁰ See Report of Joint FAO/WHO Consultation, *Strategies for assessing the safety of foods produced by biotechnology* 4.4 (1991) (Exhibit US-14).

³¹ See National Academy of Sciences, at 15-16 (Exhibit US-7).

³² See Organisation for Economic Co-operation and Development, “Safety Evaluation of Foods Derived by Modern Biotechnology: Concepts and Principles,” January 1, 1993, at 10 *available at* <<http://www.oecd.org>> (stating that modern biotechnology “does not inherently lead to foods that are less safe than those developed by conventional techniques”) (Exhibit US-15).

³³ See, e.g., Committee on Genetically Modified Pest-Protected Plants, Board on Agriculture and Natural Resources, National Research Council, *Genetically Modified Pest-Protected Plants: Science and Regulation* 6 (2000) (Exhibit US-16); Society of Toxicology, “The Safety of Genetically Modified Foods Produced Through Biotechnology” (adopted September 25, 2002) (stating, “[t]he available scientific evidence indicates that the

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.”³⁶

28. 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.”³⁷ 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.”³⁸ Finally, a report by the Royal Society of the United Kingdom stated, “[g]iven the very long history of DNA consumption from a wide variety of sources, we conclude that such consumption poses no significant risk to human health, and that additional ingestion of [genetically modified] DNA has no effect.”³⁹

potential adverse health effects arising from biotechnology-derived foods are not different in nature from those created by conventional breeding practices”) (Exhibit US-17).

³⁴ Florence Wambugu, “Why Africa needs agricultural biotech,” *Nature*, July 1, 1999, at 15-16 (Exhibit US-18).

³⁵ See, e.g., “How can genetic engineering contribute to the improvement of human health and food, and what are the obstacles to its applications in this area?” at 1 (stating that “these improvements [genetic modification] in agriculture products do not present any food safety risks that cannot be completely controlled”) (Exhibit US-5); John Innes Centre, “JIC Position Statement on Genetic Modification,” August 17, 2001, available at http://www.jic.bbsrc.ac.uk/corporate/Policy_Statements/gm_statement.html (Exhibit US-19).

³⁶ “GMOs: are there any risks?” Press Release by Research Directorate-General, European Commission, October 8, 2001 available at <http://europa.eu.int/comm/research/press/2001/pr0901en.html> (Exhibit US-20).

³⁷ National Academy of Sciences, at 15 (Exhibit US-7).

³⁸ Académie des Sciences, Institut de France, *Les plantes génétiquement modifiées* (December 13, 2002) (Exhibit US-28) The report further states that “all criticisms against GMOs can be set aside based for the most part on strictly scientific criteria.” *Id.* See also Borlaug, at 489 (stating, “there has been no credible scientific evidence to suggest that the ingestion of transgenic products is injurious to human health or the environment”) (Exhibit US-4).

³⁹ The Royal Society, “Genetically modified plants for food use and human health—an update,” February 2002, at 4 available at <http://www.royalsoc.ac.uk> (Exhibit US-22); see also Society of Toxicology (stating that “[t]he available evidence indicates that the potential adverse health effects arising from biotechnology are not different in nature from those created by conventional breeding practices”) (Exhibit US-17); Pontifical Academy of Sciences, at 522 (stating, “there is nothing intrinsic to the genetic modification of plants that causes products derived from them to be unsafe”) (Exhibit US-8).

7. Commercial Applications of Recombinant DNA Technology

29. Recombinant DNA technology is now widely used to improve the functionality and yield of economically important plants around the world. Beginning in the early 1990s, commercial cultivars of food plants transformed through recombinant DNA technology were introduced to the market. The first such product, a tomato modified to delay ripening and extend shelf life, was introduced in 1994. In 1995, a cotton cultivar resistant to the major cotton pest, bollworm, was commercialized. In 1996, a transgenic soybean tolerant to the broad-spectrum herbicide glyphosate came to market, as did corn cultivars that produce a protein fatal to a major corn pest, the European corn borer. Other types of corn, canola, cotton and fruits and vegetables were introduced in the years that followed.

30. 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.⁴⁰ Since 1996, the global land area devoted to transgenic crops has grown thirty-five-fold.⁴¹ Transgenic crops are cultivated in sixteen countries, which together account for more than half the world's population.⁴² 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.⁴³

B. Overview of Approval Procedures for Placing Biotech Products on the Market in the EC

31. The European Communities' regime for approval of biotech products consists of legal provisions that govern "the deliberate release into the environment of genetically modified organisms" (Directive 2001/18/EC⁴⁴ and its predecessor, Directive 90/220/EEC⁴⁵)⁴⁶ and that

⁴⁰ See International Service for the Acquisition of Agri-biotech Applications, "2002 Global GM Crop Area Continues to Grow for the Sixth Consecutive Year at a Sustained Rate of More than 10%," January 16, 2003 at iii (Exhibit US-23).

⁴¹ *Id.* at iii.

⁴² *Id.* at vii.

⁴³ *Id.* at 16.

⁴⁴ Directive 2001/18/EC, O.J. 17.4.2001 L106/1, preamble ("Directive 2001/18") (Exhibit US-24).

⁴⁵ Directive 90/220/EEC, O.J. 8.5.1990 L117/15, preamble, as amended by Directive 94/15/EC, O.J. 22.4.1994 L103, and Directive 97/35/EC, O.J. 27.6.1997 L169, ("Directive 90/220") (Exhibit US-25).

⁴⁶ The approval procedures required under Directive 90/220 remained in effect through October 17, 2002. As of that date, manufacturers or importers seeking approval for the placing of biotech products on the market in the European Communities must comply with the provisions identified in Directive 2001/18, which essentially expand on the approval procedures provided under Directive 90/220. See Directive 2001/18, arts. 36(1) (stating that "Directive 90/220/EEC shall be repealed on 17 October 2002") and 34(1) (stating that "Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 17 October 2002"). Manufacturers or importers who have submitted applications to place on the market biotech products under

regulate “novel foods and novel food ingredients” (Regulation 258/97⁴⁷).⁴⁸ This regime aims to ensure that human health and the environment are protected from “adverse effects . . . which might arise”⁴⁹ when biotech products are placed on the market.⁵⁰

32. The EC regime operates as a system for pre-market approval of all biotech products – *i.e.*, absent an approval obtained pursuant to the legislative requirements, a biotech product covered within the EC regime may not be placed on the market in the European Communities. The legislation outlines, *inter alia*, the procedures with which a company must comply in order to obtain approval to place a biotech product on the market and the standards by which an application for approval is judged.

33. Although the above-mentioned legislation covers different categories of products, the procedures laid down in each piece of legislation are basically similar.⁵¹ In essence, there are seven stages to the approval process:

Notification of Application. The manufacturer or importer of the product submits a notification and accompanying dossier to the competent authority of the member State where the product is to be placed on the market for the first time.⁵² The legislation specifies that the notification and dossier must include various types of information about

Directive 90/220 but whose applications have not yet been approved are subject to the provisions of the successor directive. *See* Directive 2001/18, art. 35(1). Applicants with pending notifications need not start anew but may “complement” their applications in accordance with the additional requirements contained in Directive 2001/18. *See* Directive 2001/18, art. 35(2). For the purposes of this dispute, we list the approval procedures under both Directives 2001/18 and 90/220 as the moratorium has persisted during the period in which both Directives have been in force.

⁴⁷ Regulation (EC) No. 258/97, O.J. 14.2.1997 L043/1 (“Regulation 258/97”) (Exhibit US-26).

⁴⁸ For the purposes of this dispute, the term “biotech products” includes all “genetically modified organisms” as defined in Directive 2001/18, art. 2(2) and Directive 90/220, art. 2(2), as well as all “novel foods and food ingredients” defined under Regulation 258/97, art. 1(2)(a) and 1(2)(b).

⁴⁹ Directive 2001/18, art. 4(1) and Directive 90/220, art. 4(1).

⁵⁰ *See* Directive 2001/18, art. 1; *see also* Directive 90/220, art. 1(1). Directives 2001/18 and 90/220 specifically aim to protect human health and the environment from the deliberate release of biotech products that are capable of replication or of transferring genetic material. The legislation applies in two situations: (1) the placing on the market of a biotech product; and (2) the deliberate release of a biotech product for other purposes (*e.g.*, research and development). *See* Directive 2001/18, parts C and B; *see also* Directive 90/220, parts C and B. For the purposes of this dispute, we focus on the procedures for placing a biotech product on the market. Regulation 258/97 specifically aims to protect public health by regulating novel foods and food ingredients which are placed on the market. *See generally* Regulation 258/97, preamble, second recital. Novel foods and food ingredients subject to the regulation include foods and food ingredients containing, consisting of, or produced from genetically modified organisms. Regulation 258/97, preamble and art. 1(2)(a) and (b).

⁵¹ The novel foods regulation also includes a different, simplified approval procedure for products that are determined by the competent authority of the member State that receives the initial application to be “substantially equivalent to existing foods or food ingredients.” *See* Regulation 258/97, art. 5. This simplified procedure does not require action by the Council or Regulatory Committee, and does not appear to be affected by the EC moratorium.

⁵² *See* Directive 2001/18, art. 13(1); Directive 90/220, art. 11(1); and Regulation 258/97, art. 4(1).

the notifying party, the nature of the biotech product (*e.g.*, the method of genetic modification used, the traits or characteristics introduced or modified), the commercial names to be used,⁵³ the likely uses of the product, proposals for labeling or for restrictions on use,⁵⁴ and any data on potential impacts on health and the environment.⁵⁵

Member State Assessment. The competent authority in the member State where the biotech product is to be placed on the market is responsible for an assessment of the notification and dossier⁵⁶ to ensure that they comply with the technical requirements of the relevant legislation and determine whether the product should be placed on the market.⁵⁷ After completing this assessment, the member State sends a copy of its report to the European Commission (“Commission”).⁵⁸

Circulation of Assessment for Comment. The Commission circulates copies of the assessment to the other member States for their review and comment.⁵⁹ If the assessment was favorable and there is no objection made during this comment period, the competent authority of the member State from which approval was initially sought consents in writing to placing the product on the market.⁶⁰

Commission Decisions. If a member State objects to placing the product on the market, the Commission takes a decision in accordance with specific procedures laid down in the

⁵³ See, *e.g.*, Directive 2001/18, art. 13(2)(a) and Annex IIIA and IIIB; *see also* Directive 90/220, art. 11(1) and Annex IIA and IIB.

⁵⁴ See, *e.g.*, Directive 2001/18, art. 13(2)(c) and (f); *see also* Directive 90/220, art. 11(1).

⁵⁵ See, *e.g.*, 2001/18, art. 13(2)(b) and Annexes II and III; *see also* Directive 90/220, art. 11(1); Regulation 258/97, art. 6(1).

⁵⁶ The assessment may be conducted either by the member State or by a designated assessment authority. *See* Directive 2001/18, arts. 13(1) and 14(1) (competent authority); Directive 90/220, art. 12(1) (competent authority); Regulation 258/97, art. 6(2) (competent food assessment body).

⁵⁷ *See* Directive 2001/18, arts. 13(1) and 14(1); Directive 90/220, art. 12(1); *see also generally* Regulation 258/97, art. 6(2).

⁵⁸ *See* Directive 2001/18, art. 14(2) (copy sent to Commission if assessment favorable to placing product on the market); Directive 90/220, art. 12(2)(a) (same); Regulation 258/97, art. 6(4) (copy of assessment report sent to Commission whether favorable or not). The novel foods regulation also lays down a simplified approval procedure for products that are determined by the competent authority of the member State that receives the initial application to be “substantially equivalent to existing foods or food ingredients.” *See* Regulation 258/97, art. 5.

⁵⁹ *See* Directive 2001/18, art. 14(2); Directive 90/220, art. 13(1); Regulation 258/97, art. 6(4). Member States have the opportunity to ask for additional information, provide comments, or object to placing the product on the market. *See* Directive 2001/18, arts. 14 and 15 (comments, objections, and further information); Directive 90/220, art. 13 (objections and reasons for such objections); and Regulation 258/97, art. 6(4) (comments and objections).

⁶⁰ *See* Directive 2001/18, art. 15(3) (consents to placing product on the market if decides that the product may be placed on the market and in the absence of any objection); Directive 90/220, art. 13(2) (consents to placing product on the market in the absence of any objection); and Regulation 258/97, art. 4(2) (same).

approval legislation. First, the Commission requests an opinion of the relevant Scientific Committee.⁶¹ If the Committee renders a favorable opinion, the Commission proposes a draft measure to its Regulatory Committee,⁶² which delivers an opinion within a time frame prescribed by its chairman. If the Regulatory Committee's opinion is favorable, the Commission adopts the draft measure.⁶³

Council Actions. If the Regulatory Committee does not render an opinion, or if it renders an unfavorable opinion, the Commission refers a proposal to the Council,⁶⁴ which may take action by qualified majority. If the Council has not acted within three months from the date of the referral, the Commission adopts the proposed measure.⁶⁵

Placing the Product on the Market. If, after consultation with the Regulatory Committee (and where necessary with the Council) the Commission decides to place the product on the market, the Commission informs the applicant of the decision taken⁶⁶ or the competent authority of the member State in which the approval process was initiated gives consent in writing for placing the product on the market.⁶⁷

⁶¹ See Questions and Answers on the Regulation of GMOs in the EU, MEMO/02/160, March 4, 2003 at 3 (Exhibit US-107); see also Directive 2001/18, art. 28(1); see also generally Regulation 258/97, art 11. This step is not required under Regulation 258/97 or Directive 90/220, but has become routine.

⁶² This Regulatory Committee is a Committee of member State representatives. See Questions and Answers on the Regulation of GMOs in the EU, at 3-4 (Exhibit US-107); see also generally Directive 2001/18, art. 30(2) (referencing Article 5 of Decision 1999/468/EEC); Directive 90/220, art. 21; and Regulation 258/97, art. 13(3). The Regulatory Committee acts by qualified majority – *i.e.*, a favorable decision requires 62 votes, weighted as described in Article 205(2) of the Treaty Establishing the European Community. See Directive 2001/18, art. 30(2) (referencing Article 5 of Decision 1999/468/EEC (stating that the committee shall deliver its opinion on the draft by the majority laid down in Article 205(2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission)); see also Directive 90/220, art. 21 (stating that the committee shall deliver its opinion on the draft by the majority laid down in Article 148(2) of the Treaty (currently Article 205(2)) in the case of decisions which the Council is required to adopt on a proposal from the Commission); and Regulation 258/97, art. 13(3) (same).

⁶³ See Directive 2001/18, art. 30(2) (referencing Article 5 of Decision 1999/468/EEC); Directive 90/220, art. 21; and Regulation 258/97, art. 13(4)(a).

⁶⁴ See Directive 2001/18, art. 30(2) (referencing Article 5 of Decision 1999/468/EC); Directive 90/220, art. 21; and Regulation 258/97, art. 13(4)(b). The European Parliament may also be involved in the decision-making process under certain circumstances. See Directive 2001/18, art. 30(2) (referencing Article 5 of Decision 1999/468 (providing for input from the European Parliament under certain circumstances)). In some instances, the proposal may also be amended. See *id.* (referencing Article 5 of Decision 1999/468 (providing opportunity for Commission to submit amended proposal, resubmit proposal, or present legislative proposal if Council opposes initial measure put forth by the Commission)).

⁶⁵ See Directive 2001/18, art. 30(2) (referencing Article 5 of Decision 1999/468); Directive 90/220, art. 21; Regulation 258/97, art. 13(4)(b).

⁶⁶ See Regulation 258/97, art. 7(3).

⁶⁷ See Directive 2001/18, art. 18(2); Directive 90/220, art. 13(4).

Labeling. A product approved for placement on the market must also meet applicable labeling requirements.⁶⁸ As mentioned above, proposals for labeling a product are typically required in the initial notification and accompanying dossier. At a minimum, a label is required to identify the product as containing genetically modified organisms.⁶⁹

C. Moratorium on Approvals of Biotech Products

34. Since October 1998 – the last date of a biotech product approval -- the European Communities has failed to approve any new biotech products under its novel foods or deliberate release legislation. The United States submits that this failure to approve all pending applications is the result of a de facto moratorium under which the European Communities has suspended the consideration of applications⁷⁰ for, or granting of, approval of biotech products under its pre-market approval system.

