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Precaution or Protectionism?--The Precautionary Principle, Genetically Modified Organsims, and Allowing Unfounded Fear to Undermine Free Trade

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Precaution or Protectionism? The Precautionary Principle, Genetically Modified Organisms, and Allowing Unfounded Fear to Undermine Free Trade

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I. INTRODUCTION

Addressing the National Press Club, the U.S. Secretary of Agriculture stated, "With all that technology has to offer, it is nothing if it's not accepted. This boils down to a matter of trust. Trust in the science behind the process, but particularly trust in the regulatory process that ensures thorough review–including complete and open public involvement."[1] The concomitant effect of a lack of faith in science upon the acceptance of science is especially evident in the backlash against genetically altered foods in Europe. In reaction to the fear generated by the outbreak of mad-cow disease[2] in the early 1990s, European consumers have a great lack of trust for additives, modern livestock-feeding techniques, and biotechnology in general.[3]

The United States exports more goods to the European Union (EU)[4] than it does to any other singular trading entity.[5] The crux of the trade dispute between the EU and the United States regarding genetically modified crops is the lack of a consistent and reliable regulatory process for the approval of genetically altered agricultural commodities. Nearly half of the soybeans and a third of the corn grown in the United States is genetically altered.[6] The EU's refusal to allow the importation of such a considerable portion of the United States' agricultural production results in huge economic losses.[7] The U.S. Department of Agriculture has approved fifty plant varieties, termed Genetically Modified Organisms (GMO), for use within the United States.[8] In contrast, the EU has only approved eighteen GMOs. When the EU failed to approve any GMOs for over a year, U.S. representatives claimed that the EU was

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1. Dan Glickman, Remarks of the United States Secretary of Agriculture to the National Press Club (July 13, 1999), *at* http://www.usda.gov/news/releases/1999/0285.

2. *See Cow Crunching: BSE/New Evidence on Mad Cows*, Economist, Aug. 31, 1996, 49, 49 (reporting that an estimated 500,000 cows were infected with bovine spongiform encephalopathy (mad-cow disease) and eaten before the epidemic was discovered). The infection was spread by feeding the ground-up remains of cattle and sheep to other cattle. *Id.* It is strongly suspected that the infection of a number of people with Creutzfeldt-Jakob disease is linked to the consumption of this tainted beef. *Id.*

3. Steven H. Dunphy, *The WTO: A Case of Washington Meat and French Mustard. How One Big Beef in World Trade Trickles Down to Folks on the Farm*, SEATTLE TIMES, Sept. 19, 1999, at A1.

4. The European Union (known also as the European Community) consists of the United Kingdom, France, Germany, Luxembourg, Sweden, Denmark, the Netherlands, Austria, Belgium, Greece, Ireland, Italy, Portugal, Spain, and Finland. Barbara Crutchfield George et al., *The Dilemma of the European Union: Balancing the Power of the Supranational EU Entity Against the Sovereignty of its Independent Member Nations*, 9 PACE INT'L L. REV. 111, 113 (1997).

5. *See infra* notes 108-11 and accompanying text (describing the significance of the trade relationship between the United States and the EU).

6. *See* Melody Petersen, *New Trade Threat for U.S. Farmers*, N.Y. TIMES, Aug. 29, 1999, at 1 (explaining that the 60 million acres of genetically-altered corn and soybeans planted in the United States is equal to the size of the United Kingdom).

7. *See infra* note 112 and accompanying text (noting that in 1998 the United States lost over $200 million in corn sales alone).

8. *See EU/US: Washington Recoils from Gene Food Fight*, EUR. REP., July 28, 1999, *available at* 1999 WL 8306732 [hereinafter *Gene Food Fight*]; *see also* Marian Burros, *U.S. Plans Long-Term Studies on Safety of Genetically Altered Foods*, N.Y. TIMES, July 14, 1999, at A18.

"applying protectionist rules masquerading as food safety claims."[9] The EU insists that it is regulating the introduction of GMOs into the EU[10] to protect the environment and the health of its people from unforeseen harms caused by GMOs.[11]

The EU's reluctance to adopt and approve GMOs on an "entity-wide" basis is a result of the differing levels of concern between its individual member states.[12] This reluctance produces a lack of uniformity by allowing the degree of regulation concerning GMOs to vary from state to state.[13] The conflict between the supranational EU and the member nations of Europe that comprise the EU confuses the European public. The people are unsure whether legitimate scientific concerns or political interests drive the respective actions of their governing authorities.[14] For instance, a legislative provision of the EU allows countries to reject genetically modified crops already approved[15] by the European Commission[16] if the member country has new evidence of risk.[17] The effect of this provision is that a variety of standards are permitted in determining what is safe for consumption and the

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9. *Gene Food Fight, supra* note 8 (noting the statement by the U.S. special trade negotiator, Peter Scher, that "[t]he E[U]'s approval system is not science-based, not transparent and is highly politicised.").

10. *See infra* notes 36-74 and accompanying text (discussing the laws enacted by the EU pertaining to GMOs, and in particular Directive 90/220 and Regulation No. 258/97).

11. *See* Andrew Pollack, *130 Nations Agree on Safety Rules For Biotech Food*, N.Y. TIMES, Jan. 30, 2000, at 1 (discussing the concerns regarding GMOs, such as, the possibility that herbicide resistant crops might cross-pollinate with weeds creating "superweeds" or that gene-altered fish might out-compete other fish for food and reproductive partners).

12. *See* Gerald C. Nelson et al., *The Economics and Politics of Genetically Modified Organisms In Agriculture: Implications For WTO 2000*, Bulletin 809 (Univ. Of Ill. at Urbana-Champaign College of Agricultural, Consumer and Environmental Sciences) Nov. 1999, at 58 (describing the differences between the policies of individual nation members of the EU regarding GMOs).

13. *See id.* (stating that EU policy would be less ambiguous if regional, rather than national, rules prevailed concerning the regulation of GMOs).

14. *See Who's Afraid of Genetically Modified Foods?*, ECONOMIST, June 19, 1999, 15, 15 [hereinafter *Who's Afraid?*] (referring to the public's lack of understanding of whether scientific policy is based upon protecting people or nations' positions within the world market).

15. *See, e.g.*, Commission Decision 98/293/EC Concerning the Placing on the Market of Genetically Modified Maize (Zea mays L. T25), Pursuant to Council Directive 90/220/EEC, 1998 O.J. (L 131) 30, *available in* EUR-LEX, Document 398D0293; Commission Decision 98/294/EC Concerning the Placing on the Market of Genetically Modified Maize (Zea mays L. line MON 810), Pursuant to Council Directive 90/220/EEC, 1998 O.J. (L 131) 33, *available in* EUR-LEX, Document 398D0294; Commission Decision 97/98/EC Concerning the Placing on the Market of Genetically Modified Maize (Zea mays L.) With the Combined Modification for Insecticidal Properties Conferred by the Bt-endotoxin Gene and Increased Tolerance to the Herbicide Glufosinate Ammonium Pursuant to Council Directive 90/220/EEC, 1997 O.J. (L 031) 69, *available in* EUR-LEX, Document 397D0098; Commission Decision 96/281/EC Concerning the Placing on the Market of Genetically Modified Soya Beans (Glycine max L.) with Increased Tolerance to the Herbicide Glyphosate, Pursuant to Council Directive 90/220/EEC, 1996 O.J. (L 107) 10, *available in* EUR-LEX, Document 396D0281.

16. *See infra* note 36 and accompanying text (explaining the function of the European Commission in developing policy and law for the EU); *see also infra* notes 35-62 and accompanying text (describing the approval process for a proposal of the European Commission to admit a Genetically Modified Organism).

17. *See* Council Directive 90/220, art. 16.1-.2, 1990 O.J. (L 117) 15, 20; *see also infra* notes 54-57, 66 and accompanying text (discussing the authorization given by European Council Directive 90/220/EEC to any member country to deny the importation of foods previously approved by the European Commission for trade and production within Europe).

environment. This assortment of conflicting standards creates confusion for European consumers as to what is actually safe.[18] Further, it is difficult for GMO exporters to deal with the EU as an autonomous trade entity because of the differing policies of its member states.[19] This lack of uniformity undermines the goals of free trade underlying the formation of the EU and the World Trade Organization (WTO).[20]

The purpose of forming a trade agreement between countries is to eliminate barriers to free trade that are created by a lack of uniformity in national policies.[21] In order to facilitate their ability to compete in global trade, individual nations have formed regional[22] agreements to remove domestic regulations that discriminate against trade between countries who are parties to a particular agreement.[23] The agreement that formed the WTO is a truly global trade agreement consisting of 134 member countries and thirty observers, of which both the EU and the United States are members.[24] The goal of the WTO agreement is the same as the goal of regional trade agreements: the elimination of discriminatory barriers to trade.

Trade agreements allow restrictions on the importation of goods under certain circumstances.[25] However, despite the availability of measures that allow restrictions on the importation of goods, there is a public perception that the drive for free trade results in a governmental mind-set that ignores the people's legitimate concerns. The European people are questioning their inability as consumers to enact protective measures outside of the circumstances defined by their governmental authorities in the trade agreements.[26]

The frustration of the European populace is a result of their fear that the long-term consequences of GMOs on the environment and their health is arguably unknown. This fear is enhanced both by the public's distrust of governmental authorities and by the public's inability to act outside of regulations prescribed by

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18. *See Who's Afraid?*, *supra* note 14, at 15.

19. *See id.* (commenting that the concurrent existence of national and EU regulations results in differing standards regarding the adoption of GMOs).

20. *Id.* at 60.

21. *See id.* (noting that countries once restricted regional trade agreements to removing tariffs and nontariff barriers, but as these barriers were reduced, attention was given to "hidden" barriers, including government regulations and industry standards). Harmonization of standards and mutual recognition of each member state's regulations are techniques used to eliminate these barriers. *Id.*

22. Examples of such regional agreements include the following: the EU; the North American Free Trade Agreement (NAFTA) consisting of the United States, Canada, and Mexico; and the Asia-Pacific Economic Cooperation (APEC) consisting of Australia, China, Canada, the Association of Southeast Asian Nations (ASEAN), Mexico, the United States, New Zealand, Japan, Korea, Taiwan, and Chile. Nelson, *supra* note 12, at 61 n.99.