35. 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.⁷¹

36. 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.”⁷² 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.”⁷³ An October 2001 internal Commission working paper states

⁶⁸ See Directive 2001/18, art. 13(2)(f) and Annex IV; Directive 90/220, art. 11(1) and Annex III; and Regulation 258/97, art. 8.

⁶⁹ See, e.g., Directive 2001/18, art. 13(2)(f) and Annex IV(8).

⁷⁰ In this submission, the term “notification” refers to applications submitted under Directive 2001/18 and its predecessor Directive 90/220. See Directive 2001/18, arts. 6, 13; Directive 90/220, arts. 5, 11. The term “request” refers to applications submitted under Regulation 258/97. See Regulation 258/97, art. 4. The term “applications” refers collectively to notifications and requests.

⁷¹ “Declaration by the Danish, Greek, French, Italian and Luxembourg delegations concerning the suspension of new GMO authorisations,” Council of the European Union, 2194th Council Meeting, Environment, Luxembourg, June 24/25, 1999 (Ex. US-76).

⁷² Advance Copy of Working Document of the Commission Services on Traceability and Labelling of GMOs and Products Derived from GMOs, ENV/620/2000, November 2000, at 1 (Exhibit US-93).

⁷³ Commission improves rules on labelling and tracing of GMOs in Europe to enable freedom of choice and ensure environmental safety, Commission Press Release IP/01/1095, Brussels, 25 July 2001, at 2 (Exhibit CDA-39).

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.”⁷⁴ 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.⁷⁵ A document issued by the General Secretariat of the Council of the European Union stated that the proposed rules on traceability and labelling of biotech products could “possibly lead to the lifting of the current moratorium.”⁷⁶ 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.

37. The existence of the moratorium is further evidenced by the EC’s failure to approve any biotech products for nearly five years and by numerous statements from EC officials.

1. Under the Moratorium the EC has Failed to Approve Any Biotech Products Since October 1998

38. The existence of a moratorium on approvals of biotech products is evidenced by the failure of the European Communities to approve a single biotech product since October 1998 under Directive 2001/18 (and its predecessor Directive 90/220), as well as under Article 4 of Regulation 258/97.⁷⁷

⁷⁴ EC Working Paper of DG Environment and DG Health and Consumer Protection: Resumption of the Authorization Procedure for GMOs, October 2001, at 1 [emphasis in original] (Exhibit 27). The European Parliament Committee on the Environment, Public Health, and Consumer Policy also acknowledged the existence of a moratorium on the authorization procedures. See, e.g., EC, European Parliament, Committee on the Environment, Public Health and Consumer Policy, Report on the proposal for a European Parliament and Council regulation concerning traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, FINAL A5-0229/2002, 12 June 2002 (Exhibit US-36).

⁷⁵ Question and Answers - July 2003, p. 12 (Exhibit US-107).

⁷⁶ Note from the General Secretariat - 3 July 2003 (Exhibit US-38).

⁷⁷ The European Communities has adopted this moratorium even though EC scientists consistently have found biotech products to meet EC safety requirements. See, e.g., “Resumption of the Authorisation Procedure for GMOs,” Working Paper of DG Environment and DG Health and Consumer Protection, October 2001, at 1-2 (Exhibit US-27); see also “Working Document of the Commission Services on Traceability and Labelling of GMOs and Products Derived from GMOs,” ENV/620/2000, November 2000, at 1 (stating that although no peer-reviewed scientific article reporting adverse effects on human health as a result of eating biotech food has appeared and biotech products have to undergo a scientific assessment before receiving Community authorization, hesitation to approve the placing on the market of new biotech products has brought the authorization process to a standstill) (Exhibit US-28).

39. 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 258/97.⁷⁸

40. 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.⁷⁹ 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.⁸⁰ All nine of these products received favorable initial assessments from the sponsoring member State⁸¹ and positive opinions from the Scientific Committee for Plants (“SCP”),⁸² 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.”⁸³ 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.⁸⁴

41. Under Regulation 258/97, the requests for five products have been delayed at the Commission level for as long as five years.⁸⁵ 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.⁸⁶ An additional four requests are pending with the individual member States, some of which were submitted as early as July 1998.⁸⁷

⁷⁸ See “Notifications under Directive 2001/18 (90/220)” (Exhibit US-30). Some of the applications pending approval under Regulation 258/97 were submitted for approval as early as June 1997. See “Requests Submitted under Regulation 258/97 – Novel Foods” (Exhibit US-31).

⁷⁹ See “Notifications under Directive 2001/18 (90/220)” (Exhibit US-30).

⁸⁰ The notification for oilseed rape (Falcon GS40/90) was submitted to the Commission on November 25, 1996. See Questions and Answers on the Regulation of GMOs in the EU, MEMO/02/160, March 4, 2003, at Annex 2 (“Questions and Answers on the Regulation of GMOs in the EU”) (Exhibit US-107).

⁸¹ The “sponsoring member State” is the member State to which the application was originally submitted and which issued a positive assessment under EC approval legislation.

⁸² See Questions and Answers on the Regulation of GMOs in the EU, at Annex 2 (Exhibit US-107).

⁸³ E.g., Opinion of the Scientific Committee on Plants on Genetically Modified High Amylopectin Potatoes Notified by Amylogene HB (Notification D/SE/96/3501) (SCP/GMO/165-Final) July 18, 2002, at 10 (Exhibit US-32); see also “Scientific Committee Opinions for Products with Pending Applications” (Exhibit US-100); “Resumption of the Authorisation Procedure for GMOs,” at 2 (Exhibit US-27).

⁸⁴ The notification for oilseed rape (GT73) was submitted to the Netherlands on July 7, 1998. See “Notifications under Directive 2001/18 (90/220)” (Exhibit US-30).

⁸⁵ See “Requests Submitted under Regulation 258/97 – Novel Foods” (Exhibit US-31).

⁸⁶ See “Scientific Committee Opinions for Product with Pending Applications” (Exhibit US-100); see also Questions and Answers on the Regulation of GMOs in the EU, at Annex 4 (Exhibit US-107).

⁸⁷ See “Requests under Regulation 258/97 – Novel Foods” (Exhibit US-31).

2. Statements by European Commission and Member State Officials Confirm
Existence of Moratorium

42. The statements of Commission and member State officials also 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.”⁸⁸ 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.”⁸⁹ She added that there was no other EU legislation in the same situation in which “we just simply decline to take a decision.”⁹⁰

43. 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.”⁹¹ The following year Commissioner Byrne predicted (mistakenly) that the combination of the revised legislation on deliberate release and the traceability and labeling regulation “will contribute towards the lifting of the de facto moratorium on the commercial release of GMOs and the standstill on the authorisations of GMOs and GM-products in Europe.”⁹² In October of the same year, Beate Gminder, spokeswoman for Commissioner Byrne, not only admitted to the existence of the moratorium but also stated that “[t]he moratorium has no legal basis.”⁹³ Commissioner Byrne again acknowledged the existence of the moratorium in February 2003 when he implored member States that “we must lift the moratorium.”⁹⁴

⁸⁸ “EU Moves to Break Gene Crop Deadlock,” Reuters, July 13, 2000 (Exhibit US-33).

⁸⁹ “EU Moratorium on GMOs Could Last Until Traceability, Labeling Regime in Place,” at A-8 (Exhibit US-2).

⁹⁰ *Id.*

⁹¹ “Biotechnology: Building Consumer Acceptance,” Speech by David Byrne, European Commissioner for Health and Consumer Protection, European Business Summit, June 10, 2000, at 2 (Exhibit US-1).

⁹² “The Right to Know about Genetically Modified Food,” Statement by David Byrne, European Commissioner for Health and Consumer Protection, July 25, 2001, at 3 (Exhibit US-34).

⁹³ “EU States Seek Stricter GM Labelling,” Reuters, October 17, 2001 (Exhibit US-35). The European Parliament Committee on the Environment, Public Health, and Consumer Policy also acknowledged the existence of a moratorium on the authorization procedures. *See, e.g.*, “Report on the proposal for a European Parliament and Council regulation concerning traceability and labeling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC,” Committee on the Environment, Public Health, and Consumer Policy, European Parliament, FINAL A5-0229/2002, June 12, 2002 (emphasis added) (Exhibit US-36).

⁹⁴ “Sine die postponement of inter-ministerial meeting planned on GMOs in Washington,” Agence Europe, February 6, 2003 (Exhibit US-37).

44. Other EC and member State officials have reaffirmed the continued existence of the moratorium as recently as July 2003. For example, 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*.”⁹⁵ Further, at a July 22, 2003, meeting of EC agricultural ministers, French Agriculture Minister Herve Gaymard reportedly said that further conditions must be met “in advance of lifting the moratorium.”⁹⁶ At the same meeting, Italian officials reportedly indicated that no decision had been made on “lifting the moratorium.”⁹⁷

45. 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. Prior to the imposition of the moratorium, twelve biotech products had been approved for use in the European Communities.⁹⁸ 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.”⁹⁹s.

D. Effect of the Moratorium on Pending Applications for Biotech Products

46. In this section, the United States will explain in detail the effect of the European Communities’ moratorium on individual biotech products. In particular, we will identify each of the products that have been affected by the moratorium, noting the stage of the approval process at which the European Communities suspended consideration or refused to grant approval.

⁹⁵ Council of the European Union, document # 10815/03, July 3, 2003 (emphasis in original) (Exhibit US-38).

⁹⁶ “EU Ag Ministers Approve GMO Traceability Plan Opposed by White House, U.S. Farmers,” BNA International Trade Reporter, July 23, 2003 (Exhibit US-39).

⁹⁷ *Id.*

⁹⁸ See “Biotech Products Approved Under Directive 90/220” (Exhibit US-99).

⁹⁹ “EU Moratorium on GMOs Could Last Until Traceability, Labeling Regime in Place,” BNA Daily Report for Executives, Regulation, Law & Economics, October 30, 2001, at A-8 (internal quotations omitted) (Exhibit US-2). Two of the products counted by Commissioner Wallström as approved have actually been blocked by France, which has refused to issue final consent. See Annex IA, “Notifications Under Directive 2001/18 (90/220)” (Exhibit US-30).

47. The European Communities and its member States have failed to consider for approval twenty-seven applications for biotech products under Directive 2001/18 (and its predecessor Directive 90/220) and Regulation 258/97.¹⁰⁰

1. Applications Pending Under Regulation 2001/18

48. The notifications for eighteen products were delayed at various stages of the approval process under Directive 90/220 and have been forced to re-start the process under Directive 2001/18. We discuss below each of the notifications pending under Directive 2001/18 (and, previously, under Directive 90/220). For clarity, we have grouped the notifications according to the stage in the approval process at which consideration of the notifications was suspended under Directive 90/220.

49. The European Communities suspended consideration of Bt cotton (line 531) and Roundup Ready cotton (line 1445) in February 1999 when the Commission refused to submit draft measures for either product to the European Council.¹⁰¹ The notifications for Bt cotton and Roundup Ready cotton were submitted to Spain on December 3, 1996, and June 30, 1997, respectively.¹⁰² The Spanish competent authority forwarded both notifications with favorable opinions to the European Commission, which received them on November 24, 1997.¹⁰³ The Scientific Committee on Plants (“SCP”) delivered favorable risk assessments for the two products on July 14, 1998, finding “no evidence to indicate” that either product “is likely to cause adverse effects on human health and on the environment.”¹⁰⁴ After the Commission submitted draft measures for the products to the Regulatory Committee, the Committee rejected the measures without a written opinion or justification on February 11, 1999.¹⁰⁵ According to the European Communities’ approval process, in the event of negative Regulatory Committee opinions, the Commission is required to submit the draft measure to the European Council for a decision.¹⁰⁶ The Commission refused to do so, and, as a result, further consideration of these notifications was indefinitely suspended as of February 11, 1999. Both products have been resubmitted under Directive 2001/18.

¹⁰⁰ See “Notifications under Directive 2001/18 (90/220)” (Exhibit US-30); “Requests under Regulation 258/97 – Novel Foods” (Exhibit US-31).

¹⁰¹ See “Notifications under Directive 2001/18 (90/220)” (Exhibit US-30).

¹⁰² *Id.*

¹⁰³ See Questions and Answers on the Regulation of GMOs in the EU, MEMO/02/160, March 4, 2003, at Annex 2 (Exhibit US-107).

¹⁰⁴ See Opinion of the Scientific Committee on Plants on the genetically modified cotton line, insect-tolerant notified by the Monsanto company (notification C/ES/96/02), July 14, 1998, at 7.1 (Exhibit US-40); Opinion of the Scientific Committee on Plants regarding the genetically modified cotton, tolerant to glyphosate herbicide notified by the Monsanto Company (notification C/ES/97/01), July 14, 1998, at 7 (Exhibit US-41).

¹⁰⁵ The Regulatory Committee opinions are not published.

¹⁰⁶ See Directive 2001/18, art. 30; Directive 90/220, art. 21.

50. The progress of the following seven notifications stalled when the Commission refused to submit draft measures to the Regulatory Committee as required by the approval process: oilseed rape tolerant to glufosinate ammonium (Falcon GS40/90), hybrid oilseed rape (MS8/RF3), Roundup Ready fodder beet (A5/15), a potato with modified starch composition, winter oilseed rape (Liberator), glufosinate tolerant and Bt resistant corn (Bt-11) and Roundup Ready corn (GA21).¹⁰⁷ The notifications for each of these products was forwarded by the sponsoring member State to the Commission with favorable opinions between November 1996 and May 1999.¹⁰⁸ Each of these products also received favorable risk assessments from the Scientific Committee on Plants, which found “*no evidence* to indicate” that any of the products “is likely to cause adverse effects on human health and on the environment.”¹⁰⁹ Following these favorable SCP assessments, consideration of these notifications was indefinitely suspended because the Commission refused to submit draft measures to the Regulatory Committee. Each of these products has been resubmitted under Directive 2001/18.

51. The following nine notifications were delayed at the first stage of the approval process under 90/220 because the member States declined to forward the applications to the Commission: Roundup Ready oilseed rape (GT73), Bt and Roundup Ready corn (MON 810 x GA21), Liberty Link soybeans (A2704-12 and A5547-127), Roundup Ready sugar beet, Liberty Link oilseed rape (T45 X Topas 19/2), BXN cotton, Bt corn Cry1F (1507) (separate notifications were submitted to France and the Netherlands), and Roundup Ready corn (NK603).¹¹⁰ Each of these notifications was submitted between May 1995 and December 2000.¹¹¹ Although the applicants provided answers to all of the questions raised by the sponsoring member States, the member States nonetheless delayed and ultimately suspended consideration or failed to approve these products under Directive 90/220. Each of these products has been resubmitted under Directive 2001/18.¹¹²

52. There are numerous additional notifications that were blocked under Directive 90/220 but have not been resubmitted under Directive 2001/18. For example, two product notifications, oilseed rape with glufosinate tolerance and kanamycin resistance (MS1/RF1) and hybrid oilseed rape (MS1/RF2), languished at the final stage of the process for more than five years because France, the sponsoring member State, withheld its final approval.¹¹³ Both notifications were

¹⁰⁷ See “Notifications Under Directive 2001/18 (90/220)” (Exhibit US-30).

¹⁰⁸ See Questions and Answers on the Regulation of GMOs in the EU, at Annex 2 (Exhibit US-107).

¹⁰⁹ E.g., Opinion of the Scientific Committee on Plants Regarding Submission for Placing on the Market of Glufosinate Tolerant Swede Rape Transformation Event GS40/90 Notified by the Agrevo Company [now Bayer] (notification D/DE/96/05) July 14, 1998, at 7.1 (Exhibit US-42). For a complete list of scientific committee opinions, see “Scientific Committee Opinions for Products with Pending Applications” (Exhibit US-100).

¹¹⁰ See “Notifications under Directive 2001/18 (90/220)” (Exhibit US-30).

¹¹¹ *Id.*

¹¹² Under 2001/18, NK603 corn and Roundup Ready oilseed rape (GT73) have received favorable initial assessments from the Spanish competent authority.

¹¹³ See Questions and Answers on the Regulation of GMOs in the EU, at Annex 1 (Exhibit US-107).

submitted to France in April 1995, which forwarded them with favorable opinions to the European Commission on July 27, 1995. The Commission reviewed the applications and found “no reason to believe that there will be any adverse effect on human health and the environment” from placing MS1/RF1 and MS1/RF2 on the market.¹¹⁴ Accordingly, the Commission approved both products on June 6, 1997,¹¹⁵ consistent with the favorable opinion of the Regulatory Committee.¹¹⁶ Despite the favorable decision of the Commission, France refused to complete the process by giving its final consent so that MS1/RF1 and MS1/RF2 could be placed on the market.¹¹⁷

53. In addition, the following four notifications were submitted under Directive 90/220 but later withdrawn: Bt corn (MON 809), the extended shelf-life tomato (TGT7-F), Liberty Link and Bt corn (T25 x MON 810), and high-oleic soybean (260-05).¹¹⁸ The notifications for Bt corn (MON 809) and the tomato (TGT7-F) were submitted to France and Spain in 1995 and 1996, respectively.¹¹⁹ Both notifications were forwarded to the Commission with favorable member State opinions, and they received favorable risk assessments from the Scientific Committee on Plants.¹²⁰ When the Regulatory Committee voted to reject the Commission’s draft measures for the two products in late 1998, the Commission refused to submit the measures to the European Council, and the applicants withdrew their applications. The notification for Liberty Link/Bt corn stack (T25 x MON810) was submitted to the Netherlands on June 26, 1998.¹²¹ The notification was forwarded to the Commission with a favorable member State opinion, and received a favorable risk assessment from the Scientific Committee on Plants on June 6, 2000.¹²²

¹¹⁴ Commission Decision 97/392/EC, O.J. 21.6.1997 L164, preamble, fifth recital (“Commission Decision 97/392”) (Exhibit US-43); Commission Decision 97/393/EC, O.J. 21.6.1997 L164, preamble, fifth recital (“Commission Decision 97/393”) (Exhibit US-44).

¹¹⁵ See Commission Decision 97/392 (Exhibit US-43); Commission Decision 97/393 (Exhibit US-44).

¹¹⁶ See Commission Decision 97/392, preamble, eighth recital (Exhibit US-43); Commission Decision 97/393, preamble, eighth recital (Exhibit US-44).

¹¹⁷ See Questions and Answers on the Regulation of GMOs in the EU, at Annex 1 (Exhibit US-107).

¹¹⁸ See “Notifications under Directive 2001/18 (90/220)” (Exhibit US-30).

¹¹⁹ *Id.*

¹²⁰ Opinion of the Scientific Committee on Plants regarding submission for placing on the market under directive 90/220/EEC of genetically modified processing tomato line TGT7F notified by Zeneca (notification C/ES/96/01), June 23, 1998 (Exhibit US-45); Opinion of the Scientific Committee on Plants regarding the submission for placing on the market of genetically modified, insect-resistant maize lines notified by the pioneer genetique S.A.R.L. Company (notification No C/F/95/12-01/B) May 19, 1998 (Exhibit US-46).

¹²¹ See “Notifications under Directive 2001/18 (90/220)” (Exhibit US-30).

¹²² Opinion of the Scientific Committee on Plants on the Submission for Placing on the Market of Genetically Modified Maize (*Zea Mays*) Line GA21 with Tolerance to Glyphosate Herbicide Notified by Monsanto (Notification C/ES/98/01), September 22, 2000 (Exhibit US-47); Opinion of the scientific committee on plants regarding conventionally derived crosses between approved genetically modified maize lines T25 and MON810 submitted by Pioneer (*sic*) Hi-Bred International INC. as represented by Pioneer Overseas Corporation (Notification C/NL/98/08) June 6, 2000 (Exhibit US-48).

Despite the favorable risk assessments, the Commission refused to submit a draft measure to the Regulatory Committee as required by EC law.¹²³ The notification was withdrawn on December 12, 2002.

2. Applications Pending under Regulation 258/97

54. Nine applications are currently pending under Regulation 258/97.¹²⁴ These include five products that have been delayed at the Commission stage of the process for more than five years in some cases. Roundup Ready corn (GA 21) and Bt-11 sweet corn were submitted to the Netherlands on July 24, 1998, and February 11, 1999, respectively.¹²⁵ Both requests received favorable initial assessments and were forwarded to the Commission.¹²⁶ The Scientific Committee on Food also delivered favorable risk assessments of both products, finding them to be as safe as grain derived from conventional lines.¹²⁷ The Commission, however, has refused to forward a draft measure to the Regulatory Committee as is required to complete the approval process, and thus the requests remain blocked.¹²⁸ In addition, two products, transgenic radicchio and transgenic green hearted chicory, were submitted to the Netherlands on April 8, 1998, and they also received favorable initial assessments.¹²⁹ As of May 2003, however, more than five years after the products were submitted, they remain “under assessment” by the Scientific Committee on Food.¹³⁰ The fifth product that is pending at the Commission, Roundup Ready corn (NK603), was submitted in June 2001 and received a positive assessment from the Dutch competent authorities.¹³¹

55. The member States have refused to forward an additional four applications to the Commission: , Liberty Link soybeans, MaisGard/Roundup Ready corn (MON810 x GA 21), Roundup Ready sugar beet, and Bt corn Cry1F (1507).¹³² Each of these products was submitted to the sponsoring member State between February 1999 and February 2001.¹³³

¹²³ See Directive 2001/18, art. 30; Directive 90/220, art. 21.

¹²⁴ See “Requests under Regulation 258/97 – Novel Foods” (Exhibit US-31).

¹²⁵ See Questions and Answers on the Regulation of GMOs in the EU, at Annex 3 (Exhibit US-107).

¹²⁶ See *id.*, at Annex 4 (Exhibit US-107).

¹²⁷ See Opinion of the Scientific Committee on Food on a Request to Place Genetically Modified Sweet Maize Line Bt-11 on the Market (SCF/CS/NF/DOS/14 ADD2 Final) (expressed on April 17, 2002) (Exhibit US-49); Opinion of the Scientific Committee on Food on the safety assessment of the genetically modified maize line GA21, with tolerance to the herbicide glyphosate (SCF/CS/NF/DOS/10 ADD1 Final 6 March 2002) (expressed on 27 February 2002) (Exhibit US-50).

¹²⁸ See Regulation 258/97, art. 13(3).

¹²⁹ See Questions and Answers on the Regulation of GMOs in the EU, at Annex 3 (Exhibit US-107).

¹³⁰ *Id.*

¹³¹ *Id.*

¹³² See “Requests under Regulation 258/97 – Novel Foods” (Exhibit US-31).

¹³³ *Id.*

56. In addition to the nine products with applications pending under Regulation 258/97, three products, the extended shelf life tomato (TGT7-F), Liberty Link and Bt corn (T25 x MON810), and high oleic soybean (260-05) were withdrawn because of the European Communities' excessive delay in carrying out the approval process.¹³⁴ The application for the tomato product was submitted to the United Kingdom, which forwarded the dossier, for the tomato to the European Commission. Although the product received a positive assessment from the Scientific Committee on Foods,¹³⁵ the product stalled in the approval process and was withdrawn. High oleic soybean and T25 x MON810 corn were submitted to the Netherlands on July 25, 1998, and April 20, 2000, respectively.

F. Member States' Marketing or Import Bans

57. Six EC member States – France, Germany, Austria, Italy, Luxembourg, and Greece – have invoked the so-called “safeguard” provisions in Directive 90/220¹³⁶ and Regulation 258/97¹³⁷ 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.

1. Austria

58. Austria issued three measures prohibiting the “placing on the market” of three corn biotech products: Bt-176, MON 810 and T25. The Austrian Decrees were issued on February 13,

¹³⁴ *Id.*

¹³⁵ Opinion of a request for consent to place on the market a tomato fruit genetically modified to down-regulate the production of polygalacturonase (PG) and solely intended for processing (SCF/CS/NF/TOM/6 REV 4 final), September 23, 1999 (Exhibit US-51).

¹³⁶ Article 16 of Directive 90/220 reads: “1. Where a Member State has justifiable reasons to consider that a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment, it may provisionally restrict or prohibit the use and/or sale of that product on its territory. It shall immediately inform the Commission and the other Member States of such action and give reasons for its decision. 2. A decision shall be taken on the matter within three months in accordance with the procedure laid down in Article 21.”

¹³⁷ Article 12 of Regulation 258/97 reads: “1. Where a Member State, as a result of new information or a reassessment of existing information, has detailed grounds for considering that the use of a food or a food ingredient complying with this Regulation endangers human health or the environment, that Member State may either temporarily restrict or suspend the trade in and use of the food or food ingredient in question in its territory. It shall immediately inform the other Member States and the Commission thereof, giving the grounds for its decision. 2. The Commission shall examine the grounds referred to in paragraph 1 as soon as possible within the Standing Committee for Foodstuffs; it shall take the appropriate measures in accordance with the procedure laid down in Article 13. The Member State which took the decision referred to in paragraph 1 may maintain it until the measures have entered into force.”

1997, June 10, 1999 and April 28, 2000, respectively.¹³⁸ The Scientific Committee on Plants¹³⁹ was asked, with respect to each of these actions, whether the information submitted by Austria constituted relevant scientific evidence which would cause the Committee to consider that the products at issue constituted a risk to human health and the environment. In all three cases, the Committee dismissed Austria's scientific grounds for introducing the safeguard measures.¹⁴⁰ Despite the requirements of Directive 90/220, the Commission did not submit to the Committee a draft measure, and no decisions were taken by the Committee regarding Austria's safeguard. Austria continues to maintain its import restrictions.

2. France

59. France issued two Orders on November 16, 1998, prohibiting the “placing on the market” of two rapeseed biotech products: MS1/RF1 and Topas 19/2.¹⁴¹ The Scientific Committee on Plants was asked, with respect to each action, whether the information submitted by France constituted relevant scientific evidence which would cause the Committee to consider that the products at issue constituted a risk to human health and the environment. In both cases the Committee dismissed France's scientific grounds for introducing the safeguard measures.¹⁴² Despite the requirements of the Directive, the Commission did not submit to the Committee a draft decision regarding the matter, and France continues to maintain its safeguard measures.

¹³⁸ See Federal Gazette for the Republic of Austria, 45th Ordinance, February 13, 1997 (Exhibit US-52); Federal Gazette for the Republic of Austria, 120th Ordinance, April 28, 2000, (Exhibit US-53); Federal Gazette for the Republic of Austria, 175th Ordinance, June 10, 1999 (Exhibit US-54).

¹³⁹ In the case of Bt-176, the Scientific Committees for Pesticides, Food and Animal Nutrition were consulted.

¹⁴⁰ See Opinion on the Invocation by Austria of Article 16 ('safeguard' clause) of Council Directive 90/220/EEC with respect to the placing on the market of the Monsanto genetically modified maize (MON810) expressing the Bt cryIIa(b) gene, notification C/F/95/12-02 (Opinion expressed by the Scientific Committee on Plants on September 24, 1999) (Exhibit US-55); Opinion on the invocation by Austria of Article 16 of Council Directive 90/220/EEC regarding a genetically modified maize line T25 notified by AGREVO FRANCE (now AVENTIS CROPS SCIENCE, REF. C/F/95/12-07) (Opinion adopted by the Scientific Committee on Plants on 30 November 30, 2000) (Exhibit US-56); Opinion Further Report Of The Scientific Committee For Pesticides On The Use Of Genetically Modified Maize Lines (Opinion Expressed on May 12, 1997) (Exhibit US-57); Opinion on the Additional Information from the Austrian Authorities Concerning the Marketing of Ciba Geigy Maize (expressed on 21 March 1997 (Exhibit US-58).

¹⁴¹ See Official Journal, No. 200, August 30, 2001, at 13903 (Exhibit US-59). The ban on the two oilseed rape products (Topas 19/2 and MS1/RF1) was first imposed on November 16, 1998. See Official Journal, No. 267, November 18, 1998, at 17379 (Exhibit US-60).

¹⁴² See Opinion adopted on May 18, 1999, on the Invocation by France of Article 16 ('safeguard' clause) of Council Directive 90/220/EEC with respect to a genetically modified oilseed rape notification C/UK/94/M1/1 (Plant Genetic Systems N.V.) - (SCP/GMO/150-final) (Exhibit US-61); Opinion adopted on May 18, 1999, on the Invocation by France of Article 16 ('safeguard' clause) of Council Directive 90/220/EEC with respect to a genetically modified oilseed rape notification C/UK/95/M5/1 (Agrevo) - (SCP/GMO/149-final) (Exhibit US-62).

3. Luxembourg

60. Luxembourg issued a Ministerial Order on February 7, 1997, prohibiting the “use and sale” of biotech corn Bt-176.¹⁴³ As set out above with respect to the prohibition of Bt-176 in Austria, the Scientific Committee on Food and the Scientific Committee for Pesticides were consulted on this product. These Committees, as mentioned, concluded that no scientific evidence was put forward which would cause the Committee to consider that the product at issue constituted a risk to human health and the environment.¹⁴⁴ Despite the requirements of Directive 90/220 the Commission did not submit to the Committee a draft of the measure to be taken. Therefore, Luxembourg continues to maintain its safeguard measure on Bt-176.

4. Germany

61. Germany issued a Ruling March 31, 2000, “suspending the approval” of a biotech product: Bt-176. Germany suspended the placing on the market of this product and its progeny (unless cultivation is intended for research and testing purposes in certain areas).¹⁴⁵ The Scientific Committee on Plants was asked, with respect to this product, whether the information submitted by Germany constituted relevant scientific evidence which would cause the Committee to consider that the product at issue constituted a risk to human health and the environment. The Committee dismissed Germany’s scientific grounds for introducing the safeguard measure.¹⁴⁶ Despite the requirements of the Directive, the Commission did not submit to the Committee a draft decision, and Germany continues to maintain its safeguard measure.

5. Italy

62. Italy issued a Decree (sometimes referred to as the D’Amato Decree, after the Italian President who signed the Decree into law) on August 4, 2000, suspending the “commercialization and use” of the following corn products: Bt-11, MON 810, MON 809 and

¹⁴³ Journal Officiel du Grand-Duché de Luxembourg, A – No. 10, February 28, 1997, pp. 618 (Exhibit US-63).

¹⁴⁴ See Opinion Further Report Of The Scientific Committee For Pesticides On The Use Of Genetically Modified Maize Lines (Opinion Expressed on May 12, 1997) (Exhibit US-574); Scientific Committee For Food: Opinion on the Potential for Adverse Health Effects from the Consumption of Genetically Modified Maize (*Zea Mays* L.) (Opinion expressed on December 13, 1996) (Exhibit US-64).

¹⁴⁵ Letter from Robert Koch Institute of the Federal Health Office, Center for Gene Technology, to Novartis Seeds AG, Basel, March 31, 2000 (ordering the suspension of approval to release the corn product Bt-176) (Exhibit US-65). The ruling applies except for testing purposes which relate to one or several of the following: effects on non-target or target organisms, the development of resistance, counter measures to resistance development, horizontal or vertical gene transfer, ecological assessments or the enhancement of agronomic and plant protection knowledge for practical application.

¹⁴⁶ See Opinion on the invocation by Germany of Article 16 of Council 90/220/EEC regarding the genetically modified BT-MAIZE LINE CG 00256-176 notified by CIBA-GEIGY (now NOVARTIS), notification C/F/94/11-03 (SCP/GMO/276Final - November 9, 2000) (Opinion adopted by written procedure following the SCP meeting of September 22, 2000) (Exhibit US-66).

T25.¹⁴⁷ The Scientific Committee on Food was asked “whether the information provided by the Italian authorities provided grounds, detailed or otherwise, for considering that the use of the novel foods in question endangers human health.”¹⁴⁸ The Committee dismissed Italy’s scientific grounds for introducing the safeguard measure.¹⁴⁹ Despite the requirements of Article 12(2) of Regulation 258/97, the Commission did not submit a draft decision to the Standing Committee on Foodstuffs on Italy’s safeguard measure, and the measure remains in place.