23. *Id.* at 60.

24. *See* Susan George, *'The Problem Isn't Beef, Bananas, Cultural Diversity or the Patenting of Life. The Problem Is the WTO': Leading Development Analyst Susan George on Why the World Trade Talks in Seattle Next Week Won't Help the Great Majority of People or the Environment*, THE GUARDIAN (London), Nov. 24, 1999 *available in* 1999 WL 25747614.

25. *See infra* notes 36-107 and accompanying text (discussing the various systems, regulating GMOs, of the EU, the United States, and the WTO).

26. *See Who's Afraid*, *supra* note 14, at 15.

these authorities. The enormity of the public outcry arising from the people's unalleviated fears is affecting and undermining the free, unrestricted trade envisioned by the WTO and the regional agreements.

The United States has not turned yet to the dispute settlement body of the WTO to resolve the issue of the EU's restrictions on the imports of GMOs.[27] However, the longer the European restrictions remain in place, without any new evidence that challenges the safety of GMOs, the greater the chances of a confrontation before the WTO's dispute settlement body.[28]

This Comment discusses the controversy surrounding the trade of GMOs. In particular, this Comment addresses the conflict between the regional trade entities of the EU and the United States, and its effect on the global trading agreement embodied by the WTO. Part II outlines the regulations and policies of the EU regarding GMOs of the EU,[29] the United States,[30] and the WTO.[31] Part III examines the controversy between the EU and the United States over "altered" foods, exemplified by the *Beef-Hormones* dispute.[32] *The Beef Hormones* case was the first challenge brought under the authority of the WTO, guided by the Sanitary and Phytosanitary Agreement, and has resulted in the current status of regulation under the WTO agreement regarding restrictions against "altered" foods.[33] This could soon change, however. Part IV of this Comment considers the likelihood of change in light of the emerging appeal of the "precautionary principle" as a rule of international law relating to the introduction of GMOs into a nation.[34] Finally, Part V summarizes the detrimental effects upon free trade that will result if the "precautionary principle" is applied to the trade of GMOs.[35]

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27. *See Gene Food Fight, supra* note 8 (stating that the United States has not used the WTO as a "bludgeon" to open up the EU's market for GMOs because of concerns about the reactions of European consumers).

28. *See* Petersen, *supra* note 6, at 1 (commenting that U.S. trade officials have been unsuccessful in employing diplomatic efforts to convince European leaders and agricultural ministers to lift the bans on new types of gene-altered crops).

29. *See infra* notes 36-74 and accompanying text (explaining the regulatory structure and the conflicts regarding GMOs within the EU).

30. *See infra* notes 75-93 and accompanying text (discussing U.S. regulatory authorities and policies surrounding GMOs).

31. *See infra* notes 94-107 and accompanying text (describing the regulations that encompass the free trade of GMOs under the auspices of the WTO, which governs both the United States and the EU as members of the global agreement).

32. *See infra* notes 115-58 and accompanying text (focusing on the *Beef-Hormones* dispute and its significance in providing requirements to justify any restriction of trade against GMOs).

33. *See infra* notes 108-58 and accompanying text (detailing the conflict between the United States and the EU, and the findings of the WTO dispute settlement body with regard to altered agricultural goods).

34. *See infra* notes 159-85 and accompanying text (discussing the origination of the "precautionary principle" and the possible implications of its application to the trade of GMOs).

35. *See infra* notes 186-201 and accompanying text.

II. SPECTRUM OF STANDARDS ALLOWING RESTRICTIONS OF TRADE

A. *European Community*

EU law[36] relating to protection of the environment is based on the "precautionary principle," which mandates that any person or entity that introduces any substance into the EU must take measures to avoid environmental damage before it occurs.[37] The two main laws which regulate the marketing of GMOs within the EU[38] are Council Directive 90/220 and Regulation No. 258/97.[39]

1. Directive 90/220

Directive 90/220 applies to raw materials, such as corn or soy beans, before there is any production involved in bringing the foods to market as a finished product.[40] The main requirements of the Directive are as follows: (1) there must always be an environmental risk assessment before any GMOs are released either experimentally or commercially; (2) a designated national authority must give its consent before any GMOs may be released; and (3) a uniform approval procedure for commercial releases must be established throughout the EU.[41]

Before a manufacturer or importer may market a GMO product within the EU, the party must make a request for authorization to the member state in which the product will first be sold.[42] A request to place a GMO into the market must include the scientific name of the GMO as well as any possible risks to human health or the

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36. Legislation within the EU is carried out by three legislative institutions. *See* Terence P. Stewart & David S. Johanson, *Policy in Flux: The European Union's Laws on Agricultural Biotechnology and Their Effects on International Trade*, 4 DRAKE J. AGRIC. L. 243, 252-55 (1999). The European Commission proposes legislation. *Id.* The European Council debates the proposed legislation and decides whether or not to adopt it. *Id.* at 253. The European Parliament, which contains the only directly elected representatives from the European Community, mainly serves in an advisory capacity. *Id.* However, the Maastricht Treaty of 1992 granted the Parliament veto power over legislation concerning consumer protection, health, and other related areas. *Id.* at 255.

37. Margaret Rosso Grossman, *Farmers and the Environment Under the Common Agricultural Policy of the European Union: the Agro-Environmental Measure in the United Kingdom*, 28 U. TOL. L. REV. 663, 666 (1997).

38. Legislation in the European Community is generally issued as either a "Regulation" or "Directive." Regulations affect the EU as a whole and directly apply to each of the member states. Directives also affect the EU as a whole. However, a crucial distinction between a Regulation and a Directive is that a Directive must be implemented through domestic regulation. *See* George, supra note 4, at 119. This allows each member state to choose how it will carry out the purpose of the Directive within its own borders. *See id.*

39. *See* Nelson, *supra* note 12, at 54; *see also* Stewart & Johanson, *supra* note 36, at 266-67.

40. Stewart & Johanson, *supra* note 36, at 256 (noting that one of the purposes of Directive 90/220 is to harmonize the law throughout the EU pertaining to GMOs in their raw form before the food is produced in any way).

41. *See* Nelson, *supra* note 12, at 55-56 (commenting that, under the directive, all deliberate releases of GMOs into the environment must be reviewed on a step-by-step and case-by-case basis before being approved).

42. *See* Council Directive 90/220, *supra* note 17, art. 11.1, 1990 O.J. (L 117) 15, 18; *see also* Nelson, *supra* note 12, at 56 (explaining that while a GMO that is approved in a member state is automatically approved in any other member state, most companies register the GMO in each of the member states for marketing purposes).

environment that could result from releasing the GMO into the environment.[43] The member state that receives the request must examine it to make sure that it follows the requirements of Directive 90/220[44] and then it has ninety days to approve or deny the release of the GMO.[45] If the authorities of the member state decide to approve the release of the GMO, they must submit the information concerning the possible effects of the proposed GMO and their resulting approval to the European Commission,[46] who will forward it to all of the member states.[47]

Objections by any of the other member states to the placement of the GMO on the market must be made to the European Commission within sixty days after each member state received a copy of the notification of approval.[48] If an objection to the release of the GMO cannot be resolved between the member states, the Commission delegates consideration of the proposal to a committee consisting of representatives from each of the member states.[49] If the committee determines that a GMO should not be permitted to enter the market or makes no decision, the Commission submits the measure to the European Council,[50] who must vote upon the measure within three months.[51] The failure of the Council to vote upon the proposal acts as an approval.[52] Directive 90/220 states that once release of a GMO is approved in one member state, other member states need not be notified of an intent to release the GMO within their boundaries.[53] Once the product meets the requirements of the

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43. *See* Council Directive 90/220, *supra* note 17, Annex II, arts. II(A)(1), II(C)(2)(i), IV(c)(1), at 23-26; *see also* Stewart & Johanson, *supra* note 36, at 257 (observing that a risk assessment must be undertaken concerning any possible effects of a particular GMO upon human health or the environment).

44. *See* Council Directive 90/220, *supra* note 17, art. 12.1, at 19.

45. *See id.* art. 12.2, at 19; *see also* Stewart & Johanson, *supra* note 36, at 258 (quoting Directive 90/220's admonition that a member state "[give] particular attention to the environmental risk assessment" when reviewing the notification of a manufacturer or importer of a GMO).

46. *See supra* note 36 (explaining that the European Commission's role is to propose legislation).

47. *See* Council Directive 90/220, *supra* note 17, art. 13.1, at 19; *see also* Stewart & Johanson, *supra* note 36, at 258 (noting that if the member state that received the request provides its consent to the import or development of the GMO within the market, that state must so inform the Commission and the other member states).

48. *See* Council Directive 90/220, *supra* note 17, art. 13.2, at 19; *see also* Nelson, *supra* note 12, at 56; *see also* Stewart & Johanson, *supra* note 36, at 258 (stating that where there is no objection within 60 days the member state approving the GMO "shall" provide its consent).

49. *See* Council Directive 90/220, *supra* note 17, art. 21, at 21; *see also* Stewart & Johanson, *supra* note 36, at 259 (explaining that the Commission will adopt the opinion of the committee if the committee favors acceptance).

50. *See supra* note 36 (explaining that the role of the European Council is to decide whether to adopt proposals for legislation made by the European Commission).

51. *See* Council Directive 90/220, *supra* note 17, art. 21, at 21; *see also* Stewart & Johanson, *supra* note 36, at 259.

52. *See* Council Directive 90/220, *supra* note 17, at 21; *see also* Stewart & Johanson, *supra* note 36, at 259 (noting that if the Council does not reach a decision within three months, the Commission will adopt the proposed measures, thus allowing the member state who originally sent the notification to grant consent, which is then applicable throughout the EU).