6. Greece

63. Greece issued a Decree September 8, 1998, prohibiting the importation of Agrevo oilseed rape (Topas 19/2) seed into Greece.¹⁵⁰ The Scientific Committee on Plants was asked to advise the Commission “whether the information submitted by Greece constitutes new relevant scientific evidence which was not taken into account by the Committee at the time its Opinion was delivered” and whether “this information [would] cause the Committee to consider that this product constitutes a risk to human health and the environment.”¹⁵¹ The Committee dismissed Greece’s scientific grounds for introducing the safeguard measure.¹⁵² Despite the requirements of Directive 90/220, the Commission did not submit a draft decision to the Committee on Greece’s safeguard measure, and the measure remains in place.

G. **Impact on Developing Countries**

64. The European Communities’ moratorium has blocked exports of developing countries that, like the United States, produce biotech crops. In this way, the EC moratorium has hindered these countries’ agricultural and economic development. But the moratorium has also contributed to the decisions by some developing country governments to restrict or even reject shipments of biotech commodities offered as emergency food assistance. In addition, the moratorium has prompted some developing countries to limit access to improved biotech seeds by resource-poor farmers. Finally, the EC’s moratorium and the reaction by these developing country governments has impeded biotech research activities that are needed to address the agronomic and nutritional issues of particular concern to developing countries.

¹⁴⁷ Official Gazette of the Italian Republic, Decree of the President of the Council of Ministers, General series—No. 184, August 8, 2000 (Exhibit US-67).

¹⁴⁸ Opinion of the Scientific Committee on Food concerning a submission from the Italian Authorities raising concerns for the safety of certain products approved under the notification procedure of Regulation (EC) 258/97 (Opinion expressed on September 7, 2000) (CS/NF/DOS/11 ADD 4 Rev 2 Final) at 2 (“SCF Opinion on the Submission from the Italian Authorities”) (Exhibit US-68).

¹⁴⁹ SCF Opinion on the Submission from the Italian Authorities, at 3 (Exhibit US-68).

¹⁵⁰ Official Journal issued by the Greek Government, September 25, 1998, at 1008 (Exhibit US-69).

¹⁵¹ Opinion of the Scientific Committee on Plants, adopted on May 18, 1999, on the Invocation by Greece of Article 16 (“safeguard” clause) of Council Directive 90/220/EEC with respect to a genetically modified oilseed rape notification C/UK/95//M5/1 (Agrévo) – (SCP/GMO/148-final) (Exhibit US-70).

¹⁵² *Id.*, at 2.

65. With respect to food aid, in the fall of 2002, with nearly 3 million of its people starving, the Zambian government rejected corn donated by the United States that was produced using biotechnology. According to Zambia’s Agriculture Minister Mundia Sikatana, the shipment was rejected “for fear of losing [Zambia’s] export market [to the European Communities] that is doing well.”¹⁵³ Other developing countries have imposed burdensome and unnecessary restrictions on biotech food aid shipments, thus reducing the value and benefit of such assistance. For example, Zimbabwe and Mozambique require that biotech corn be milled before delivery to ensure it cannot be planted.¹⁵⁴ This expensive and unnecessary step imposes logistical delays in the delivery of assistance, shortens the shelf life of the product, and increases risk of spoilage because the seed coat has been removed from the whole grain, exposing the meal to damage by moisture, microbes and insects. As with Zambia, Mozambique and Zimbabwe imposed these restrictions for fear of losing access to the EC market, which remains closed to many of the world’s biotech products because of the moratorium.

66. Second, the EC’s moratorium has also prompted most African governments to restrict unnecessarily the importation and cultivation of biotech seeds, which, as discussed above, could substantially boost agricultural productivity and reduce pest damage and pesticide use. These African countries have blocked the use of biotechnology by their own farmers, notwithstanding the fact that scientists from the region have insisted that the technology is crucial to boosting food production in Africa and breaking the cycle of malnutrition and starvation. These scientists have also indicated that the European Communities’ moratorium is hindering significantly their efforts to introduce the technology in the African continent.¹⁵⁵

IV. Legal Discussion

A. Measures at Issue and Order of Analysis of the Claims

1. Measures at Issue

67. The United States challenges the following measures, imposed by the European Communities and its member States on biotech products:

- (i) the EC approval system as it is subject to a suspension by the European Communities and its member States of the

¹⁵³ Ochieng Rapuro, “Cynicism Still Hangs Over Biotechnology Foods,” *The East Africa African Standard*, November 12, 2002 (Exhibit US-90).

¹⁵⁴ See Sebastian Mallaby, “Phony Fears Fan a Famine,” *Washington Post*, September 2, 2002, at A-23 (Exhibit US-91).

¹⁵⁵ See, e.g., Joe Kirwin, “Crop Scientists From Africa Fault European On GMO Moratorium, Favor U.S. WTO Action,” *BNA International Trade Daily*, January 30, 2003, at A-13 (Exhibit US-92).

consideration of applications for, or granting of, approval of any and all biotech products since 1998 (the “general moratorium”);

(ii) the EC approval system as it is a failure by the European Communities and its member States to consider for approval each of twenty-seven existing applications of biotech products under the European Communities’ approval system, listed in Exhibit US-83 (the “product-specific moratoria”); and

(iii) the measures enacted by six EC member States that prohibit the importation or marketing of certain biotech products that the European Communities approved under Directive 90/220 and Regulation 258/97.

68. To be clear, with respect to the general and product-specific moratoria, the United States is not asking the Panel to make findings on the WTO-consistency of the EC novel foods and deliberate release approval legislation per se. Instead, the United States is asking the Panel to make findings on the EC’s general and product-specific moratoria: the suspension of consideration of applications for, or granting of, approval of any and all biotech products under the EC approval system.

2. Order of Analysis of the Claims

69. The analysis below (1) addresses the inconsistency of the general moratorium with the SPS Agreement, (2) addresses the inconsistency of the product-specific moratoria with the SPS Agreement, and (3) the inconsistency of the various national marketing or import bans with the SPS Agreement and the GATT 1994.¹⁵⁶

B. The SPS Agreement

1. General Moratorium Violates the SPS Agreement

70. The general moratorium violates several provisions in the SPS Agreement. We discuss first the applicability of the SPS Agreement to the general moratorium and then discuss the specific provisions of the SPS Agreement that the general moratorium violates.

¹⁵⁶ The United States submits that the measures subject to this dispute are within the scope of the SPS Agreement. Should the EC in its First Submission argue otherwise, the United States reserves the right to explain, in the alternative, the manner in which the EC measures are inconsistent with the Agreement on Technical Barriers to Trade.

a. SPS Agreement Applies to the General Moratorium

71. Article 1.1 of the SPS Agreement states that the Agreement applies to “all sanitary [or] phytosanitary measures which may, directly or indirectly, affect international trade.” Thus, the SPS Agreement applies when the following two criteria are met: (1) the measure at issue is a sanitary or phytosanitary measure; and (2) the measure affects international trade. As discussed below, the general moratorium meets both requirements.

72. Annex A, paragraph 1 of the SPS Agreement defines a sanitary or phytosanitary measure, in pertinent part, as

“Any measure applied:

(a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;

(b) to protect human or animal life or health within the territory of the Member from the risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages, or feedstuffs;

(c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or

(d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, . . . testing, inspection, certification and approval procedures; . . . ”¹⁵⁷

73. Thus, whether a measure constitutes a “sanitary or phytosanitary measure” depends on whether the measure is applied to address one or more of the enumerated risks covered by the Agreement.¹⁵⁸

¹⁵⁷ SPS Agreement, Annex A, paragraph 1.

¹⁵⁸ See, e.g., Panel Report, *EC Measures Concerning Meat and Meat Products (Hormones) (Complaint by the United States)*, WT/DS26/R/USA, adopted 13 February 1998 (“*EC – Hormones*”), at para. 8.22 (considering the purpose of the measures at issue, e.g., to protect human life or health from risks from “contaminants,” in determining whether the measures were SPS measures); Panel Report, *Australia – Measures Affecting Importation of Salmon*, WT/DS18/R, adopted 6 November 1998 (“*Australia – Salmon*”), at paras. 8.34-8.37 (considering the objective of the measures at issue, e.g., to protect life and health of animals from risks from certain disease, when determining whether measures were SPS measures).

(i) General Moratorium is an SPS Measure

74. The general moratorium is one component of the EC’s biotech approval regime; in particular, the the general moratorium is a moratorium on approvals under the novel foods and deliberate release legislation.

75. The European Communities’ biotech approval regime is unquestionably an SPS measure. Directive 2001/18 states that one of the objectives of the Directive is “to protect human health and the environment” when, among other things, “placing on the market genetically modified organisms as or in products within the Community.”¹⁵⁹ 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.”¹⁶⁰ 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.”¹⁶¹

76. 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.”¹⁶² 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*.”¹⁶³ Thus, based on the objectives in the approval legislation, statements made by EC and member State officials and a relevant EC document, it is clear that the “purpose” of the general moratorium is to protect human, animal, or plant life or health from certain risks.

¹⁵⁹ Directive 2001/18, art. 1; *see also id.*, art. 23(1) (stating that a member State may restrict or prohibit the use and/or sale of a previously approved biotech product where new or additional information provides detailed grounds for considering that the product constitutes a risk to “human health or the environment”).

¹⁶⁰ Directive 90/220, art. 1.

¹⁶¹ Regulation 258/97, art. 3(1).

¹⁶² *See, e.g.*, “EU Moratorium on GMOs Could Last Until Traceability, Labeling Regime in Place” (stating that French Environment Minister Yves Cochet said that supporters of the moratorium are motivated by a desire “to ensure the *safety of citizens* and the *protection of the environment*”) (emphasis added) (Exhibit US-2); Pascal Lamy, European Commissioner for Trade, “Steeling The EU-US Relationship For The Challenges Ahead,” The Woodrow Wilson International Center for Scholars, January 25, 2002 (stating that the “current moratorium is not plucked out of thin air by the member States . . . it reflects the fact that *food safety* is a highly sensitive and political issue for European citizens”) (emphasis added) (Exhibit US-89).

¹⁶³ *Advance Copy of Working Document of the Commission Services on Traceability and Labelling of GMOs and Products Derived from GMOs*, ENV/620/2000, at 1 (emphasis added) (Exhibit US-93).

77. The specific *risks* that underlie the EC approval regime, including general moratorium, can also be inferred from the detailed requirements in the approval legislation regulating biotech products, including Directive 2001/18, unambiguous statements by EC and member State officials, and, additionally, comments by the Scientific Committee on Plants and the Scientific Committee on Food. The specific risks articulated include toxic or allergenic effects on humans and/or animals,¹⁶⁴ development of antibiotic resistant bacteria,¹⁶⁵ and cross-contamination.¹⁶⁶

78. 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.”

79. 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.*,

¹⁶⁴ See, *e.g.*, Directive 2001/18, Annex III.A.II.C(2)(i)(i) (requiring notification to include information concerning “toxic or allergenic effects of the GMOs” for “considerations for human health and animal health, as well as plant health”), Annex III.A.II.A(11)(d) (requiring notification to include information regarding, among others, toxigenicity, allergenicity, and host range of pathogenicity including to non-target organisms), and Annex III.B(B)(7) (requiring in notification information on “toxic effects [of genetically modified organisms] on humans, animals and other organisms”).

¹⁶⁵ See, *e.g.*, Opinion of the Scientific Committee on Food on the Safety Assessment of the Genetically Modified Maize Line GA21, with Tolerance to the Herbicide Glyphosate, at 6 (evaluating risk that GA21 plants may, among other things, transfer antibiotic resistance to bacteria with which they come into contact) (Exhibit US-47); see also Directive 2001/18, Annex III.A.II.A(11)(e) (requiring notification to include information regarding “antibiotic resistance”).

¹⁶⁶ See, *e.g.*, Joe Kirwin, “EU Must Move Beyond ‘Emotion’ in GMO Policy, Commissioner Says,” BNA International Trade Daily, February 14, 2002 (implying that one of the concerns underlying the moratorium is that “organic farmers [be able to] produce food without fear of cross contamination from farms using GMO seeds”) (Exhibit US-87); see also Directive 2001/18, Annex III.A.IV.B(3)(a) (requiring notification to include information regarding “post-release transfer of genetic material from [genetically modified organisms] into organisms in affected ecosystems”).

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,¹⁶⁷ defined in the *New Shorter Oxford English Dictionary* as “plant[s] that grow[] . . . where [they are] not wanted.”¹⁶⁸ Thus, a measure based on this risk falls within the definition of Annex A, paragraph 1(d).

80. In short, the EC approval regime, including that part of the regime modified by the general moratorium, is plainly a “sanitary or phytosanitary” measure as defined in Annex A.

(ii) General Moratorium Is a “Measure”

81. 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. As the Appellate Body explained in *Japan Sunset*:

In the practice under the GATT, most of the measures subject, as such, to dispute settlement, were *legislation*. We nevertheless observed in *Guatemala – Cement I* that, in fact, a broad range of measures could be submitted, as such, to dispute settlement.¹⁶⁹

In short, the EC measure blocks biotech approvals just as effectively as would a written amendment to the EC legislation.

82. 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.”¹⁷⁰ Under the ordinary meaning of the term “procedure,” a suspension by

¹⁶⁷ Annex A, footnote 4, states, in pertinent part, that “[f]or the purpose of the[] definitions [in Annex A], . . . ‘pests’ include weeds.”

¹⁶⁸ *The New Shorter Oxford English Dictionary* at 3648.

¹⁶⁹ Appellate Body Report, *United States – Sunset Review of Anti-Dumping Duties on Corrosion-Resistant Carbon Steel Flat Products from Japan*, WT/DS244/AB/R, adopted 9 January 2004 (“*Japan Sunset*”), para. 85 (emphasis in original).

¹⁷⁰ *The New Shorter Oxford English Dictionary* at 2363.

the EC of the consideration of applications for, or granting of, approval of biotech products is an unwritten procedure covered under the SPS Agreement.

83. 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. As the Appellate Body explained in *Japan Sunset*:

“In principle, any act or omission attributable to a WTO Member can be a measure of that Member for purposes of dispute settlement proceedings. The acts or omissions that are so attributable are, in the usual case, the acts or omissions of the organs of the state, including those of the executive branch.

In addition, in GATT and WTO dispute settlement practice, panels have frequently examined measures consisting not only of particular acts applied only to a specific situation, but also of acts setting forth rules or norms that are intended to have general and prospective application.”¹⁷¹

84. 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.

(iii) General Moratorium Affects International Trade

85. The general moratorium also “affects international trade” and, thus, meets the second requirement under Article 1.1. Biotech products may not be placed on the market in the EC without first being approved under the required legislation.¹⁷² The EC’s general moratorium has since October 1998 precluded the placing on the market of any and all biotech products in the European Communities, including imported biotech products. The general moratorium, thus, is effectively an import ban that affects any and all foreign biotech products and, thus, the “international trade” in those products. As stated by the Panel on *EC — Hormones*, “[i]t cannot be contested that an import ban affects international trade.”¹⁷³

¹⁷¹ *Japan Sunset*, para. 81-82.

¹⁷² See, e.g., Directive 2001/18; Directive 90/220; Regulation 258/97.

¹⁷³ Panel Report, *EC — Hormones*, at para. 8.23.