53. *See* Council Directive 90/220, *supra* note 17, art. 13.5, at 20; *see also* Stewart & Johanson, *supra* note 36, at 259 (explaining that once the requirements of the approval procedures are satisfied, Directive 90/220 does not mandate any further notice than that previously required).

Directive, no member state may inhibit its placement in the market within the member state's territory.[54]

The only circumstance that allows a member state to "provisionally restrict" an approved product's placement in the market is when the member state has "justifiable reasons"[55] to believe that the GMO poses a risk to human health or the environment.[56] The Commission considers the argument of the concerned member state and, within three months, decides whether to approve the provisional restriction under the same guidelines used for an objection to an initial notification.[57] The failure to reach a decision acts as an approval of the provisional restriction.[58]

2. Regulation No. 258/97

There is no requirement under Directive 90/220 to further notify other member states once approval to place the GMO on the market has been obtained.[59] Due to this fact it is foreseeable that a product could enter the territory of a member state without the member state's knowledge that it contains GMOs. The likelihood of this occurring, however, is minimized by Regulation No. 258/97, also known as "The Novel Foods Regulation."[60] The Regulation requires the labeling of all foods that "may" contain GMOs, whether they are processed or unprocessed.[61] Also included are foods that do not contain any GMOs but are produced from GMOs.[62] GMO foods must also be labeled if they are changed to the degree that they no longer have the same make-up of an existing food.[63] Regulation 258/97 only applies to GMO foods that are placed on the market within the EU.[64] Notably, the Regulation

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54. *See* Council Directive 90/220, *supra* note 17, art. 15, at 20; *see also* Stewart & Johanson, *supra* note 36, at 259 (observing that Directive 90/220 prohibits all of the member states from taking any action that may "restrict or impede the placing on the market of products containing, or consisting of, GMOs which comply with the requirements of [the] Directive").

55. *See infra* note 68 and accompanying text (describing "justifiable reasons" as new scientific evidence that a GMO constitutes a risk to "human health and the environment").

56. *See* Council Directive 90/220, *supra* note 17, art. 16.1, at 20; *see also* Stewart & Johanson, *supra* note 36, at 259.

57. *See* Council Directive 90/220, *supra* note 17, art.16.1-.2, at 20; *see also* Stewart & Johanson, *supra* note 36, at 260.

58. *See* Council Directive 90/220, *supra* note 17, art. 21, at 21; *see also* Stewart & Johanson, *supra* note 36, at 259 (stating that although the product is already authorized to be placed on the European market, the failure of the Council to address a provisional restriction by a member state acts as support for the validity of the restriction).

59. *See* Council Directive 90/220, *supra* note 17, art. 13.5, at 20.

60. Commission Regulation 258/97, 1997 O.J. (L043) 1, 1.

61. *See* Nelson, *supra* note 12, at 56. The Regulation does not specify the amount of GMOs within a finished food that would require labeling, but on October 21, 1999, the Commission approved a requirement that all foods containing at least 1% of GMOs be labeled. *Id.*

62. *See* Commission Regulation 258/97, *supra* note 60, art. 1(2)(b) at 2.

63. *See* Nelson, *supra* note 12, at 56.

64. Commission Regulation 258/97, *supra* note 60, art. 1(1) at 1.

imposes no labeling requirements upon EU exporters or producers that export GMOs outside of the EU.[65]

3. *Lack of Faith in the Regulatory Process*

France, Austria, and Luxembourg recently exercised their right under EU law to freeze the future import of GMOs into their respective countries.[66] The Commission submitted the evidence supporting the provisional restrictions to the Scientific Committee for Food, the Scientific Committee for Animal Nutrition, and the Scientific Committee for Pesticides for investigation.[67] These committees found no new evidence of risk to human health or the environment.[68] Despite these findings, the Regulation Committee of the European Council issued no opinion

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65. *See id.*

66. *Food for Thought: Public Hostility to the Genetic Modification of Crops Risks Slowing Down the Development of a Potentially Important Technology—Which is Why More Must be Done to Reassure Consumers*, ECONOMIST, June 19, 1999, at 19; *see also* Stewart & Johanson, *supra* note 36, at 266-67 (discussing the utilization of Article 16 of European Community Directive 90/220/EEC by Austria and Luxembourg, which permits a member country to "provisionally restrict" a GMO that has been previously approved if the member country has "justifiable reasons" to believe that the product might be a danger to human health or the environment).

67. Austria, and later Luxembourg, claimed that the pesticidal attributes of Monsanto's *Bacillus thuringiensis* (Bt) corn, which had been shown to adversely affect the monarch butterfly in a study conducted in North America, might constitute a risk to "human health and the environment." *See Opinion of the Scientific Committee on Plants 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, notification C/F/9512-02 (Opinion expressed by the Scientific Committee on Plants on 24 September 1999)* http://europa.eu.int/comm/dg24/health/sc/scp/out49_en.htm.l (visited Nov. 24, 1999) [hereinafter *Opinion on Austria*]. It may adversely affect other non-target insects that are subject to predation and/or increase the resistance of target pests, which could result in an expanding effect on the environment. *See id.* France claimed that the resistance of modified oilseed rape to herbicide might spread through cross-pollination with other vegetation, resulting in adverse effects to "human health and the environment." *See Opinion of the Scientific Committee on Plants, 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 notification C/UK/94/M1/1 (Plant Genetic Systems N.V.)-(SCP/GMO/150-final)* http://europa.eu.int/comm/dg24/health/sc/scp/out38_en.html (visited Nov. 24, 1999) [hereinafter *Opinion on France*].

68. *See* Stewart & Johanson, *supra* note 36, at 267; *see also Opinion on Austria*, *supra* note 67, 68 (stating that no new evidence or "justifiable reasons" exist to permit the restriction for the following reasons: the limited distance that a significant amount of pollen can travel; the short period of time when there is a juxtaposition of pollen release and local butterfly reproduction and larval feeding; and the inconclusive nature of the laboratory-based study concerning the monarch butterfly); *see also EU Scientists Reject Austrian GM Maize Ban*, AGRA EUROPE, Oct. 22, 1999, at EP4 (referring to the Scientific Committee on Plants' statement that the laboratory study of the effects of genetically modified pollen upon the monarch butterfly could not be extrapolated into the field and that the "precautionary principle" of Article 16 of Directive 90/220 is only justified in the absence of concrete scientific data); *see also Opinion on France*, *supra* note 67 (stating that the cross-pollination of glufosinate-resistant crops with other plants will not result in a predominance of cross-bred glufosinate-resistant plants outside of areas where glufosinate is used).

about whether the bans were justified.[69] In the absence of an opinion from the Council, the restrictions remained legally justified.[70]

On June 25, 1999, the Council recommended that Directive 90/220 be amended to adopt a precautionary approach that prevents the authorization of a GMO until there is positive proof that it does not affect human health or the environment.[71] All the member states of the EU agreed to follow this approach.[72] Despite the member states' assertion that they would enforce the moratorium, seven member states have simultaneously proposed eleven new GMO products for authorization.[73] As a result of the inconsistency in enforcement of GMO regulation between the national governments and the supranational EU government, people have no reliable information on whether these governmental bodies are protecting consumers or industry; thus the European public has little confidence in regulatory authorities.[74]

B. *The United States*

The United States has no major laws regulating GMOs.[75] The agencies responsible for monitoring the safety of GMOs in the United States are the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA), the Environmental Protection Agency (EPA), and the U.S. Food and Drug Administration (FDA).[76]

The APHIS regulates the movement or release into the environment of any organism that could be a potential plant pest to U.S. agriculture.[77] In addition, the APHIS regulates any new plants introduced into the United States that might have pathogenic properties affecting other existing plants.[78] Generally, the APHIS is responsible for protecting U.S. agriculture from pests or diseases, but is not involved with processed foods made from or containing GMOs.

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69. *See* Stewart & Johanson, *supra* note 36, at 267 (commenting that although the Commission submitted a proposal to the Council to have Austria and Luxembourg repeal their bans on GMO corn, the Council failed to reach a decision on the matter).

70. *See id.* (noting that the absence of a decision by the Council allowed Austria and Luxembourg to continue to restrict the import of Bt Corn).

71. *See* Nelson, *supra* note 12, at 57.

72. *Id.*

73. *See EU Calls Halt to New GMO Approvals; Genetically Modified Organisms*, AGRA EUROPE, June 25, 1999, at EP1.

74. *See* ECONOMIST, *supra* note 66 at 19.

75. Stewart & Johanson, *supra* note 36, at 247. In fact, the Food and Drug Administration sees no fundamental difference between foods modified through biotechnology and foods developed through traditional breeding techniques stating that both are forms of genetic manipulation. *See* Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22, 984 (1992).

76. *See* Nelson, *supra* note 12, at 48.

77. *See id.* at 48-49 (explaining that any party who wishes to move or field-test a genetically engineered plant within the United States must submit a permit for review to APHIS, who will conduct a subsequent analysis of any possible risks to the environment associated with an organism's transport between states or limited release through field trials).

78. *See* Stewart & Johanson, *supra* note 36, at 250.

The EPA regulates pesticides and organisms with pesticidal properties.[79] In addition to safely maintaining the public's and the environment's exposure to pesticides, the EPA attempts to prevent the development of pesticide-resistant insects or weeds.[80]

Under the Federal Food, Drug, and Cosmetic Act (FFDCA),[81] the FDA is authorized to safeguard most foods, including GMOs.[82] The FDA asks the party introducing the product into the American market for assurances that the product is safe, but the FDA does not require the testing of GMO products.[83] The FFDCA holds the party introducing the product legally responsible, and if the product is subsequently proven unsafe, that party is subject to criminal prosecution.[84] The problem with this laissez-faire regulatory system is that even when a company does not meet its food safety responsibilities, the FDA only takes action after some harm has resulted.[85] No U.S. agency has the adequate staff or resources to test all of the genetically modified foods that are introduced into the U.S. market.[86] At most, the FDA inspects two percent of import shipments and conducts few food-plant inspections outside of the United States.[87] However, because the FDA has broad

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79. *See* Nelson, *supra* note 12, at 48. The EPA regulates and sets acceptable levels of pesticide in the environment and in foods on the market. *See* Stewart and Johanson, *supra* note 36, at 249. This includes GMOs that contain Bt toxin, which acts as a pesticide against the European Corn Borer. *See id.*

80. *See* Nelson, supra note 12, at 52. The EPA is concerned that long-term exposure to plants containing the Bt toxin will, through natural selection, breed insects resistant to the Bt toxin, thereby nullifying the GMO's effectiveness and again requiring the use of pesticides. *See id.* at 38.