86. Thus, because the general moratorium is (1) a measure as defined under Annex A of the Agreement (it satisfies the “purpose” and the “form” element); and (2) a measure that affects international trade, as required by Article 1.1, the SPS Agreement applies. Below, the United States will discuss generally the importance in the SPS Agreement of requiring that an SPS measure have a basis in science. Then, the United States will set out that the SPS measure at issue, the general moratorium, violates various provisions of the SPS Agreement.

b. The General Moratorium Imposes “Undue Delay” in the EC’s Approval Procedures in Violation of Article 8 and Annex C

87. The European Communities has failed to comply with the requirements of Article 8 of the SPS Agreement. Article 8 obligates Members to:

*observe the provisions of Annex C in the operation of control, inspection and approval procedures, including national systems for approving the use of additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs, and otherwise ensure that their procedures are not inconsistent with the provisions of this Agreement.*¹⁷⁴

Annex C, paragraph 1(a) requires, in pertinent part, 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”¹⁷⁵

88. The European Communities’ approval process for biotech products is subject to the requirements of Article 8 and Annex C. First, the European Communities’ process is an “approval procedure” under the Agreement. Annex C defines “approval procedures,” as including, *inter alia*, “procedures for sampling, testing and certification.”¹⁷⁶ Because biotech products must be approved before they can be placed on the market,¹⁷⁷ the procedures are analogous to the types of procedures specifically articulated in Annex C, *e.g.*, procedures for certification. As such, the procedures fall within the definition of “approval procedures” provided for under the Annex. Second, these procedures are imposed to “ensure” that the requirements of the European Communities’ approval legislation for biotech products are met. Third, the European Communities’ approval legislation is a “sanitary or phytosanitary measure” as defined in Annex A, paragraph 1 of the SPS Agreement because it is applied for the purpose of protecting human, animal, or plant life or health or preventing or limiting other damage within the territory of the Member from certain enumerated risks in Annex A. Thus, the European Communities’ approval procedures for biotech products must comply with Article 8 and Annex

¹⁷⁴ Emphasis added.

¹⁷⁵ SPS Agreement, Annex C, para. 1(a).

¹⁷⁶ SPS Agreement, Annex C, n.7.

¹⁷⁷ See Directive 2001/18, arts. 6(8) and 19(2); Directive 90/220, arts. 6(4) and 11(5); Regulation 258/97, art. 4(2).

C, including the requirement that such procedures be “undertaken and completed without undue delay.”

89. 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.¹⁷⁸ The ordinary meaning of “undue” is “inappropriate, unsuitable, improper; unrightful; unjustifiable. Going beyond what is warranted or natural; excessive; disproportionate.”¹⁷⁹ 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”.

90. 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.¹⁸⁰ 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.¹⁸¹

91. 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.

c. EC Has Violated Article 7 and Annex B by Failing to “Publish Promptly”
the General Moratorium

92. The European Communities has also violated Article 7 and Annex B, paragraph 1 of the SPS Agreement. Article 7 specifically states that

¹⁷⁸ Vienna Convention, art. 31(1). See, e.g., Appellate Body Report, *United States – Standards for Reformulated and Conventional Gasoline*, WT/DS2/AB/R, adopted 20 May 1996, at p. 17.

¹⁷⁹ The New Shorter Oxford English Dictionary, vol. 2 (Oxford: Clarendon Press, 1993)

¹⁸⁰ See, e.g., “EU Moratorium on GMOs Could Last Until Traceability, Labeling Regime in Place,” BNA Daily Report for Executives, Regulation, Law & Economics, October 30, 2001, at A-8 (quoting EC Environment Commissioner Margot Wallström as stating “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.”)

¹⁸¹ See *Supra* para 35-36.

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.*¹⁸²

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.¹⁸³

“Sanitary and phytosanitary regulations” are defined in a footnote to this paragraph as “measures such as laws, decrees or ordinances which are applicable generally.”¹⁸⁴

93. In order for a measure to be subject to the publication requirement in Annex B, the following three conditions must be met: “(1) the measure ‘[has] been adopted’; (2) the measure is a [sanitary or] ‘phytosanitary regulation’, namely a [sanitary or] phytosanitary measure such as a law, decree or ordinance, which is (3) ‘applicable generally.’”¹⁸⁵ The general moratorium satisfies all three conditions and, therefore, is subject to the publication requirements.

94. First, the *general moratorium* is an adopted measure. As discussed above, the general moratorium has existed since October 1998. Second, the measure is generally applicable: from 1998, the general moratorium has applied to all new biotech products subject to the EC’s approval procedures. Third, as discussed above, the general moratorium is a “sanitary or phytosanitary regulation[]” as defined in the footnote to paragraph 1.

95. 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.

d. The General Moratorium is Inconsistent with the Procedural Requirements of Article 8 and Annex C(1)(B)

96. The general moratorium, as explained above, is an unpublished, non-transparent de facto measure under which the EC does not allow its approval procedures to proceed to conclusion. As such, the general moratorium is inconsistent with each of the related procedural obligations in Annex C(1)(b) of the SPS Agreement.

¹⁸² Emphasis added.

¹⁸³ Emphasis added.

¹⁸⁴ SPS Agreement, Annex B, para. 1, n.5.

¹⁸⁵ Panel Report, *Japan – Measures Affecting Agricultural Products*, WT/DS76/R, adopted 19 March 1999 (“*Japan – Agricultural Products*”), at para. 8.109 (as affirmed in Appellate Body Report, *Japan – Measures Affecting Agricultural Products*, WT/DS76/AB/R, adopted 19 March 1999, at para. 108).

97. Each of those obligations, and their inconsistency with the general moratorium, are set forth below:

(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.

(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.

(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.

(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.

(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.

In sum, the EC’s adoption of a defacto, unpublished general moratorium is fundamentally inconsistent with all of the procedural obligations in Annex C(1)(b) governing approval procedures.

e. Sanitary or Phytosanitary Measures Must Have a Basis in Science

98. One of the most important concepts in the SPS Agreement is that any sanitary or phytosanitary measure must have a basis in science. Article 2.2 of the Agreement explicitly obligates Members to “ensure that any sanitary or phytosanitary measure is . . . based on scientific principles and is not maintained without sufficient scientific evidence.” This requirement was intended to allow Members to protect against real concerns regarding food

safety and human and animal health while reducing potential abusive uses of SPS measures for protectionist rather than legitimate purposes.

99. Particularly critical in furthering the requirement that all sanitary and phytosanitary measures be based on science is the risk assessment requirement. The Agreement requires that a Member first determine, through either a scientific risk assessment or adherence to an international standard, that a risk to human, animal or plant life or health exists. If such a risk exists, then the Member is free to choose a measure that establishes the level of protection that it considers appropriate to address that risk.¹⁸⁶ As we discuss below, the European Communities has not met either criterion with respect to the general moratorium.

f. General Moratorium Is Not Based on a Risk Assessment as Required under Article 5.1

100. To the extent the the European Communities’ suspension of consideration of applications for, or granting of, approval of biotech products (the general moratorium) is preventing the sale or marketing of biotech products, the general moratorium violates Article 5.1 of the SPS Agreement. Article 5.1 requires that Members’:

sanitary or phytosanitary measures [be] based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.

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”¹⁸⁷ The European Communities has not met either requirement. Each is analyzed separately below.

(i) EC Has Not Put Forth a “Risk Assessment” as Defined by Article 5.1 and Annex A, Paragraph 4

101. The European Communities has not put forward either of the two types of risk assessments defined in Annex A, paragraph 4. Under the first definition, a risk assessment is an “evaluation of the likelihood of entry, establishment or spread of a pest or disease within the

¹⁸⁶ SPS Agreement, arts. 3 and 5.

¹⁸⁷ Panel Report, *Australia – Measures Affecting Importation of Salmon: Recourse to Article 21.5 by Canada*, WT/DS18/RW, adopted 20 March 2000, at para. 7.39; *see also* Appellate Body Report, *Australia – Measures Affecting Importation of Salmon*, WT/DS18/AB/R, adopted 6 November 1998, at paras. 120 and 136 and Appellate Body Report, *EC Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998, at paras. 182, 188-209.

territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences.”¹⁸⁸ This type of risk assessment has been applied to measures defined under Annex A, paragraph 1(a) of the SPS Agreement.¹⁸⁹ It also applies to measures defined under paragraph 1(d), which refers to the entry, establishment or spread of pests.¹⁹⁰

102. The second type of risk assessment addresses risks from substances in food, beverages, or feedstuffs, and has been applied to measures defined under Annex A, paragraph 1(b).¹⁹¹ Under this second definition, a risk assessment is an “evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.”¹⁹²

103. WTO dispute settlement reports have applied two different tests in determining whether a risk assessment falls within the specific definitions identified in Annex A. For a risk assessment to fall within the first definition, it must: “(1) *identify* the diseases [or pests] whose entry, establishment or spread a Member wants to prevent within its territory, as well as the potential biological and economic consequences associated with the entry, establishment or spread of these diseases [or pests]; (2) *evaluate the likelihood* of entry, establishment or spread of these diseases [or pests], as well as the associated potential biological and economic consequences; and (3) evaluate the likelihood of entry, establishment or spread of these diseases [or pests] *according to the SPS measures which might be applied*.”¹⁹³ This evaluation may be expressed in either “quantitative” or “qualitative” terms.¹⁹⁴

104. For a risk assessment to fall within the second definition, it must (1) “identify the adverse effects on human health (if any)” arising from the presence of the additives, contaminants, toxins, or disease-causing organisms in food, beverages, or feedstuffs at issue; and (2) “if any such adverse effects exist, evaluate the potential . . . occurrence of such effects.”¹⁹⁵ In contrast with

¹⁸⁸ SPS Agreement, Annex A, para. 4.

¹⁸⁹ See Appellate Body Report, *Australia – Salmon* at para. 120 and n.67 (stating that for SPS measures that fall within the definition of Annex A, paragraph 1(a), the type of risk assessment required is the type defined in the first part of Annex A, paragraph 4).

¹⁹⁰ SPS Agreement, Annex A, para. 1(d).

¹⁹¹ See Appellate Body Report, *EC – Hormones* at para. 182 (applying risk assessment defined in the second part of Annex A, paragraph 4 to measures applied to protect human life or health from risks arising from contaminants in foods (according to paragraph 1(b) of Annex A)).

¹⁹² SPS Agreement, Annex A, para. 4.

¹⁹³ Appellate Body Report, *Australia – Salmon* at para. 121 (emphasis in original).

¹⁹⁴ Appellate Body Report, *Australia – Salmon* at para. 124.

¹⁹⁵ Appellate Body Report, *EC – Hormones* at para. 183.

the first type of risk assessment, the second type only requires that the risk assessment evaluate the potential for adverse effects on human or animal health.¹⁹⁶

105. The European Communities has failed to put forth either of the two types of risk assessments defined in Annex A, paragraph 4.¹⁹⁷ As discussed above, 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). Thus, either the first or second type of risk assessment would have been an appropriate means to evaluate the purported risks of biotech products. The European Communities, however, did not utilize either type of risk assessment when it imposed the general moratorium. Indeed, there is no evidence in the public record that the general moratorium is based on any scientific assessment whatsoever, much less one of the two types of risk assessments defined by Annex A, paragraph 4.

106. By imposing an SPS measure that is not based on a risk assessment, the European Communities has acted inconsistently with Article 5.1 of the SPS Agreement.

(ii) General Moratorium Is Not “Based On” a Risk Assessment

107. 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 “the results of the risk assessment [] *sufficiently warrant*—that is to say, *reasonably support*—the SPS measure at stake . . . [and] there [must] be a *rational relationship between the measure and the risk assessment*.”¹⁹⁸ Thus, the Article 5.1 obligation that a measure be “based on” a risk assessment requires that there be a “rational relationship” between the measure at issue and the risk assessment.

108. The European Communities cannot argue that the general moratorium bears a relationship, rational or otherwise, to a risk assessment when there is no evidence that any risk assessment ever existed. For this reason as well, the general moratorium is inconsistent with Article 5.1 of the SPS Agreement.

¹⁹⁶ Appellate Body Report, *EC – Hormones* at para. 184; *see also* Appellate Body Report, *Australia – Salmon* at para. 123 and n.69.

¹⁹⁷ As we discuss below (product-specific moratoria), the EC *has* put forth risk assessments for certain individual products (though the EC’s measures are not “based on” these assessments). The EC has not, however, put forth a risk assessment with respect to the moratorium on any and all biotech products, *i.e.*, the general moratorium.

¹⁹⁸ Appellate Body Report, *EC – Hormones* at para. 193 (emphasis added); *see also* Article 21.5 Panel Report, *Australia – Salmon* at para. 7.72-7.73 (applying standard articulated by Appellate Body in *EC – Hormones*).

_____g. General Moratorium Is Not Based on Scientific Principles and Is
Maintained without Sufficient Scientific Evidence in Violation of Article
2.2

109. The general moratorium is also inconsistent with the European Communities' obligation under Article 2.2 of the SPS Agreement. Article 2.2 specifically requires that Members

ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5.

The “sufficient scientific evidence” obligation requires that there be a “rational or objective relationship between the SPS measure and the scientific evidence.”¹⁹⁹

110. The basic obligations provided in Article 2.2 have been viewed as being specifically applied in Article 5.1.²⁰⁰ 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.”²⁰¹ As the general moratorium is not based on a risk assessment as required under Article 5.1 and Annex A, paragraph 4, it has, by implication, also violated the provisions of Article 2.2 of that Agreement.

111. In the absence of *any* risk assessment, and, thus, in the absence of sufficient scientific evidence, supporting the EC's suspension of consideration of applications for, or granting of, approvals of biotech products, the European Communities is clearly in violation of its obligations stated in Articles 2.2 and 5.1 of the SPS Agreement.

¹⁹⁹ Appellate Body Report, *Japan – Measures Affecting Agricultural Products*, WT/DS76/AB/R, adopted 19 March 1999, at para. 84.

²⁰⁰ *See, e.g.*, Appellate Body Report, *EC – Hormones* at para. 180.

²⁰¹ Article 21.5 Panel Report, *Australia – Salmon* at para. 7.85; *see also* Panel Report, *Australia – Salmon* at para. 8.52 (finding that “in the event a sanitary measure is not based on a risk assessment as required in Articles 5.1 and 5.2, this measure can be presumed, more generally, not to be based on scientific principles or to be maintained without sufficient scientific evidence. We conclude, therefore, that if we find a violation of the more specific Article 5.1 or 5.2 such findings can be presumed to imply a violation of the more general provisions of Article 2.2.”) (upheld by Appellate Body, in *Australia – Salmon* at paras. 137-38); *see also generally* Appellate Body Report, *EC – Hormones* at para. 180 (stating that “Articles 2.2 and 5.1 should constantly be read together. Article 2.2 informs Article 5.1: the elements that define the basic obligation set out in Article 2.2 impart meaning to Article 5.1.”).

h. EC Has Applied Arbitrary or Unjustifiable Distinctions in the Levels of Protection Against Risk that Have Resulted in Discrimination or a Disguised Restriction on International Trade in Violation of Article 5.5

112. The general moratorium 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. Specifically, Article 5.5 requires, in pertinent part, that

[w]ith the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade.

113. The general moratorium meets each of the three required elements necessary for establishing a violation of Article 5.5. First, the European Communities has adopted different appropriate levels of sanitary or phytosanitary protection in “different situations.” Second, those levels of protection exhibit differences that are “arbitrary or unjustifiable.” Third, the measure embodying those differences, the general moratorium, results in “discrimination or a disguised restriction on international trade.”²⁰² Each element is analyzed separately below.

(i) EC Applies Different Levels of Protection for “Different Situations”

114. As indicated above, the European Communities has set forth distinct levels of sanitary protection in “different situations,” which is the first element required to establish a violation of Article 5.5. This element has two aspects. First, different levels of protection must exist; and second, the levels of protection must apply to “different situations.” With regard to the latter requirement, the Appellate Body has stated that situations exhibiting different levels of protection can only be compared if they are “comparable,” that is, if they present “some common element or elements” that are sufficient to render them “comparable.”²⁰³ “Comparable” situations can include the “same substance,” the “same adverse health effect,”²⁰⁴ or “either a risk of entry, establishment or spread of the same or a similar disease, or a risk of the same or similar ‘associated potential biological and economic consequences.’”²⁰⁵

²⁰² See Appellate Body Report, *Australia – Salmon* at para. 140; see also Appellate Body Report, *EC – Hormones* at para. 214.

²⁰³ Appellate Body Report, *EC – Hormones* at para. 217.

²⁰⁴ Panel Report, *EC – Hormones* at para. 8.176 (upheld by Appellate Body at paras. 216-17).

²⁰⁵ Appellate Body Report, *Australia – Salmon* at para. 146 (emphasis in original).

115. The European Communities has identified different levels of sanitary and phytosanitary protection in two different yet “comparable” situations:²⁰⁶

- (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.