81. 21 U.S.C. §§ 301-95. (West 1994 & Supp. II 1997).

82. *See* Stewart and Johanson, *supra* note 36, at 248.

83. *See* Burros, *supra* note 8, at A18; *see also* Peter Barton Hutt, *Philosophy of Regulation Under the Federal Food, Drug and Cosmetic Act*, 50 FOOD DRUG L.J. 101, 106 (1995) (stating that without self-regulation it would be impossible for the FDA to monitor the extensive amount of industry for which the agency is responsible).

84. *See* Stewart & Johanson, *supra* note 36, at 248-49; *see also* Hutt, *supra* note 80, at 106 (commenting that in order for a system of self-regulation to work there must be some form of sanction for failure to comply).

85. *See* Michael R. Taylor, *Preparing America's Safety System for the Twenty-First Century: Who Is Responsible for What When it Comes to Meeting the Food Safety Challenges of the Consumer-Driven Global Economy?*, 52 FOOD DRUG L.J. 13, 16 (1997); *see, e.g.*, Marc Kaufman, *Biotech Critics Cite Unapproved Corn in Taco Shells*, WASH. POST, Sept. 18, 2000, at A2 (reporting an independent lab's finding of a genetically modified corn, approved for use in animal feed but denied approval for human consumption because of problems concerning allergies and human digestion in Taco Bell brand taco shells manufactured in Mexico and sold in grocery stores throughout the United States). Anti-biotech activists claim that the FDA is forgetting its responsibility to safeguard the U.S. food supply in its enthusiastic acceptance of GMOs and that this raises questions as to the safety of all genetically modified foods approved by the FDA. Dale Kasler, *Tortilla Maker Recalls Products*, SACRAMENTO BEE, Oct. 14, 2000, at A1. *But see* Kaufman, *supra*, at A2 (recounting the statements of biotech industry officials that Genetic Id, the independent laboratory who made the findings, had been incorrect in their detection of genetically modified material in a product at least once before). An independent test by Peggy Lemaux, a biotech expert at the University of California, Berkeley, showed that a person would have to eat "over 100,000" taco shells before experiencing an allergic reaction. Kasler, *supra*, at A1.

86. *See* Burros, *supra* note 8, at A18.

87. *See* Taylor, *supra* note 85, at 27; *see also* Alexandra Marks, *U.S. Poised for a Biotech Food Fight*, CHRISTIAN SCIENCE MONITOR, Nov. 17 1999, at 1 (observing that while the FDA requires strict tests and procedures before approving new foods, it only recommends a consultation by biotech companies bringing a GMO to market, as long as the GMO has not significantly altered the food from its conventional counterpart).

post-market authority to ensure the safety of foods, most companies voluntarily consult with the FDA before marketing their products.[88] Despite the minimal testing conducted by the FDA, the United States' food safety system has worked very well and is internationally respected.[89] Parties tend to adhere to FDA standards because of the potential legal liabilities and the agency's practice of reviewing information given by the party introducing a GMO.[90]

Contrary to the Regulation within the EU that requires the labeling of any food containing significantly traceable amounts of GMOs,[91] the FDA only requires labeling of genetically modified foods if the composition of the food differs significantly from the food from which it was derived or if it may pose a health threat.[92] The U.S. Congress may consider a bill for the mandatory labeling of foods containing GMOs, similar to the EU's "Novel Food Regulation." However, the U.S. Secretary of Agriculture has stated that federal requirements for labeling are unlikely.[93]

C. *World Trade Organization*

While the United States and the EU are free to govern trade within internal markets, membership in the WTO subjects both of these regional trade entities to the WTO Agreement's international trade regulations.[94] A WTO member may impose stronger safety measures than those required to meet international standards.[95] International standards are defined by the Codex Alimentarius Commission

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88. *See* United States Trade Representative, U.S. Regulation of Products Derived from Biotechnology http://www.ustr.gov/reports/index.html (visited Nov. 22, 1999).

89. *See* Taylor, *supra* note 85, at 28.

90. *See id.* (noting that most consumers realize that outbreaks of food borne illnesses or other food safety problems can never be totally eliminated).

91. *See supra* notes 57-62 and accompanying text (discussing Regulation No. 258/97).

92. *See* Nelson, *supra* note 12, at 51. For instance, if a genetically modified food contains a protein from a nut or some other common allergen, a label must be included to warn people that may be susceptible to an allergic reaction from ingesting the food. *See* Stewart & Johanson, *supra* note 36, at 250-51.

93. *See* James Cox, *Bio-foods Backlash: European Biotech Companies, Under Siege for Altering Food Genes, Warily Watch Opposition Grow in the USA*, USA TODAY, Jan. 13, 2000, at 2B.

94. *See supra* notes 22-24 and accompanying text (describing the formation of the regional and global trade agreements); *see also* Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex Ia, art. 3, para. 1, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 31; 33 I.L.M. 81 (1994) [hereinafter SPS Agreement] (emphasizing the necessity for uniform standards). Article 3.1 of the Agreement reads: "To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided for in this Agreement, and in particular in paragraph 3." *Id.*

95. *See* David A. Wirth, *International Decisions: European Communities -- Measures Concerning Meat and Meat Products. WTO Doc. WT/DS26/AB/R & WT/DS48/AB/R. World Trade Organization Appellate Body, January 16, 1998*, 92 A.J.I.L. 755, 758 (1998).

(Codex),[96] the International Office of Epizootics (OIE),[97] the International Plant Protection Convention (IPPC),[98] and other international organizations identified by the WTO Committee on Sanitary and Phytosanitary Measures.[99] The establishment of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)[100] allows WTO members to impose stronger measures, but only when there is sufficient "scientific justification" to support a member's determination that there is a need for stricter standards.[101] This requirement is intended to prevent agricultural protectionism by a WTO member who may be seeking to evade its free trade commitments to other member countries.[102] The existence of a verifiable standard removes the ability of a member country to inhibit free trade by a mere assertion unsupported by science.

In order to scientifically justify safety measures in excess of international standards, the SPS Agreement requires a "risk assessment" to evaluate the likelihood of adverse biological and economic consequences.[103] The risk assessment must be

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96. The Food and Agricultural Organization (FAO) of the United Nations and the World Health Organization (WHO) founded the Codex in 1962 to establish international standards for foods and their relation to human health. Terence P. Stewart & David S. Johanson, *The SPS Agreement of the World Trade Organization and International Organizations: The Roles of the Codex Alimentarius Commission, the International Plant Protection Convention, and the International Office of Epizootics*, 26 SYRACUSE J. INT'L L. & COM. 27, 41 (1998) [Hereinafter *Roles of International Organizations*]. The standards may concern additives, contaminants, veterinary drugs, and pesticide residues in foods. *Id.* The Codex utilizes committees, made up of delegates from its 162 member countries, to research and propose standards. *Id.* Then, an eight-step process takes place, which gives members an opportunity to comment on the proposals. *Id.*

97. The OIE is the oldest veterinary association in the world and is comprised of 151 countries. *Id.* at 49. Since 1924, the OIE has set advisory international standards involving the trade of animals and animal products. *Id.* Unlike the Codex and the IPPC, the OIE was not created by nor does it act through the authority of the United Nations. *Id.*

98. The FAO created the IPPC to oversee and coordinate international efforts with regard to the control of plant species and related issues. *Id.* at 46. The IPPC was principally established to determine international standards for plant issues. *Id.*

99. *See* Warren Maruyama, *A New Pillar of the WTO: Sound Science*, 32 INT'L LAW. 651, 668 (1998) (noting that Article 3.1 of the SPS Agreement requires WTO members to adopt international measures if they exist).

100. SPS Agreement, *supra* note 92.

101. Wirth, *supra* note 95, at 757. Article 3.3 of the SPS Agreement states:

> Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5. Notwithstanding the above, all measures which result in a level of sanitary or phytosanitary protection different from that which would be achieved by measures based on international standards, guidelines or recommendations shall not be inconsistent with any other provision of this Agreement.

SPS Agreement, *supra* note 92, art. 3, para. 3.

102. Maruyama, *supra* note 99, at 665.

103. *See* Wirth, *supra* note 95, at 758. The SPS Agreement attempts to harmonize the efforts of member countries in the setting of particularized national or regional standards and article 5.1 states generally: "members shall ensure that their sanitary or phytosanitary measures are 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 organisations."

based on an examination and evaluation of available scientific information.[104] The test for determining if a risk assessment is sufficient to permit the imposition of a protective measure is whether there is a "rational relationship" between the measure and the risk assessment.[105]

A WTO member who provides a sufficient scientific justification to impose a higher level of protection for the "human, animal or plant life or health within its territory" is not immune from challenge. If a nation's measures conform to international standards, the SPS Agreement states that they are "deemed to be necessary . . . and presumed to be consistent with [the Agreement]."[106] However, the presumption that international standards are consistent with the level of protection allowed by the SPS Agreement is rebuttable, and a nation may challenge the sufficiency of the international standards that presumptively define the maximum acceptable requirements for the imposition of protective measures.[107] Therefore, stricter protective national measures, as justified by a risk assessment, are likely more susceptible to challenge if applied beyond presumptively acceptable international standards.

SPS Agreement, *supra* note 92, art. 5, para.1.

104. *See* Wirth, *supra* note 95, at 757. Article 5.2 of the SPS Agreement requires consideration of what is currently scientifically known. *See* SPS Agreement, supra note 92, art. 5, para. 2. "In the assessment of risks, Members shall take into account available scientific evidence; relevant processes of specific diseases or pests; existence of pest-or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment." *Id.*

105. Steve Charnovitz, *Environment and Health Under WTO Dispute Settlement*, 32 INT'L LAW. 901, 915 (1998). Article 5.5 of the SPS Agreement attempts to harmonize international and individual standards by requiring reasonableness. *See* SPS Agreement, *supra* note 92, art. 5, para. 5. It states:

> With the objective of achieving consistency in the application of the concept of appropriate level of sanitary and 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.

Id.

106. Charnovitz, *supra* note 105, at 913. Article 3.2 of the SPS Agreement confirms the validity of a nation's standards where the nation has adopted international standards. *See* SPS Agreement, *supra* note 92, art. 3, para. 2. as it provides: "Sanitary or phytosanitary measures which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this Agreement and of the GATT 1994."
Id.

107. Charnovitz, *supra* note 105, at 913-14.

III. CONFLICTING POLICIES

A. Bone of Contention

The EU is working to harmonize standards in an effort to establish a "Single Market" for the member states.[108] The U.S. Department of Commerce estimates that the EU's effort will eventually affect fifty percent of U.S. exports to Europe.[109] Currently, the EU and the United States are one another's single largest trading partner, each responsible for nineteen percent of its counterpart's exports.[110] Because the EU's combined population is over 370 million and the U.S. population is 265 million, this trading relationship is vital to their respective economies.[111]

In 1998, the United States lost $200 million in corn sales alone because of delays in the EU's approval process for GMOs.[112] In a statement to EU officials last fall, U.S. Commerce Undersecretary David Aaron claimed that because the EU did not have the scientific grounds to reject products containing GMOs, it had resorted to "a variety of ploys and political maneuvers to delay and deny" the product's approval.[113] The circumstances surrounding the dispute over GMOs are substantially embodied by the conflict between the EU and the United States over the use of hormones in beef production.[114]

B. The Beef-Hormones Dispute

In 1980, the illegal use of hormones in veal production caused hormonal irregularities in some European children.[115] The EU then banned the use of hormones for anything other than therapeutic reasons in an effort to restore

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108. U.S. TRADE REPRESENTATIVE, 1999 TRADE POLICY AGENDA AND 1998 ANNUAL REPORT OF THE PRESIDENT OF THE UNITED STATES ON THE TRADE AGREEMENTS PROGRAM 217 (1999), *available at* http://www.ustr.gov/reports/tpa/1999/index.html.

109. *See id.*

110. THE EU COMM. OF THE AM. CHAMBER OF COMMERCE IN BELGIUM, Business Guide to EU Initiatives 1998/1999, ch. 10 (1998), LEXIS, Europe Library, EUINIT File [hereinafter BUSINESS GUIDE TO EU INITIATIVES 1998/1999]. Trade between the EU and the United States supports an estimated six million jobs. *Id.*

111. George, *supra* note 4, at 112 n.6; *see also* Nelson, *supra* note 12, at 1 (commenting that in 1998, the EU imported $1.5 billion worth of soy products from the United States).

112. BUSINESS GUIDE TO EU INITIATIVES 1998/1999, *supra* note 110, at ch. 10.

113. James Cox, *supra* note 93, at 2B (quoting Undersecretary Aaron's assertion that GMOs are so safe that "not one sneeze, not one cough, [and] not one rash" has been caused by them).

114. *See Roles of International Organizations*, *supra* note 96 at 34-35 (noting the claims of North American cattle producers that there was no scientific foundation for banning the import of hormone-treated beef). U.S. cattle producers claimed the ban was a protectionist measure for EU beef producers. *See id.* In opposition, the EU stated that beef hormones "might" threaten human health and that science supported its position. *See id.*; *see also* Stewart and Johanson, *supra* note 36, at 290 n.370 (comparing the similarity of a dispute concerning GMOs under the SPS Agreement with the *Beef-Hormones* dispute).

115. Particularly the use of diethylstilbene (DES) which, in some instances, caused babies to develop breasts and begin menstruation. Layla Hughes, Note, *Limiting the Jurisdiction of Dispute Settlement Panels: The WTO Appellate Body Beef Hormone Decision*, 10 GEO. INT'L ENVTL. L. REV. 915, 916 (1998).

consumer confidence in the beef market.[116] In 1995, the United States and Canada, as members of the WTO, employed the dispute settlement proceedings provided under the SPS Agreement to successfully challenge the EU's ban on beef produced with hormones.[117]

1. *Burden of Proof*

The allocation of the burden of proof may be determinative of a party's ability to show whether or not a heightened measure is valid under the SPS Agreement.[118] The complaining party must first establish a prima facie case of an inconsistency with the SPS Agreement.[119] In order to meet the burden of proof, the Dispute Settlement Panel (Panel)[120] in *Beef-Hormones* required that the complaining party sufficiently demonstrate a violation of the SPS Agreement.[121] Satisfying this initial burden creates, what the Appellate Body[122] has termed, a "presumption."[123] A presumption that a violation has occurred must be rebutted by the responding party.[124] The Appellate Body rejected the Panel's finding that when the member country's standards exceeded international standards, the initial burden of proof shifted to the party defending an SPS measure.[125] The Appellate Body believed that the ability of a member to choose its own "appropriate level of protection" is an "important right" embodied in the SPS Agreement and that this right would be

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116. Iain Sandford, *Hormonal Imbalance? Balancing Free Trade and SPS Measures After the Decision in Hormones*, 29 VUWLR 389, 404 (1999).

117. Wirth, *supra* note 95, at 755; *see also* Maruyama, *supra* note 99, at 672.

118. *See* Sandford, *supra* note 116, at 407-08 (explaining that a member state has the right to establish height measures where it can show "justifiable reason" and that placing the initial burden of proof upon that member state would effectively be penalizing it for exercising that right).

119. *See id.* at 407 (discussing the Panel's reliance on the prior ruling by the WTO Appellate Body in a dispute between the United States and India concerning the importation of textiles into the United States); *see also United States–Measures Affecting Imports of Woven Wool Shirts and Blouses from India*, AB-1997-1, WT/DS33/AB/R (Apr. 25, 1997) [hereinafter *Wool Shirts*].

120. A Dispute Settlement Panel consists of three to five individuals appointed from the member states of the WTO and include "well-qualified governmental and non-governmental individuals." Jonathan C. Spierer, *Dispute Settlement Understanding: Developing a Firm Foundation for Implementation of the World Trade Organization*, 22 SUFFOLK TRANSNAT'L L. REV. 63, 69 (1998).

121. *See* Sandford, *supra*, note 113, at 407 (requiring that the claims be sufficiently "substantiated" through factual and legal arguments when showing a violation of the SPS Agreement).

122. The Dispute Settlement Body of the WTO appoints the members of the Appellate Body. Spierer, *supra* note 120, at 77. The representatives, picked from the member countries of the WTO, are experienced in international trade law. *Id.* The duty of the Appellate Body is to review disputes over lower panel decisions regarding the General Agreement on Tariffs and Trade (GATT Agreement), which includes the SPS Agreement. *Id.*

123. *See* Sandford, *supra* note 116, at 407 (noting that the terminology used in *Wool Shirts* concerning the "presumption" of a violation is synonymous with the establishment of a "prima facie" case).

124. *Id.* at 408.

125. *See* Maruyama, *supra* note 99, at 668 (explaining that Article 3.3 of the SPS Agreement, which allows a member to impose higher standards than those recognized internationally where there is scientific justification, is not an exception to the rule that the burden of proof lies with the complaining party); *see also* Sandford, *supra* note 116, at 409.

severely undermined by allocating the burden of proof based upon whether a member conformed to international standards.[126] Only after a complaining party establishes a prima facie case of inconsistency with the SPS Agreement, does the party defending its heightened standards need to show scientific justification for the adopted measures.[127]

2. *Scientific Justification*

Consistent with the findings of the Codex, scientific studies commissioned by the EU found that consumption of the treated beef is unlikely to threaten human health if hormones are administered to cattle in accordance with good animal husbandry practice.[128] Despite these findings, the EU tried to justify its ban on hormone-treated beef by stating that the scientific studies did not remove all possibilities of risk.[129]

The Appellate Body of the WTO upheld the Panel's decision that the basis for imposing greater restrictions on trade under the SPS Agreement could not be a policy of "zero risk."[130] However, the Appellate Body rejected the Panel's ruling that a member's standards must "conform" to rather than be "based on" international standards.[131]

The Appellate Body's reading of the SPS Agreement gives a member state a much broader ability to raise its standards above the level set by international standards, as long as it possesses sufficient scientific evidence.[132] This more generous authority to raise standards is subject to review by dispute settlement

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126. *See* Sandford, *supra* note 116, at 409 (describing the Appellate Body's determination that the policy of harmonization of sanitary and phytosanitary measures that guided the creation of Articles 3.1, 3.2, and 3.3 of the SPS Agreement, did not mandate a reversal of the burden of proof, which would establish an exception to a member state's right to enact heightened standards with "justifiable reasons"); *see also* Maruyama, *supra* note 99, at 668 (quoting the Appellate Body as saying, "It is clear . . . that a decision of a Member not to conform a measure to an international standard does not authorize the imposition of a generalized or special burden of proof upon that Member, which may, more often than not amount to a penalty.").

127. *See supra* note 101 and accompanying text (concerning the requirement of Article 3.3 for "scientific justification" for heightened SPS measures).

128. *See* Maruyama, *supra* note 99, at 667; *see also* Sandford, *supra* note 116, at 405 (stating that the various scientific surveys conducted to research the effects on humans from the residues of hormonal growth promotants in food showed little health risk).

129. *See supra* note 111 (noting that the EU did not want to allow hormone-treated beef into the country because it "might" cause harm).