116. According to the Appellate Body, each Member has the “prerogative”²⁰⁷ and an “implicit obligation”²⁰⁸ to determine its level of protection. This level of protection is distinct from the SPS measure itself; the former is the sanitary or phytosanitary “objective,” and the latter is the “instrument” designed to fulfill that objective.²⁰⁹ If a Member fails to determine its appropriate level of protection or if that level of protection is insufficiently clear,²¹⁰ then “the appropriate level of protection may be established by [the panel] on the basis of the level of protection reflected in the SPS measure actually applied.”²¹¹

117. The European Communities identifies a different appropriate level of protection for biotech products than it identifies for products produced with biotech processing aids.²¹²

²⁰⁶ See generally Appellate Body Report, *EC – Hormones* at para. 217 (stating that a “comparison of several levels of sanitary protection deemed appropriate by a Member is necessary if a panel’s inquiry under Article 5.5 is to proceed at all”).

²⁰⁷ Appellate Body Report, *Australia – Salmon* at para. 199; see also Appellate Body Report, *EC – Hormones* at para. 172.

²⁰⁸ Appellate Body Report, *Australia – Salmon* at para. 206.

²⁰⁹ Appellate Body Report, *Australia – Salmon* at para. 200.

²¹⁰ The Appellate Body in *Australia – Salmon* found that Australia had determined explicitly its level of protection by stating in its First Submission and Rebuttals that its level of protection is “a high or ‘very conservative’ level of sanitary protection aimed at reducing risk to ‘very low levels’, ‘while not based on a zero-risk approach’.” Appellate Body Report, *Australia – Salmon* at para. 197 (citing the Panel Report). According to the Panel Report in *Australia – Salmon*, Australia submitted that “it has consistently adopted a high, conservative approach with respect to the appropriate level of [SPS] protection” because it is an “island state free of many pests and diseases” and is economically dependent on its “agriculture production and exports.” Panel Report, *Australia – Salmon* at para. 8.106. The Panel in *Japan – Agricultural Products* found that Japan had determined its level of protection by establishing a mortality rate for codling moths that any quarantine treatment had to achieve. Panel Report, *Japan – Agricultural Products* at paras. 8.81-82.

²¹¹ Appellate Body Report, *Australia – Salmon* at para. 197 (referring to an import prohibition).

²¹² In this submission, the phrase “biotech products” refers to those products covered by EC Directives 90/220 and 2001/18 and Regulation 258/97. See Directive 2001/18/EC, arts. 2(2) (defining “genetically modified organisms” as “organism[s] . . . in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination”) and 2(7) (defining “product” as a “preparation consisting of, or containing, a GMO or a combination of GMOs”); Directive 90/220/EEC, art. 2(2) and 2(4) (same); Regulation 258/97, art. 1(2)(a) and (b) (applying to foods and food ingredients containing, consisting of, or produced from (but not containing) genetically modified organisms).

Products produced with biotech processing aids, which are not covered by the legislation cited above, are a class of foods that have been produced using materials such as yeasts, bacteria or enzymes that have been modified using recombinant DNA technology to improve their efficiency or functionality in food production. For example, cheese is produced using “chymosin” which is an enzyme that serves as a catalyst in the clotting of milk products to assist in the processing of cheese.²¹³ Previously, the source of “chymosin” was the stomach of animals. Through biotechnology, that enzyme is now produced in the laboratory.²¹⁴ Similarly, some starch derivatives are produced with genetically modified enzymes, and beer may be produced with genetically modified yeast.²¹⁵ Such production methods that apply biotech organisms are widely used throughout the world, including in the European Union.²¹⁶

118. The European Communities does not regulate products produced with biotech processing aids as such. While products produced using “food additives” are covered under EC Directive 89/107, which concerns food additives authorized for use in foodstuffs,²¹⁷ the legislation specifically does not apply to products produced using “processing aids,” defined, in relevant part, as “any substance . . . used in the processing of raw materials, foods or their ingredients, to fulfil a certain technological purpose during treatment or processing.”²¹⁸ Nor are products produced with biotech processing aids subject to any other EC-wide legislation.²¹⁹

119. In contrast to new biotech processing aids, which are not regulated, the EC has imposed a general moratorium on other new biotech products, resulting in an appropriate level of protection of zero risk.

²¹³ European Food Information Council, *Chymosin and Cheese Making* (visited January 6, 2003) <<http://www.eufic.org/gb/tech/tech02e.htm>> (Exhibit US-102).

²¹⁴ See Suslow, at 12 (Exhibit US-3).

²¹⁵ University of Reading, *Genetically Modified Yeasts* (last modified September 8, 2000) <<http://www.ncbe.reading.ac.uk/NCBE/GMFOOD/yeasts.html>> (Exhibit US-103).

²¹⁶ European Food Information Council (stating that “[g]enetically modified chymosin has been approved in most European countries”) (Exhibit US-102).

²¹⁷ Directive 89/107, O.J. 11.2.1989 L040/27, art. 1(2) (Exhibit US-104) (defining “food additive” as “any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods”) (“Directive 89/107”).

²¹⁸ Directive 89/107, art. 1(3)(a), n.1 (defining “processing aid” as “any substance not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or their ingredients, to fulfil a certain technological purpose during treatment or processing and which may result in the unintentional but technically unavoidable presence of residues of the substance or its derivatives in the final product, provided that these residues do not present any health risk and do not have any technological effect on the finished product”).

²¹⁹ National Biosafety Association, Workshop – Industrial Enzymes for Food Production, Regulations of Enzymes Used in Food in the European Union (EU) Assessment <<http://www.anbio.org.br/english/worksh42htm>> (Exhibit US-105).

120. These distinct levels of protection are applied in comparable situations. As the definition of “processing aids” under Directive 89/107 indicates, it may be “technically unavoidable” for residues of processing aids, including processing aids that have been modified using recombinant DNA, to be present in the final product.²²⁰ In other words, 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. Thus, under the Appellate Body’s definition, the two products are “comparable.” Because the European Communities applies different levels of protection to biotech products as compared to products produced using biotechnology in “comparable” situations, the first element of an Article 5.5 violation is met.

(ii) “Arbitrary or Unjustifiable” Differences in Levels of Protection Exist in the EC

121. The difference between the level of protection for biotech products and the level of protection for products produced with biotech processing aids is likewise “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.

(iii) Arbitrary or Unjustifiable Differences in Levels of Protection Have Resulted in “Discrimination or a Disguised Restriction on International Trade”

122. The European Communities has applied the general moratorium in a manner that results in “discrimination or a disguised restriction on international trade,” which is the third element in an Article 5.5 violation.²²¹ In determining whether a measure has been applied in a manner that results in “discrimination or a disguised restriction on international trade,” the Appellate Body has considered certain factors (*e.g.*, “warning signals” and “additional factors”). These warning signals and additional factors have been considered on a case-by-case basis and have been considered cumulatively—suggesting that the mere presence of one warning signal or additional factor would be insufficient to support a finding that the third element has been satisfied.²²²

123. The following “warning signals” have been considered by the Appellate Body in determining whether an implementing measure discriminates or provides a disguised restriction on international trade: (1) the arbitrary or unjustifiable character of the differences in levels of protection; (2) the degree of difference in levels of protection; and (3) whether the measure at

²²⁰ Directive 89/107, art. 1(3), n.6.

²²¹ Appellate Body Report, *EC – Hormones* at para. 215.

²²² *See, e.g.*, Appellate Body Report, *EC – Hormones* at para. 215.

issue is based on a risk assessment under Articles 5.1 and 2.2 of the SPS Agreement.²²³ The “additional factors” considered by the Appellate Body in *Australia – Salmon* were specific to the facts of that dispute and included: (1) the difference in conclusions between draft reports on how the importation of certain products are to be treated, based on no real evidence suggesting such a change would be warranted; and (2) the level of protection on the internal movement of products compared with the level of protection on imported products (*e.g.*, lack of internal control compared with prohibition of imports).²²⁴

124. The European Communities’ application of the general moratorium exhibits all three “warning signals” and an “additional factor” which indicate that the measure discriminates or provides a disguised restriction on international trade.

125. 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.

126. Finally, the “additional factor” is a disproportionate effect of the general moratorium on producers outside the European Communities as compared to producers within the European Communities. In 2001, the European Communities accounted for less than four-tenths of one percent of the worldwide land area devoted to growing biotech products.²²⁵ In contrast, the United States, Argentina, Canada, and China accounted for ninety-nine percent of the total land area devoted to biotech products in 2001.²²⁶ For producers in these countries, the moratorium on approvals of biotech products has had a substantial negative effect. The disproportionate impact of the general moratorium on internal versus imported products is an “additional factor” as it is a strong indication that the measure is discriminatory or a disguised restriction on international trade.

127. In sum, the European Communities has identified different levels of protection in comparable situations; those differences are arbitrary and unjustifiable; and the measure embodying those differences, the general moratorium, has resulted in discrimination or a disguised restriction on international trade. Therefore, the EC has acted inconsistently with its obligations under Article 5.5 of the SPS Agreement.

²²³ Appellate Body Report, *Australia – Salmon* at paras. 159-77.

²²⁴ See, *e.g.*, Appellate Body Report, *Australia – Salmon* at paras. 159-77.

²²⁵ Jan-Peter Nap, at 2 (Exhibit US-101).

²²⁶ See Jan-Peter Nap, at 2 (Exhibit US-101).

i. General Moratorium Arbitrarily or Unjustifiably Discriminates between Members and Results in a Disguised Restriction on International Trade in Violation of Article 2.3

128. The European Communities also has violated Article 2.3 of the SPS Agreement, which states, in pertinent part, that

Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members.

The second sentence additionally obligates Members not to apply such measures “in a manner which would constitute a disguised restriction on international trade.”²²⁷

129. The general obligations set out in Article 2.3 are applied more specifically under Article 5.5.²²⁸ 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 2.3.²²⁹ As the European Communities has, by maintaining the general moratorium, acted inconsistently with its obligations under Article 5.5, it has, by implication, also acted inconsistently with its obligations under Article 2.3.

²²⁷ SPS Agreement, art. 2.3.

²²⁸ See, e.g., Panel Report, *Australia – Salmon* at para. 8.48 (stating that the provisions in Article 5.5 provide “more specific and detailed rights and obligations than the ‘Basic Rights and Obligations’ set out in rather broad wording in the provisions [in Article 2.3]”); see also generally Appellate Body Report, *EC – Hormones* at para. 212 (characterizing Article 5.5 as “marking out and elaborating a particular route leading to the same destination set out in Article 2.3”).

²²⁹ See Appellate Body Report, *Australia – Salmon* at paras. 248-52 (stating that as the third and decisive element of Article 5.5 requires a finding that the SPS measure results in discrimination or a disguised restriction on international trade, “a finding of violation of Article 5.5 will necessarily imply a violation of Article 2.3, first sentence, or Article 2.3, second sentence”).

2. Product-Specific Moratoria Violate the SPS Agreement

130. As explained above, the United States submits that the EC has adopted a general moratorium affecting all biotech approvals, and that this moratorium is a “measure” under the SPS Agreement. 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.

131. In particular, the United States is also challenging the European Communities’ failure to consider for approval each of the twenty-seven applications for biotech products that are pending in the approval process (product-specific moratoria). These applications include eighteen notifications that were submitted under Directive 90/220 and now are pending under Directive 2001/18²³⁰ as well as ten requests pending under Regulation 258/97.²³¹

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

133. In this section, the United States will first show that the product-specific moratoria are “sanitary [or] phytosanitary measures” that “affect international trade” and, thus, are covered by the SPS Agreement.²³² We will then demonstrate that the European Communities has violated various provisions of the SPS Agreement by: (1) imposing “undue delay” on the undertaking and completion of approval procedures;²³³ (2) failing to publish promptly the product-specific moratoria;²³⁴ and (3) applying its approval procedures in a non-transparent manner;²³⁵ (4) failing to base the product-specific moratoria on risk assessments and scientific principles;²³⁶ and (5) applying arbitrary or unjustifiable distinctions in its levels of protection which have resulted in discrimination or a disguised restriction on trade.²³⁷

²³⁰ See “Notifications under Directive 2001/18 (90/220)” (Exhibit US-30).

²³¹ See “Requests Submitted under Regulation 258/97 – Novel Foods” (Exhibit US-31).

²³² SPS Agreement, art. 1.1.

²³³ SPS Agreement, art. 8 and Annex C.

²³⁴ SPS Agreement, art. 7.

²³⁵ SPS Agreement, art. 8, Annex C.

²³⁶ SPS Agreement, arts. 5.1 and 2.2.

²³⁷ SPS Agreement, arts. 5.5 and 2.3.

a. SPS Agreement Applies to the Product-Specific Moratoria

134. Article 1.1 of the SPS Agreement applies to “all sanitary [or] phytosanitary measures which may, directly or indirectly, affect international trade.” Like the general moratorium, the product-specific moratoria (1) are sanitary or phytosanitary measures, which (2) affect international trade.

(i) Product-Specific Moratoria Are Sanitary or Phytosanitary Measures

135. The product-specific moratoria are SPS measures as defined by Annex A, paragraph 1 of the SPS Agreement. As with the general moratorium, the EC approval regime, including that part of the regime modified by the product-specific moratoria, are plainly “sanitary or phytosanitary” measures as defined in Annex A. Similarly, the product-specific moratoria, although unwritten, are “measures” under the SPS Agreement, just as the general moratorium affecting all products is a “measure” under the Agreement.²³⁸

(ii) Product-Specific Moratoria Affect International Trade

136. Like the general moratorium, the product-specific moratoria “affect international trade” and, thus, the measures meet the second element of Article 1.1. The European Communities, by failing to consider for approval each of the twenty-seven applications of biotech products, is preventing these products, including products that would be imported from abroad, from being placed on the EC market. By imposing what are effectively import bans, the product-specific moratoria indisputably “affect international trade.”²³⁹

b. Product-Specific Moratoria Impose “Undue Delay” in the EC’s Approval Procedures in Violation of Article 8 and Annex C

137. Like the general moratorium, the product-specific moratoria violate Article 8 and Annex C(1)(a) of the SPS Agreement, which requires Members to undertake and complete their “approval procedures” “without undue delay.” As discussed above, the European Communities’ process for approving biotech products is an “approval procedure[.]” under Annex C. The European Communities’ longstanding refusal to undertake and complete its approval procedures for each of the twenty-seven applications for approval of biotech products violates Article 8 and Annex C(1)(a) because it is both “excessive” and “unjustified.”

138. Although time alone is not dispositive, in light of the acknowledgment by EC officials of the existence of a moratorium on approvals, the delay in undertaking and completing their approval procedures for the twenty-seven pending applications of biotech products is undue:

²³⁸ See *supra* para. 81.

²³⁹ See, e.g., Panel Report, *EC – Hormones* at para. 8.23.

- a. The nine notifications pending under Directive 2001/18 that were stalled at the Commission level at the time Directive 90/220 expired have been pending for an average of six and one half years.²⁴⁰
- b. The nine notifications that individual member States have failed to advance through the approval process under Directive 90/220 and have been resubmitted under Directive 2001/18 have languished at this first stage for an average of three years and ten months.²⁴¹
- c. the five requests to place biotech products on the market that are pending at the Commission level under Regulation 258/97 have been pending for an average of four years and six months.²⁴²
- d. The four requests for biotech products that the member States have failed to forward to the Commission have been delayed at this first stage of the process by an average of three and one half years.²⁴³

In contrast, before the EC adopted its moratorium, all approval procedures for notifications under Directive 90/220 were undertaken and completed in less than three years.

139. As for the general moratorium, where the EC's own legislation provides procedures and timelines for the approval of biotech products, a suspension of that approval procedure, without any scientific justification, must be considered "undue delay" under Annex C of the SPS Agreement.

- c. EC Has Violated Article 7 and Annex B by Failing to "Publish Promptly" the Product-Specific Moratoria

140. As with the general moratorium, the European Communities has violated Article 7 and Annex B, paragraph 1 of the SPS Agreement by failing to "publish[] promptly" the product-specific moratoria. The product-specific moratoria fall within the scope of Article 7 and Annex

²⁴⁰ The length of the delay is calculated from time the application was first submitted to the member State until the establishment of the panel in August 2003. The average submission date of the eight notifications that stalled at the Commission level under Directive 90/220 is February 1997. See "Notifications under Directive 2001/18 (90/220)," (Exhibit US-30).

²⁴¹ The average submission date of the eight notifications pending at the member State level is October 1999. See "Notifications under Directive 2001/18 (90/220)" (Exhibit US-30).

²⁴² The average submission date of the four requests pending at the Commission is February 1999. See "Requests Submitted under Regulation 258/97 – Novel Foods" (Exhibit US-31).

²⁴³ The average submission date of the six requests pending at the member State level is February 2000. See "Requests Submitted under Regulation 258/97 – Novel Foods" (Exhibit US-31).

B for the same reasons as the general moratorium.²⁴⁴ Because the European Communities has failed to publish, and, therefore, to “publish[] promptly,” the existence of the product-specific moratoria, the European Communities has acted inconsistently with its obligations under Article 7 and Annex B.

d. Product-Specific Moratoria Violate the Transparency Requirements in Article 8 and Annex C

141. Under the product-specific moratoria, the EC does not allow its approval procedures to proceed to conclusion. As such, the product-specific moratoria are inconsistent with each of the related procedural obligations in Annex C(1)(b) of the SPS Agreement.

142. Each of those obligations, and their inconsistency with the product-specific moratoria, are set forth below:

(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 product-specific moratoria those processing periods are not followed. Instead, the EC has imposed an indefinite delay. However, since the EC does not acknowledge the moratoria, the standard processing period is not published, and the anticipated processing period is not communicated to the applicant.

(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 product-specific moratoria, 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.

(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 product-specific moratoria, 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.

(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 product-specific moratoria, the EC does not proceed as far as practicable in the approval process. Instead, one again, application are stalled in the approval process.

²⁴⁴ See discussion *supra* para. 92-95.

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

In sum, the EC’s adoption of unpublished, product-specific moratoria is fundamentally inconsistent with all of the procedural obligations in Annex C(1)(b) governing approval procedures.

e. Product-Specific Moratoria Are Not Based on Risk Assessments as Required under Article 5.1

143. Like the general moratorium, to the extent the product-specific moratoria are preventing the sale or marketing of biotech products, each failure by the European Communities to consider for approval a pending application of a biotech product is an SPS measure that is not “based on” a risk assessment as required by Article 5.1 of the SPS Agreement. With respect to fourteen of the pending applications, the European Communities has not put forth any risk assessments whatsoever.²⁴⁵ As for the remaining fourteen applications, the European Communities has undertaken risk assessments but the product-specific moratoria are not based on these assessments.²⁴⁶ We will discuss separately each of these categories of products below.

(i) EC Has Not Put Forth “Risk Assessments” as Defined by Article 5.1 and Annex A, Paragraph 4 for All Pending Applications

144. As discussed above, the SPS Agreement requires WTO Members to put forth one of the following two types of risk assessments: (1) an “evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences;” or (2) an “evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.”²⁴⁷

145. The European Communities 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

²⁴⁵ See “Notifications under Directive 2001/18 (90/220)” (Exhibit US-30); “Requests Submitted Under Regulation 258/97 – Novel Foods” (Exhibit US-31).

²⁴⁶ The Scientific Committee on Plants rendered opinions on eight of the sixteen notifications that were submitted under Directive 90/220 and now are pending under Directive 2001/18. See “Scientific Committee Opinions for Products with Pending Applications” (Exhibit US-100). The Scientific Committee on Food has rendered opinions on two of the ten requests pending under Regulation 258/97. *Id.*

²⁴⁷ SPS Agreement, Annex A, para. 4.

Committee on Food.²⁴⁸ 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*,²⁴⁹ 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*.²⁵⁰ 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.²⁵¹

146. For the remaining fourteen applications for approval of biotech products, the European Communities has not put forth a risk assessment of any kind, not to mention one that conforms to the definition of “risk assessment” in Annex A, paragraph 4. By not putting forth a risk assessment that would provide a basis for failing to consider these products for approval, the European Communities has violated Article 5.1 of the SPS Agreement.

(ii) Product-Specific Moratoria Are Not “Based On” Risk Assessments

147. Although the European Communities has put forth risk assessments for fourteen of the twenty-seven pending applications for approval of biotech products, the product-specific moratoria are not “based on” these risks assessments as required by Article 5.1. Specifically, there is no “rational relationship” between the European Communities’ risk assessments and the product-specific moratoria.²⁵² 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

²⁴⁸ See “Scientific Committee Opinions for Products with Pending Applications” (Exhibit US-100). The following three products pending under Regulation 258/97 have received favorable member State assessments but have not yet received scientific committee opinions: transgenic radicchio, green hearted chicory, and NK603 corn. The remaining eleven applications have received positive member State assessments and scientific committee opinions.

²⁴⁹ See, e.g., Opinion of the Scientific Committee on Plants regarding submission for placing on the market of Glufosinate tolerant swede rape transformation event GS 40/90 notified by the agrevo company (notification C/DE/96/05), July 14, 1998, at 6 (concluding that the biotech swede rape is “no more invasive,” *i.e.* no more likely to become a weed or “pest,” than non-biotech swede rape) (Exhibit US-42).

²⁵⁰ See, e.g., Opinion of the Scientific Committee on Plants regarding submission for placing on the market of fodder beet tolerant to glyphosate notified by DLF-Trifolium, Monsanto and Danisco seed (notification C/DK/97/01), June 23, 1998, at 4 (stating that in the highly unlikely event that the transgene would transform the intestinal bacteria of the consuming human or animal, the resulting protein would be similar to plant enzymes consumed in larger amounts in human and animal diets) (Exhibit US-108).

²⁵¹ See, e.g., Opinion regarding submission for placing on the market of Glufosinate tolerant oilseed rape transformation event liberator PHOE 6/AC notified by the Hoechst Schering AGREVO COMPANY [NOW AVENTIS CROPSCIENCE] (notification C/DE/98/6), November 30, 2000, at 9 (concluding that “[t]here is no evidence to indicate that the placing on the market” of Liberator oilseed rape “is likely to cause adverse effects on human or animal health and on the environment”) (Exhibit US-106).

²⁵² Appellate Body Report, *EC – Hormones* at para. 193.

on” the European Communities’ risk assessments, the measures are inconsistent with Article 5.1 of the SPS Agreement.

148. With respect to the fourteen applications for which the European Communities has failed to put forth any risk assessment, it is apparent that the product-specific moratoria are not “based on” risk assessments as required by Article 5.1. In the absence of a risk assessment, there cannot be a “rational relationship” between a sanitary or phytosanitary measure and a risk assessment. Because the product-specific moratoria are not “based on” a risk assessment of any kind, the measures are inconsistent with Article 5.1 of the SPS Agreement.

149. In summary, the European Communities’ failure to consider for approval each of the twenty-seven applications for biotech products is not based on risk assessments as required by Article 5.1. Where the European Communities has put forth risk assessments for biotech products with pending applications, those assessments have supported the approval of the products, not the failure to consider those products for approval. For the remaining applications, the European Communities has failed to put forth any scientific evidence, not to mention a risk assessment as defined by Annex A, paragraph 4. Thus, the European Communities’ failure to consider for approval each of these twenty-seven applications of biotech products is inconsistent with Article 5.1.

f. Product-Specific Moratoria Are Not Based on Scientific Principles and Are Maintained without Sufficient Evidence in Violation of Article 2.2

150. Like the general moratorium, the product-specific moratoria are inconsistent with the obligations under Article 2.2 to apply SPS measures only “to the extent necessary to protect human, animal, or plant life or health” and that any such measures must be “based on scientific principles” and not maintained “without sufficient scientific evidence.” As noted above, the basic obligations provided in Article 2.2 have been viewed as being specifically applied in Article 5.1.²⁵³ Thus, the product-specific moratoria are inconsistent with Article 2.2 because they are not based on risk assessments as required by Article 5.1 and Annex A, paragraph 4.

g. EC Has Applied Arbitrary or Unjustifiable Distinctions in the Levels of Protection Against Risk that Have Resulted in “Discrimination or a Disguised Restriction on International Trade” in Violation of Article 5.5

151. The product-specific moratoria violate Article 5.5 of the SPS Agreement, which requires that Members aim to be consistent in the application of the appropriate level of sanitary or phytosanitary protection against risks to human, animal, or plant life or health. Article 5.5 specifically directs that “each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in

²⁵³ See, e.g., Appellate Body Report, *EC – Hormones* at para. 180.

discrimination or a disguised restriction on international trade.” The product-specific moratoria violate Article 5.5 for the same fundamental reasons as the general moratorium.

152. Like the general moratorium, the product-specific moratoria meet all three elements that are required to establish a violation of Article 5.5. First, the European Communities has set forth distinct levels of sanitary protection in “different situations”: products produced with biotech processing aids and other biotech products.²⁵⁴ Second, those levels of protection exhibit differences that are “arbitrary or unjustifiable.”²⁵⁵ Third, the product-specific moratoria result in “discrimination or a disguised restriction on international trade.”²⁵⁶

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

153. The United States is also challenging nine measures enacted by six EC member States that prohibit the importation or marketing of certain biotech products that the European Communities approved under Directive 90/220 and Regulation 258/97 (“member State bans” or “member State measures”). In this section, the United States will show that these measures are “sanitary [or] phytosanitary measures” that “affect international trade” and, thus, are covered by the SPS Agreement.²⁵⁷ We will further demonstrate that the member States have violated various provisions of the SPS Agreement by (1) failing to base their measures on risk assessments and scientific principles,²⁵⁸ and (2) applying arbitrary or unjustifiable distinctions in their levels of protection against risk that have resulted in discrimination or a disguised restriction on international trade.²⁵⁹

a. SPS Agreement Applies to member State Marketing or Import Bans

154. Article 1.1 of the SPS Agreement states that the Agreement applies to “all sanitary [or] phytosanitary measures which may, directly or indirectly, affect international trade.” Like the moratoria (general and product-specific), the member State measures are (1) sanitary or phytosanitary measures, which (2) affect international trade. We analyze each element of Article 1.1 below.

(i) Member State Bans Are Sanitary or Phytosanitary Measures

155. The member State bans are SPS measures as defined by Annex A, paragraph 1 of the SPS Agreement. In this section, we will demonstrate that the member States enacted these measures

²⁵⁴ SPS Agreement art. 5.5; *see also* Appellate Body Report, *EC – Hormones* at para. 214.

²⁵⁵ SPS Agreement art. 5.5; *see also* Appellate Body Report, *EC – Hormones* at para. 214.

²⁵⁶ SPS Agreement art. 5.5; *see also* Appellate Body Report, *EC – Hormones* at para. 214.

²⁵⁷ *See* SPS Agreement, art. 1.1.

²⁵⁸ *See* SPS Agreement, arts. 5.1 and 2.2.

²⁵⁹ *See* SPS Agreement, arts. 5.5 and 2.3.

to protect “human,” “animal,” or “plant” “life or health,” or “prevent or limit other damage,” within their territories.²⁶⁰ In addition, we will show that the “risks” against which the measures are designed to protect fall within the risks enumerated in Annex A, paragraph 1, *e.g.*, the “spread of pests,” the “entry” of “disease-causing organisms,” or the presence of “contaminants” or “toxins” in “foods” or “feedstuffs.” Finally, we will show that the form of each member State measure is consistent with Annex A, paragraph 1, which defines “measures” to include “laws, decrees, regulations, requirements, and procedures.”

156. 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*.”²⁶¹ 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*.”²⁶² 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. In the section below, we will analyze separately each of the member State measures to demonstrate that they were adopted to protect human, animal, or plant life or health against risks that fall within those enumerated in Annex A, paragraph 1.

157. Austria has imposed three measures to ban the “placing on the market,” “use,” or “commercialization” of three corn products that were authorized under Directive 90/220: Bt-176, MON 810, and T25. In the ban on Bt-176, Austria cited its concern over the effect of Bt toxin on non-target organisms as well as a concern for the potential transfer of antibiotic resistant genes to humans and animals.²⁶³ Austria’s measure banning MON 810 also refers to adverse effects of Bt toxin on non-target organisms and a concern that insects could develop resistance to the Bt toxin and, thus, become more difficult to manage and control.²⁶⁴ In the measure banning T25, Austria

²⁶⁰ SPS Agreement, Annex A, para. 1.

²⁶¹ Directive 90/220, art. 16 (emphasis added).

²⁶² Regulation 258/97, art. 12 (emphasis added).

²⁶³ See Federal Gazette for the Republic of Austria, 45th Ordinance, February 13, 1997, at 2 and 5 (English translation) (Exhibit US-52); see also Further Report of the Scientific Committee for Pesticides on the Use of Genetically Modified Maize Lines (Notification C/F/94/11-03), May 12, 1997 (Exhibit US-57); Opinion [of the Scientific Committee on Foods] on the Additional Information from the Austrian Authorities Concerning the Marketing of Ciba Geigy Maize (Notification C/F/94/11-03), March 21, 1997 (Exhibit US-58).

²⁶⁴ See Federal Gazette for the Republic of Austria, 175th Ordinance, June 10, 1999, at 2 (English translation) (Exhibit US-54).

cites the European Commission’s failure, at the time it approved the product, to set forth “protection for ecologically sensitive regions.”²⁶⁵ Based on these justifications, the measures imposed by Austria are “[s]anitary or phytosanitary measures” because they are applied “to protect animal life or health” from “disease-causing organisms;” “to protect human life or health” from “toxins” or “disease-causing organisms in foods;” or “to prevent or limit [] damage” from the “spread of pests.”²⁶⁶ In addition, the form of each Austrian measure is an “ordinance,” which the *New Shorter Oxford English Dictionary* defines as “[a]n authoritative decree or command.”²⁶⁷ A “decree” is among the types of measures explicitly mentioned in Annex A, paragraph 1. Each Austrian measure, therefore, meets the “purpose” and “form” elements of a sanitary or phytosanitary measure as defined in Annex A, paragraph 1.

158. France has imposed two national measures to suspend the “marketing” of the two oilseed rape products that the European Communities approved under Directive 90/220: Topas 19/2, MS1/RF1.²⁶⁸ According to the Scientific Committee on Plants, France justified the ban based on its “concern over the environmental impact of genetic escape” and the “spread of herbicide tolerance” to other plants.²⁶⁹ This justification indicates that the French measures are sanitary or phytosanitary measures as they are applied “to protect . . . plant life or health” from the “spread of pests;” and “prevent or limit other damage” from the “spread of pests.”²⁷⁰ In addition, the form of each measure is a “decree” from the French Minister of Agriculture and Fishing, which is among the types of measures explicitly mentioned in Annex A, paragraph 1. The French measures, therefore, meet the “purpose” and “form” elements of a sanitary or phytosanitary measure as defined in Annex A, paragraph 1.

159. Germany has imposed a national measure suspending “the approval for commercialization” of Bt-176 corn.²⁷¹ The concerns expressed by the German government

²⁶⁵ See Federal Gazette for the Republic of Austria, 120th Ordinance, April 28, 2000, at 2 (English translation) (Exhibit US-53).

²⁶⁶ SPS Agreement, Annex A, paragraph 1.

²⁶⁷ *New Shorter Oxford English Dictionary* at 2017.

²⁶⁸ See Official Journal, No. 200, August 30, 2001, at 13903 (Exhibit US-59). The ban on the two oilseed rape products (Topas 19/2 and MS1/RF1) was first imposed on November 16, 1998. See Official Journal, No. 267, November 18, 1998, at 17379 (Exhibit US-60).

²⁶⁹ Opinion adopted on 18 May 1999, on the Invocation by France of Article 16 (‘safeguard’ clause) of Council Directive 90/220/EEC with respect to a genetically modified oilseed rape [Topas 19/2], at 1 (Exhibit US-61).

²⁷⁰ SPS Agreement, Annex A, paragraph 1. As noted above, the definition of “pests” includes “weeds.” SPS Agreement, Annex A, n.4.