130. *See* Maruyama, *supra* note 99, at 670; *see also EC Measures Concerning Meat and Meat Products*, WTO Doc.WT/DS26/AB/R, paras. 189, 193 (Jan. 16, 1998) [hereinafter *Hormones Appeal*], *available at* http://www.wto.org/wto/dispute/distab.htm (stating that there is always some degree of scientific uncertainty about whether a given substance will ever have adverse health effects and that this fact alone cannot be found to be the sufficient risk necessary to justify the imposition of trade restrictions).

131. *See* Maruyama, *supra* note 99, at 669 (commenting that where a member state's standards "conform" to international standards, a presumption of their validity under the SPS Agreement is created, but there is no requirement under the rules that the member state's standards must strictly adhere to international standards).

132. *See id.* at 670.

panels and is limited by the requirement that a "rational substantive relationship exist between the risk assessment[133] and the measure adopted."[134] A member does not have to prove that it actually took the risk assessment into account.[135]

A member country need not rely on "mainstream" scientific opinion to establish sufficient scientific evidence as required by the SPS Agreement, but can rely upon what may be a divergent opinion coming from qualified and respected sources.[136] A panel is given a great deal of discretion in determining what constitutes sufficient scientific evidence.[137] Further, in rejecting the Panel's distinction between the factors used to assess a risk and those used to manage a risk, the Appellate Body combined these factors, allowing consideration of social value judgments to support the validity of a risk assessment.[138] The Appellate Body stated,

> It is essential to bear in mind that the risk to be evaluated in a risk assessment under Article 5.1 is not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die.[139]

Even with a liberal reading of what constitutes sufficient scientific evidence on which a member country may base its heightened measures, the Appellate Body

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133. The SPS Agreement defines "risk assessment" as follows:

> The 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 the 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.

SPS Agreement, *supra* note 92, art. 5, para. 1.

134. Wirth, *supra* note 95, at 758; *see also Hormones Appeal*, *supra* note 130, at paras. 192-93 & 253(l); *see also* Maruyama, *supra* note 99, at 676 (stating that the SPS standard is not based on sufficient scientific evidence if it does not bear a rational relationship to the scientific risk assessment that supports it).

135. *See* Charnovitz, *supra* note 105, at 915 (stating such a procedural requirement would be "meddlesome to national decision-making"). If there is a dispute concerning trade restrictive safety measures above international standards, all that must be shown is that a rational relationship exists. *See id.*

136. *See Hormones Appeal*, *supra* note 130, para. 253(j) (observing that the use of a divergent source of scientific information does not in itself indicate the lack of a reasonable relationship between the SPS measure and the risk assessment, especially where there is perceived risk of a clear and imminent threat to public health and safety); *see also* Wirth, *supra* note 95, at 758.

137. *See* Wirth, *supra* note 95, at 758 (noting that the Appellate Body will not reverse a Panel's determination of scientific integrity unless the findings amount to a "deliberate disregard of evidence or gross negligence amounting to bad faith" or "deliberate disregard or distortion of evidence").

138. *See* Sandford, *supra* note 116, at 413 (observing that the Panel's separation of the "risk assessment" from "risk management" resulted in stricter guidelines for "sufficient scientific evidence" upon which a member could base protective measures).

139. *Hormones Appeal*, *supra* note 130, para. 187; *see also* Sandford, *supra* note 116, at 413 (commenting that the EU embraced this finding to justify its consideration of consumer concerns in its decision to impose the restriction on hormone-treated beef).

found that the EU's ban on hormone-treated beef was not rationally supported.[140] In the process of finding that the EU did not undertake a valid risk assessment as mandated by Article 5.1, the Appellate Body considered how the verification of acceptable levels of protection should be undertaken.[141]

3. *Appropriate Level of Protection*

The Appellate Body stated that three variables must be shown to determine that the EU had violated the provisions of Article 5.5 that determine the acceptable incorporation of appropriate levels of protection.[142] All three of the following requirements must be met: (1) the member applied different standards of protection for different situations, (2) the differences between the standards are "arbitrary and unjustifiable," and (3) the "arbitrary and unjustifiable" differences result in "discrimination or disguised restriction" on trade.[143] After dismissing the first two issues in the dispute,[144] the Appellate Body agreed with the Panel and concluded that the heightened level of protection applied by the EU to hormone-treated beef was "arbitrary and unjustifiable" because no similar restriction was imposed on the use of two agricultural chemicals[145] that had similar effects as the hormones.[146] The Appellate Body did not, however, affirm the Panel's finding that the invalidated standard was a "disguised restriction on international trade."[147] The fact that the Appellate Body did not challenge the Panel's treatment of the factors indicating a violation, but only challenged the application of the factors to the facts, implies that

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140. *See* Charnovitz, *supra* note 105, at 915.

141. *See* Sandford, *supra* note 116, at 415 (reviewing the Panel's decision regarding the application of Art. 5.5).

142. *See supra* note 105 (reporting the text of Art. 5.5 of the SPS Agreement that relates to acceptable levels of protection).

143. Sandford, *supra* note 116, at 415; *see also* Maruyama, *supra* note 99, at 677.

144. First, the Appellate Body reversed the Panel's decision that the differences between regulating naturally occurring hormones in beef cattle from hormones that had been artificially added proved that the restrictions were arbitrary or unjustified. *See* Sandford, *supra* note 116, at 416. The Appellate Body found that there is a "fundamental distinction" between the two situations and that the intervention necessary to regulate the naturally occurring hormones in beef would be unacceptable. *See id.* The second issue concerned the lack of regulation of hormones administered to cattle for therapeutic reasons. *See id.* The Appellate Body found that the differences between the application of hormones for therapeutic reasons and the application of hormones to fatten up the beef cattle were too great to say that the distinctions were "arbitrary and unjustifiable." *See id.*

145. The EU's lack of restrictions imposed on carbonax and olaquidox allowed unlimited residues of these known carcinogenic chemicals to be present in beef for consumption. Consequently, the Panel found this to be evidence of the EU's protectionist intentions, especially when it professed concern for the possibilities that hormone-treated beef might cause cancer. Maruyama, *supra* note 99, at 677.

146. *See* Sandford, *supra* note 116, at 416-17 (stating that it appears that since the Appellate Body did not consider ways in which measures might be discriminatory toward international trade, a finding that a member state's measures are "discrimination or disguised restriction[s]" is assessed by the effect that the measures have in protecting domestic industry).

147. *See id.*

a violation will only be found where the application of the arbitrary measure has a protective effect on the domestic market.[148]

The result of the Appellate Body's judgment affirms that a trade restriction must have a scientific justification and may not otherwise be disguised as a sanitary measure.[149] Further, even where scientific justification exists to warrant a level of protection higher than international standards, any restriction imposed may not be greater than that necessary to protect against the particular risk.[150] The Appellate Body also concluded that a member state's standards need not "conform to" international standards.[151] Instead, the Appellate Body upheld a member state's right to find risks greater than those recognized by international standards, provided the finding is supported by an objective risk assessment.[152]

The Panel and the Appellate Body both agreed with the EU's argument that the "precautionary principle"[153] is embodied within Article 5.7[154] of the SPS Agreement, which states that there may be a provisional application of an SPS measure "in cases where relevant scientific evidence is insufficient."[155] However, the reviewing bodies both rejected the EU's invocation of the "precautionary principle."[156] Upon finding that the status of the "precautionary principle" in international law remains undecided, the Appellate Body refused to rule that a precautionary measure could override the risk assessment requirements of Articles 5.1 and 5.2 and be implemented without sufficient scientific evidence to support its necessity.[157]

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148. *See id.*

149. *See* Nelson, *supra* note 12, at 98.

150. *See id.* (commenting that these limitations upon a member state's ability to impose restrictions at a heightened level of protection also apply to sanitary measures that existed before the adoption of the SPS Agreement).

151. *See supra* note 131 and accompanying text (stating that there is no requirement for a complete adoption of international standards for food safety regulations).

152. *Id.* (maintaining that even though the EU's ban on hormone-treated beef was invalidated by the decision of the relevant dispute settlement bodies of the WTO, that the affirmation of a right to impose higher standards was an important victory for the EU).

153. *See infra* notes 156-70 and accompanying text (defining the "precautionary principle").

154. The formulation of the "precautionary principle" as found within the SPS Agreement is as follows:

> In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.

SPS Agreement, *supra* note 92, art. 5, para. 7.

155. Hughes, *supra* note 115, at 931, 932; *cf.*, Maruyama, *supra* note 99, at 667 (commenting that there may be an exception under Article 5.7 for provisional regulations where there is scientific uncertainty).

156. Sandford, *supra* note 116, at 426; *see also* Wirth, *supra* note 95, at 758.

157. *See* Charnovitz, *supra* note 105, at 913 n.89 (stating that the United States' and Canada's success in having the "precautionary principle" rejected might backfire on efforts to convince developing countries to prevent global warming by failing to prevent industrial emissions before irreversible damage results); *see also* Hughes, *supra* note 115, at 918, 919; *see also* Wirth, *supra* note 95, at 758-59.

However, the Appellate Body did not discount the possibility that the "precautionary principle" could become a relevant doctrine of international law.[158]

IV. THE "PRECAUTIONARY PRINCIPLE"

A. *Origin and Meaning of the "Precautionary Principle"*

After several years of ineffective regulation, accumulations of toxic substances contaminated the world's atmosphere, oceans, rivers, and subsequently the tissues of plants, animals, and humans.[159] The "precautionary principle" was originally conceived as a rule to control pollution.[160] The basic premise of the principle is that where there is a "threat of serious or irreversible damage," even in the absence of clear evidence of harm or risk of harm, governments should take precautions to protect public health and the environment, regardless of the costs of such action.[161] On a localized level, the "precautionary principle" imposes a substantive duty of care within a nation or among parties in a regional international agreement; this duty requires environmental impact assessments or other regulatory investigations before permitting actions that may be potentially harmful to the environment.[162]

On a global level, international obligations impose a duty on nations to avoid damaging the environments of other nations.[163] This international duty, however, has not been applied where a nation has not taken precautionary measures.[164]

The first significant recognition of the "precautionary principle" as a method of protecting the environment occurred during the United Nations Conference on

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158. Charnovitz, *supra* note 105, at 913 n.89.