²⁷¹ Letter from Robert Koch Institute of the Federal Health Office, Center for Gene Technology, to Novartis Seeds AG, Basel, March 31, 2000 (English translation) (“Letter from Robert Koch Institute”) (Exhibit US-65). The notice suspends commercialization of Bt-176 “until such time as the Council of the European Communities makes its decision per Article 16 in conjunction with Article 21 of Directive 90/220/EEC.” Letter from Robert Koch Institute, at 1. Although Article 16 requires that a decision be rendered “within three months,” the European Communities has thus far refused to do so, and, thus, the measure remains in effect. Directive 90/220, art. 16; see

concerning Bt-176 corn included the following: the effect of Bt toxin on non-target organisms; the development of insects resistant to Bt toxin; and the transfer of antibiotic resistant genes to humans and animals.²⁷² From these justifications, it is clear that the German measure is a sanitary or phytosanitary measure as it is applied “to protect animal life or health” from “disease-causing organisms;” or “protect human life or health” from “toxins” or “disease-causing organisms in foods;” or “to prevent or limit [] damage” from the “spread of pests.”²⁷³

160. In addition, the form of the German measure is a “notice” from the government agency with responsibility for the regulation of biotech products. Through this “notice,” the German Government “hereby ordered” the suspension of the approval for commercialization for Bt-176 corn. The *New Shorter Oxford English Dictionary* defines “order” as “an authoritative direction.”²⁷⁴ This definition is the same as the definition of “regulation,” which the *New Shorter Oxford English Dictionary* also defines as “an authoritative direction.”²⁷⁵ As a “regulation” is among the types of measures explicitly mentioned in Annex A, paragraph 1, the German ban on Bt-176 also meets the “form” element of the definition of a sanitary or phytosanitary measure in Annex A, paragraph 1.

161. Greece has imposed a measure banning the importation of the seeds of oilseed rape, Topas 19/2.²⁷⁶ According to the Scientific Committee on Plants, Greece justified the ban based on its concern for “genetic escape” and the consequences that could have on “agriculture, the natural environment and consumer health.”²⁷⁷ In this context, similar to the French measures, concerns arising from “genetic escape” relate to adverse effects from the transfer of the herbicide tolerant gene to other plants or to consuming organisms. With this as its justification, the Greek measure is a sanitary or phytosanitary measure as it is applied to protect “plant life or health” from the “spread of pests;” to protect “human life or health” from “contaminants” or “disease-causing organisms in food;” or “to prevent or limit other damage” from the “spread of pests.”²⁷⁸

162. The form of the Greek measure is a ministerial decision, which prohibits the importation of Topas 19/2. A ministerial “decision” is synonymous with a “regulation,” which is one of the types of measures explicitly mentioned in Annex A, paragraph 1. The Greek measure, therefore,

also Directive 2001/18, art. 23 (which incorporates by reference the procedures of Article 30(2), which in turn incorporates the regulatory procedures of Articles 5 and 7 of Commission Decision 1999/468/EC).

²⁷² See Letter from the Robert Koch Institute (Exhibit US-65).

²⁷³ SPS Agreement, Annex A, paragraph 1.

²⁷⁴ *New Shorter Oxford English Dictionary* at 2016.

²⁷⁵ *New Shorter Oxford English Dictionary* at 2530.

²⁷⁶ Government Gazette [Efimeris Tis Kyverniseos] of the Hellenic Republic, Issue No. 1008, September 25, 1998, at 3 (Exhibit US-69).

²⁷⁷ Opinion of the Scientific Committee on Plants, adopted on 18 May 1999, on the Invocation by Greece of Article 16 (‘safeguard’ clause) of Council Directive 90/220/EEC, at 1 (Exhibit US-70).

²⁷⁸ SPS Agreement, Annex A, paragraph 1.

meets the “purpose” and “form” elements of a sanitary or phytosanitary measure as defined in Annex A, paragraph 1.

163. Italy has imposed a decree suspending the “commercialization and the use” of all four of the corn products that were approved under Article 5 of Directive 258/97: Bt-11, MON 809, MON 810, and T25.²⁷⁹ According to the Scientific Committee on Food, one of the documents provided by the Italian government suggested that the herbicide tolerant biotech products (Bt-11, T25) could have adverse effects on consuming animals. With respect to the products protected by Bt toxin (Bt-11, MON 810, MON 809), Italy cited another report about “occupational allerg[ies] to Bt bacterium spores in farmers using Bt pesticides.”²⁸⁰ Based on these justifications, the Italian measure is a sanitary or phytosanitary measure as it is applied “to protect . . . animal life or health” from “contaminants, toxins or disease-causing organisms” in “feedstuffs;” or “to protect human life or health” from “toxins” in “foods.”²⁸¹ In addition, the form of the Italian measure is a presidential “decree.” “Decrees” are among the types of measures explicitly referenced in Annex A, paragraph 1. Consequently, the Italian ban meets the “purpose” and “form” elements of a sanitary or phytosanitary measure as defined in Annex A, paragraph 1.

164. Finally, Luxembourg has imposed a ban on the “use and sale” of Bt-176 corn.²⁸² The preamble to the measure indicates that it was taken in consideration of the presence of an antibiotic resistant gene and a concern that this resistance could be transferred to humans.²⁸³ Like the German measure discussed above, the Luxembourg measure is a sanitary or phytosanitary measure because it is applied “to protect human life or health” from “toxins or disease-causing organisms in foods.”²⁸⁴ In addition, the form of the measure is a ministerial “decree.” “Decrees” are among the types of measures explicitly referenced in the Annex A, paragraph 1. As such, the Luxembourg ban on Bt-176 meets the “purpose” and “form” elements of a sanitary or phytosanitary measure as defined in Annex A, paragraph 1.

(ii) Member State Bans Affect International Trade

165. The nine member State measures also “affect international trade,” either “directly or indirectly,” and, thus, meet the second requirement under Article 1.1. The three Austrian

²⁷⁹ Official Gazette of the Italian Republic, Decree of the President of the Council of Ministers, General series—No. 184, August 8, 2000, at 3 (English translation) (Exhibit US-67).

²⁸⁰ Opinion of the Scientific Committee on Food Concerning a Submission from the Italian Authorities Raising Concerns for the Safety of Certain Products Approved under the Notification Procedure of Regulation (EC) 258/97, September 7, 2000, at 3 (Exhibit US-68).

²⁸¹ SPS Agreement, Annex A, paragraph 1.

²⁸² *Journal Officiel du Grand-Duché de Luxembourg*, A – No. 10, February 28, 1997, at 618 (Exhibit US-63).

²⁸³ *Id.*

²⁸⁴ SPS Agreement, Annex A, paragraph 1.

measures and the two French measures prohibit the “placing on the market” of the prohibited corn and oilseed rape products. The German measure suspends “the approval for commercialization” of the banned corn product.²⁸⁵ Similarly, the Italian measure bans the “commercialization and use” of the four corn products subject to the measure. The Greek measure prohibits the “importation” of the banned oilseed rape product. The Luxembourg measure prohibits the “use and sale” of the banned corn product. Each of these measures prohibits the sale of the targeted biotech product in the country that maintains the measure. 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.”

166. In summary, each of the nine member State measures is a sanitary or phytosanitary measure that affects international trade, and, thus, each measure is within the scope of the SPS Agreement.

b. Member State Bans Are Not Based on a Risk Assessment as Required under Article 5.1

167. 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. The member States have failed to put forth risk assessments to support their measures banning certain EC-approved products. In the absence of risk assessments, the member State measures are not “based on” such assessments.

(i) Member States Have Not Put Forth “Risk Assessment[s]” as Defined by Article 5.1 and Annex A, Paragraph 4

168. As discussed above, the SPS Agreement requires WTO Members to put forth one of the following two types of risk assessments: (1) an “evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences;” or (2) an “evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.”²⁸⁶

169. Under EC law, member States that restrict the trade or use of an approved biotech product must provide “justifiable reasons to consider that [the] product constitutes a risk to human health

²⁸⁵ The German government may issue “commercialization permits” to sell up to 12 million tons of Bt-176 corn seed per year, which may be planted only for research and testing purposes. See Letter from Robert Koch Institute at 1-2 (Exhibit US-65).

²⁸⁶ SPS Agreement, Annex A, para. 4.

or the environment.”²⁸⁷ 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.²⁸⁸

170. 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.²⁸⁹ For example, the Scientific Committee on Plants concluded that the information provided by Austria in support of its ban on MON 810 corn did not “constitute new significant information that was not already considered in [the committee’s] original risk assessment.”²⁹⁰ The Scientific Committee on Plants similarly found that information put forth by France to justify its bans on two oilseed rape products did not change the committee’s favorable risk assessment.²⁹¹ The scientific committees reached similar conclusions with respect to the biotech products subject to

²⁸⁷ Directive 90/220, art. 16; *see also* Directive 2001/18, art. 23; Regulation 258/97, art. 12.

²⁸⁸ *See, e.g.*, Federal Gazette for the Republic of Austria, 120th Ordinance, April 28, 2000, at 2 (English translation) (stating a concern that “T25 was not tested under realistic conditions of herbicide use and agricultural practice”) (Exhibit US-53); Government Gazette of the Hellenic Republic, Issue No. 1008, Vol 2, September 25, 1998, at 11942 (asserting that the banned product “harbors dangers to the natural environment of Greece”) (Exhibit US-69); Letter from Robert Koch Institute, at 2 (English version) (stating that “harmful effects” of the Bt toxin on non-target organisms “cannot be ruled out”); *see also* Opinion adopted on 18 May 1999, on the Invocation by France of Article 16 (‘safeguard clause’) of Council Directive 90/220/EEC with Respect to a Genetically Modified Oilseed Rape [MS1/RF1], at 1 (stating that France’s “justification of this prohibition is concern over the environmental impact of genetic escape”) (Exhibit US-61); Opinion on the Invocation by Austria of Article 16 of the Council Directive 90/220/EEC Regarding the Genetically Modified Maize Line T25 Notified by AGREVO FRANCE (Now AVENTIS CROPSCIENCE), at 3 (noting that Austria provided to the committee studies that relate to “concepts of GMO-free environmentally sensitive areas”) (Exhibit US-55).

²⁸⁹ “Question and Answers on the regulation of GMOs in the EU,” at 4 (Exhibit US-107).

²⁹⁰ Opinion on the Invocation by Austria of Article 16 (‘safeguard’ clause) of Council Directive 90/220/EEC with Respect to the Placing on the Market of the Monsanto Genetically Modified Maize (MON810) expressing the Bt cryia(b) gene, at 5, September 24, 1999 (Exhibit US-55).

²⁹¹ *See* Opinion adopted on 18 May 1999, on the Invocation by France of Article 16 (‘safeguard clause’) of Council Directive 90/220/EEC with Respect to a Genetically Modified Oilseed Rape [MS1/RF1] (Exhibit US-61); Opinion adopted on 18 May 1999, on the Invocation by France of Article 16 (‘safeguard clause’) of Council Directive 90/220/EEC with Respect to a Genetically Modified Oilseed Rape [Topas 19/2] (Exhibit US-62).

national bans in Germany,²⁹² Greece,²⁹³ Luxembourg,²⁹⁴ and Italy.²⁹⁵ Because the member States failed either to put forth their own risk assessments or to provide sufficient information to overturn the European Communities’ earlier positive assessments, the member States have violated Article 5.1.

(ii) Member State Bans Are Not “Based On” Risk Assessments as Required by Article 5.1

171. The member State bans are not “based on” a risk assessment as required by Article 5.1. First, as discussed above, the member States themselves did not put forth “risk assessments” as defined in Annex A, paragraph 4 of the SPS Agreement. In the absence of risk assessments, the member State measures cannot be “based on” risk assessments as required by Article 5.1.

172. Second, unlike the member States, the European Communities has put forth *positive* risk assessments for all of the approved biotech products, including those products that were subsequently banned by the member States. Further, when some member States challenged these approvals by enacting national bans, the scientific committees rejected the information provided by the member States and reaffirmed their original, favorable risk assessments. Despite these positive assessments, the six member States have nevertheless maintained marketing or import bans on EC-approved products. In this way, the member State measures do not bear a “rational relationship” to the European Communities’ positive risks assessment.²⁹⁶ Thus, the member States’ sanitary or phytosanitary measures are not “based on” a risk assessment, in violation of Article 5.1.

²⁹² See Opinion on the Invocation by Germany of Article 16 of Council 90/220/EEC regarding the genetically modified BT-MAIZE LINE CG 00256-176 notified by CIBA-GEIGY (now NOVARTIS) (Exhibit US-66).

²⁹³ See Opinion of the Scientific Committee on Plants on the Invocation by Greece of Article 16 (‘safeguard clause’) of Council Directive 90/220/EEC with Respect to a Genetically Modified Oilseed Rape (stating that the information submitted by Greece does not change the SCP’s assessment regarding the risk of genetic escape) (Exhibit US-70).

²⁹⁴ We have been unable to locate an SCP opinion concerning Luxembourg’s invocation of Article 16 to prohibit the “use and sale” of Bt-176. According to the European Commission, however, the SCP has conducted such a review and found that the information submitted by Luxembourg did not justify its ban. See “Question and Answers on the regulation of GMOs in the EU,” at 4 (Exhibit US-107).

²⁹⁵ See Opinion of the Scientific Committee on Food Concerning a Submission from the Italian Authorities Raising Concerns for the Safety of Certain Products Approved under the Notification Procedures of Regulation (EC) 258/97, at 3 (stating that “[t]he Committee is of the opinion that the information provided by the Italian Authorities does not provide detailed scientific grounds for considering that the use of the novel foods in question endangers human health”) (Exhibit US-68).

²⁹⁶ Appellate Body Report, *EC – Hormones* at para. 193.

c. Member State Bans Are Not Based on Scientific Principles and Are Maintained without Sufficient Scientific Evidence in Violation of Article 2.2

173. The member State measures are inconsistent with the obligations under Article 2.2 to apply SPS measures only “to the extent necessary to protect human, animal, or plant life or health” and that any such measures must be “based on scientific principles” and “not maintained without sufficient scientific evidence.” As noted above, the basic obligations provided in Article 2.2 have been viewed as being specifically applied in Article 5.1.²⁹⁷ Thus, the member State measures are inconsistent with Article 2.2 because they are not based on a risk assessment as required by Article 5.1 and Annex A, paragraph 4.

C. Greek Import Ban Violates Article XI

174. The Greek import ban on rapeseed Topas 19/2 violates Article XI:1 of the GATT 1994, which states, in pertinent part, “[n]o prohibitions or restrictions other than duties, taxes or other charges . . . shall be instituted or maintained by any contracting party on the importation of any product of the territory of any other contracting party.” Since September 9, 1998, Greece has maintained a prohibition on the importation of rapeseed Topas 19/2, including from the United States. 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.

V. CONCLUSION

175. For all the reasons set forth above, the United States submits that this Panel should find that the EC measures covered in the U.S. panel request are inconsistent with the obligations of the European Communities under the SPS Agreement and the GATT 1994.

²⁹⁷ See, e.g., Appellate Body Report, *EC – Hormones* at para. 180..

EXHIBIT LIST

- US-3 Trevor V. Suslow, et al., “Biotechnology Provides New Tools for Plant Breeding,” Agricultural Biotechnology in California Series, University of California, Davis, March 2001
- US-4 Norman E. Borlaug, “Ending World Hunger. The Promise of Biotechnology and the Threat of Antiscience Zealotry,” 124 PLANT PHYSIOLOGY (2000)
- US-5 Report of the National Academy of Medicine and National Academy of Pharmacology (l’Académie Nationale de Médecine et de l’Académie Nationale de Pharmacie), “How can genetic engineering contribute to the improvement of human health and food, and what are the obstacles to its applications in this area?” November 26, 2002 (in original French and English translation)
- US-6 Martina McGloughlin, “Why Safe and Effective Food Biotechnology is in the Public Interest”
- US-7 National Academy of Sciences, Transgenic Plants and World Agriculture (July 2000)
- US-8 Pontifical Academy of Sciences, Study Document on the Use of Genetically Modified Food Plants to Combat Hunger in the World (2001)
- US-9 Leonard P. Gianessi, et al., “Plant Biotechnology: Current and Potential Impact for Improving Pest Management in U.S. Agriculture,” June 2002
- US-10 Food and Agriculture Organization of the United Nations, “FAO Statement on Biotechnology” (2000)
- US-11 Florence Wambugu, “Modifying Africa: How Biotechnology Can Benefit the Poor and the Hungry” (2001)
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