159. *See* Naomi Roht-Arriaza, *Precaution, Participation, and the "Greening" of International Trade Law*, 7 J. ENVTL. L. & LITIG. 57, 61 (1992) (claiming that after the environment becomes polluted, the only effective response is complete elimination of the source of pollution rather than a mere reduction).

160. *See* Catherine Tinker, *Is a United Nations Convention the Most Appropriate Means to Pursue the Goal of Biological Diversity?: Responsibility for Biological Diversity Conservation Under International Law*, 28 VAND. J. TRANSNAT'L L. 777, 793 (1995) (discussing the origin of the "precautionary principle" as the international application of the German law principle of precautionary action (vorsorgeprinzip) and as a duty to avoid risk of harm).

161. *See id.* at 793-94 (noting that several United Nations documents advocate the use of the precautionary principle where there are "threats of serious or irreversible damage" and that a "lack of full scientific certainty shall not be used as a reason [to] postpon[e]" preventive action); *see also* Frank Cross, *Paradoxical Perils of the Precautionary Principle*, 53 WASH. & LEE L. REV. 851, 851 (1996) (stating that the "precautionary principle" simply reflects the old saying, "better safe than sorry").

162. *See* Tinker, *supra* note 160, at 793 (noting that the imposition of a duty before the occurrence of any environmental harm could be used as a theory and justification for environmental strict liability which would compensate victims for harms caused by a lack of precaution).

163. *See* Tinker, *supra* note 160, at 797 (commenting that the Stockholm Declaration of 1972 created an international principle of state responsibility to compensate victims of pollution or other environmental damage).

164. *See Hormones Appeal*, *supra* note 127, para. 123 (stating that the "precautionary principle" has not been authoritatively accepted as a doctrine of international law); *see also* Tinker, *supra* note 160, at 786.

Environment and Development (UNCED) in 1992.[165] The Rio Declaration of the UNCED stated a version of the "precautionary principle" in Principle 15, which provides that "[i]n order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."[166] In addition, the United Nations Convention on Biological Diversity (CBD) also resulted from the UNCED.[167] The CBD treaty included the "precautionary principle" within its preamble, but changed the command "shall" to "should" and did not limit its guidelines to measures that were "cost-effective" or within the "capabilities" of treaty's signatories.[168]

The main difference between the CBD's and the Rio Declaration's formulations of the "precautionary principle" is that the Convention removed from consideration the cost of precautionary measures in relation to the environmental harm caused, a major factor in the Rio Declaration.[169] Unlike the Rio Declaration, which would allow costs to prevent the application of a precautionary measure, the language in the CBD's treaty would not restrict the "precautionary principle" by economic factors.[170] However, use of the term "should" indicates that the CBD's directive to take precautionary action is only a guideline and not an absolute command; it is a suggestion that countries not eschew instituting protective measures because of a lack of scientific evidence.[171] There is insufficient proof of the existence of an

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165. *See* Chris W. Backes & Jonathan M. Verschuuren, *The Precautionary Principle in International, European, and Dutch Wildlife Law*, 9 COLO. J. INT'L ENVTL. L. & POL'Y 43, 46 (1998) (commenting that prior to the UNCED, the "precautionary principle" had only been recognized internationally only for a number of specific treaties relating to the protection of water quality and the ozone layer).

166. Rio Declaration on Environment and Development, UConference on Environment and Development, June 15, 1992, UNCED Doc. A/CONF.151/5/Rev.1, princ. 15, *reprinted in* 31 I.L.M. 874 (1992) [hereinafter Rio Declaration]; *see also* Backes & Verschuuren, *supra* note 165, at 49.

167. *See* Backes & Verschuuren, *supra* note 165, at 46.

168. *See* United Nations Convention on Biological Diversity, June 5, 1992, S. Treaty Doc. No. 20, pmbl., para. 9 (1993), *reprinted in* 31 I.L.M. 818 (1992) [hereinafter Convention on Biological Diversity]; *see also* Roht-Arriaza, *supra* note 154, at 793-94; *see also* Tinker, *supra* note 160, at 796 (maintaining that if a treaty uses "should" and not "shall," a state that violates the treaty provision is not bound and therefore is not liable for the violation).

169. *See* Backes & Verschuuren, *supra* note 165, at 50.

170. *Id.* at 52.

171. *See id.* A justification for foregoing a requirement of "scientific certainty" is within the language of the preamble which provides:

> Aware of the general lack of information and knowledge regarding biological diversity and of the urgent need to develop scientific, technical and institutional capacities to provide the basic understanding upon which to plan and implement appropriate measures,
>
> Noting that it is vital to anticipate, prevent and attack the causes of significant reduction or loss of biological diversity at source,
>
> Noting also that where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat....

Convention on Biological Diversity, *supra* note 168, at 818-22.

international rule of law when the language of an international agreement is not binding nor intended to be binding.[172] Because the CBD treaty is merely a guideline for the implementation of precautionary measures, no legal duty is imposed upon states to adhere to the treaty's advice–that precautionary measures "should" be implemented despite a lack of sufficient scientific evidence if there is some evidence of possible irreversible harm.[173]

B. The Cartagena Protocol of the Convention on Biological Diversity

During the last week of January 2000, delegates from 140 countries participated in the fifth meeting of the Conference of the Parties of the Convention on Biological Diversity[174] in Montreal. The Montreal agreement, called the "Cartegena Protocol,"[175] may be a sign that the application of the "precautionary principle" to the international trade of GMOs is becoming a rule of international law.[176] The Cartegena Protocol, which opened for signature at the full Convention in Nairobi in May 2000,[177] requires exporters of "live" GMOs, termed "LMOs," to obtain advance permission from the importing country before the initial shipment of the particular LMO.[178] The EU, along with most other countries in the world, successfully

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172. *See* Tinker, *supra* note 160, at 795 (stating that although states may ratify the language of international documents, without the intent that the language be binding, ratification is not enough in itself to create international law); *see also id.* at 786 (observing that where a state breaches an international duty it accepted as binding through a treaty, the breach is an "internationally wrongful act" that subjects the state to liability).

173. *See supra* note 168 and accompanying text (explaining that the language of the CBD treaty does not create a binding duty to implement the precautionary principle where there is a lack of scientific certainty of harm). *But see* Backes & Verschuuren, *supra* note 165, at 52 (noting that Article 14 of the Biodiversity Convention does impose a duty to carry out an environmental impact assessment of proposed projects that are likely to cause harm even though scientific certainty may be lacking).

174. The United Nations Convention on Biological Diversity was formed as a multinational effort to preserve the Earth's biological resources. *See* Tinker, *supra* note 160, at 779. Since the 1992 Earth Summit in Rio de Janeiro that spawned the treaty, 176 countries have signed this agreement. *See* John Burgess, *Talks to Open on Divisive Issue of Gene-Altered Foods*, WASH. POST, Jan. 24, 2000, at A1848.

175. *See* Bill Lambrecht, *Nations OK Pact on Genetically Modified Foods: Treaty Regulates Technology but Allows Its Use; Monsanto, Greenpeace Hail Accord*, ST. LOUIS POST-DISPATCH, Jan. 30, 2000, at A1 (reporting that the agreement reached in Montreal is called the "Cartagena Protocol" because it is the culmination of five years of negotiation that started in Cartagena, and when the agreement is officially approved by 50 nations, it will become part of the Convention of Biological Diversity); *see also* Pollack, *supra* note 15, at 1.

176. *See Biosafety: Montreal Agreement on Trade in GMOs*, EUR. REP., Feb. 2, 2000, *available at* 2000 WL 8840303.

177. As of September 15, 2000, the "Cartagena Protocol" has been signed by 75 countries and "regional economic integration organizations" (regional trade agreements). Cartagena Protocol on Biosafety, *Signatures to the Biosafety Protocol* http://www.biodiv.org/biosafe/Protocol/index.html (last modified Sept. 15, 2000).

178. *See* Pollack, *supra* note 11, at 1 (reporting that only "living modified organisms" released into the environment, such as seeds that are planted or fish that are put into rivers or lakes, must receive permission before their first introduction into states which are parties to the Agreement). Principle 10 of Annex I of the Montreal Protocol provides:

> No intentional introduction should take place without proper authorization from the relevant national authority or agency. A risk assessment, including environmental impact assessment, should be carried out as part of the evaluation process before coming to a decision on whether or not to authorize a

acquired the right to use the "precautionary principle" for new imports of LMOs.[179] The right to restrict the import of LMOs may not rise to the level of a state's duty to implement precautionary measures, but it does signal a significant shift in the treatment and recognition of the "precautionary principle" in international law.[180] Although the United States has not ratified the original Convention on Biological Diversity,[181] U.S. companies that export to countries participating in the treaty must comply with the treaty's rules.[182] Government officials stated that the United States will honor the treaty once it is signed.[183] The United States, in its status as an observer, led the diplomatic efforts of a group of six of the biggest farm exporters in the world.[184] One key concession the United States received was that the new agreement will not affect previous trade agreements adjudicated within the WTO.[185]

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proposed introduction. States should authorize the introduction of only those alien species that, based on this prior assessment, are unlikely to cause unacceptable harm to ecosystems, habitats or species, both within that State and in neighbouring States. The burden of proof that a proposed introduction is unlikely to cause such harm should be with the proposer of the introduction. Further, the anticipated benefits of such an introduction should strongly outweigh any actual and potential adverse effects and related costs. Authourization of an introduction may, where appropriate, be accompanied by conditions (e.g., preparation of a mitigation plan, monitoring procedures, or containment requirements). The precautionary approach should be applied throughout all the above-mentioned measures.

Conference of the Parties to the Convention on Biological Diversity, Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA), 5th mtg., Annex I, princ. 10, U.N. Doc. UNEP/CBD/COP/5/3 (2000).

179. *See* Bill Lambrecht, *The Deal has been Struck on Gene-Altered Foods, and More Than One Side is Claiming Victory*, ST. LOUIS POST-DISPATCH, Feb. 6, 2000, at A14.

180. *See id.*

181. On June 4, 1993, President Clinton signed the Convention on Biological Diversity, but the United States still has not ratified the treaty. *See* Tinker, *supra* note 160, at 815 n.147 (commenting that President Bush did not sign the Convention in 1992 because intellectual property rights were not sufficiently protected under the treaty). As developing countries established domestic regulations that recognized intellectual property rights, the issue lost much of its importance, as evidenced by the U.S. President's willingness to sign the agreement. *See id.*; *see also* Pollack, *supra* note 11, at 1.

182. *See* Pollack, *supra* note 11, at 1 (noting that the United States cannot become a party to the Cartegena Protocol because it is not a party to the original Convention on Biological Diversity concluded in Rio de Janeiro in 1992).

183. *See id.*

184. *See* Burgess, *supra* note 174, at A8 (reporting that the group of farm exporting nations, called the "Miami Group," consisted of Canada, Chile, Argentina, Uruguay, Australia, and the United States).

185. *See* Lambrecht, *supra* note 173, at A14 (stating that due to this concession, the treaty will not give nations unlimited authority to terminate existing agreements, which could potentially restrict the shipment of billions of dollars of genetically modified products that have been previously approved).

V. THE CONFLICT BETWEEN THE "PRECAUTIONARY PRINCIPLE" AND FREE TRADE

In this era of free global trade, trade law has been directly opposed to the foundation upon which the "precautionary principle" is based.[186] Trade restrictions intended to protect a country's domestic industry have been found to be direct violations of free trade laws.[187] Critics opposed to the "precautionary principle" claim that it will in effect contravene the principles of free trade and give other nations an indiscriminate right to reject biotechnology in the future.[188] Even where there is sufficient scientific evidence to satisfy international standards, a country could still conceivably impose precautionary measures simply because it does not believe the science.[189] Under a regulatory scheme that utilizes the "precautionary principle" for the approval of imported goods, a country may interpose what is arguably a purely subjective justification for restricting the importation of a product that cannot be shown to have zero risk.[190]

In an attempt to create a balance between the goals of free trade and respect for a country's legitimate safety concerns, the WTO Appellate Body in *Beef-Hormones*[191] only required that there be a "rational relationship" between the "risk assessment"[192] and the member state's adopted safety measures.[193] The EU has ignored the rationale of this scientifically based principle and has adopted a principle based on zero risk.[194] Under the EU's formulation of safety measures, the reasonable level of proof required under the *Beef-Hormones* decision to enact safety measures

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186. *See* Roht-Arriaza, *supra* note 156, at 63 (remarking that the free trade approach of "grow now, pay later," which maintains the need for economic growth before a country will be able and willing to spend on environmental regulations, will lead to irreversible environmental degradation).

187. *See id.* at 70 (commenting that a violation may be found even where national regulations treat imported and domestic products equally because the effect of these regulations incidentally favor the domestic industry).

188. *See* Lambrecht, *supra* note 173, at A14 (noting that critics claim that the policy of precaution could "take us back to the 19th century" when no scientific reasons were required to restrict the free trade of genetically modified products).

189. *See id.*

190. *See* Sandford, *supra* note 116, at 426-27 (stating that the EU's invocation of the "precautionary principle" in the *Beef-Hormones* dispute shifted the focus away from the uncertainty of scientific knowledge, upon which the necessity of the "precautionary principle" was postulated, to a new level based on an aversion to scientific data); *see also supra* notes 124-25 and accompanying text (explaining that a risk assessment cannot be based on a requirement that there be a complete absence of risk).

191. *See supra* notes 115-55 and accompanying text (outlining the findings of the Appellate Body regarding what is required to restrict the importation of any good under the SPS Agreement and in particular "altered" foods).

192. *See supra* note 104 and accompanying text (defining the meaning of a "risk assessment" under Article 5.1 of the SPS Agreement).

193. *See supra* notes 129-38 and accompanying text (noting a member state is not procedurally required to prove that it "actually" took a "risk assessment" into account when enacting heightened measures, but only that a "rational relationship" exists between the assessment and the measures).

194. *See supra* notes 71-72 and accompanying text (reporting the recommendation of the European Council to amend Directive 90/220 to require the demonstration of no adverse effects before any further GMO may be authorized to enter the EU market).

higher than those suggested by international standards is eliminated.[195] The EU's justification for adopting the "precautionary principle" is that it allows the regulatory authorities to take consumers' concerns into account.[196] However, what drives consumers' concerns is a distrust of the motives of their regulatory authorities, the honesty of their politicians, and the objectivity of their scientists rather than fear of any genuine danger created by GMOs.[197] Contrary to the allocation of the burden of proof among parties in a free market,[198] the "precautionary principle" requires the placement of the burden of proof upon the party attempting to introduce a new product into the international market. Requiring the importing party to show that there is no unacceptable scientific risk, as the "precautionary principle" requires, may be an insurmountable task where the importing country is the arbiter of what is acceptable.[199] The ability of a country to arbitrarily deny the import of a good, regardless of the validity of any scientific evidence as to the safety of the product, is of great concern to the United States due to the enormity of the United States' commitment to the production of GMO crops.[200] Beyond the dispute over the trade of GMOs, use of the "precautionary principle," which lacks the requirement of scientific justification to support a trade restriction, may undermine the incentive to develop any technological advancements in the production of food by restricting access to the global market.[201]

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195. *See supra* notes 125-23 and accompanying text (mentioning the Appellate Body's opinion that in deference to the right of a member state to choose its own "appropriate level of protection," which is a vital part of the SPS Agreement, after a complaining party establishes a prima facie case, the sole requirement of proof for the member state is to show a "relationship" between the heightened measures and the risk assessment).

196. *See* Nelson, *supra* note 12, at 58 (explaining that because of a lack of public confidence in government and government-sponsored science, the EU is not willing to test its credibility with the European people by endorsing the acceptance of GMOs); *see also* Stewart & Johanson, *supra* note 36, at 294 (questioning whether the EU is protecting its consumers' genuine concerns about GMO products or whether its recently enacted policies are only a political reaction to public fears following the "mad cow disease" scare).

197. *See* Nelson, *supra* note 12, at 73 (stating that only 25% of people surveyed trusted their national governments or EU authorities to tell them the truth about their food supply); *see also supra* notes 4-8 and accompanying text (referring to the confusion generated by the variety of safety standards among the EU and the national governments that comprise the EU).

198. *See* Roht-Arriaza, *supra* note 159, at 65 (remarking that in a free trade context, e.g., the GATT Agreement, the burden of proof is upon the party defending the enactment of a protective measure (i.e., Europe) to show that the measure is necessary and supported by a provable risk to human, animal, or plant health); *see also supra* Part III.B.1. (reporting that the Appellate Body decision in the *Beef-Hormones* dispute required that after a prima facie case demonstrating a violation of the SPS Agreement is established, a showing of sufficient scientific evidence to support a risk assessment must be proven before a trade restriction in excess of the protection mandated by international standards can be imposed).

199. *See* Nelson, *supra* note 12, at 79 (describing the viewpoint that if restrictions are based on adverse consumer reaction, rather than a system of scientific justification that is understandable, transparent, and reasonably constant, protectionism may be unavoidable).

200. *See supra* notes 9-11 and accompanying text (commenting on the economic significance of the trade relationship between the United States and the EU).

201. *See* Jonathan H. Adler, *More Sorry Than Safe: Assessing the Precautionary Principle and the Proposed International Biosafety Protocol*, 35 TEX. INT'L L.J. 173, 204 (2000) (stating that use of the "precautionary principle" results in domestic protectionism that undermines the international trade necessary to promote the economic growth needed to support both technological development and a "willingness-to-pay" for environmental

VI. CONCLUSION

The EU's adoption of the "precautionary principle" for GMOs resulted in the principle being included within a world-wide treaty. The adoption of the "precautionary principle" is an overreaction to the public's resistance to GMOs, which is a result of the public's distrust of science and governmental regulation. The answer is not to adopt a vague system of regulation that may inevitably lead to protectionism, but to build the public's trust in a system with a clear set of standards based on science. The present system of regulation under the SPS Agreement works, but in order to gain the public's trust from the outset, there must be complete and open public involvement in the implementation of the system. An open market benefits all participants, but a nation must have the right to restrict trade when there may be a risk to its people and its environment. The risk, however, cannot be supported by unfounded fears resulting from unrelated tragedies, such as mad-cow disease[202] or the unlawful administration of hormones to veal.

U.S. Supreme Court Justice Oliver Wendell Holmes stated:

> Great cases, like hard cases, make bad law. For great cases are called great, not by reason of their real importance in shaping the law of the future, but because of some accident of immediate overwhelming interest which appeals to the feelings and distorts the judgment. These immediate interests exercise a kind of hydraulic pressure which makes what previously was clear seem doubtful, and before which even well settled principles of law will bend.[203]

Such is the case here where concerns for consumers' fears are being used to create a regulatory system for global trade that cannot simultaneously achieve the goal of free trade. The argument may not be so much about what constitutes sufficient science to protect the world's environment or human health as it is about how far a nation may go to protect its own market.

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protection). Examples of the benefits derived from GMOs include the decrease in the use of pesticides for, and the increased productivity derived from, the reduction in crop damage of Bt corn due to its pest-resistant attributes. *See id.* at 200. Also, the improved nutrition of some GMOs increases the ability of these foods to efficiently feed the world. *Id.* In order to meet the demands of a world population that will reach 10 billion this century, an alternative to using GMOs to increase agricultural productivity may be to increase the amount of cropland utilized. *See id.* at 201-02. However, the loss of habitat resulting from conversions of undeveloped land including the world's forests into cropland, is a continuing harm to the environment and may result in the extinction of at least one quarter of the species alive today. *See id.* at 201.

202. *See supra* note 2 (explaining "mad-cow disease" and the suspected link between the epidemic and the practice of feeding cattle the ground-up remains of sheep and other cattle).

203. Northern Securities Co. v. United States, 193 U.S. 197, 400-01 (1904) (Holmes, J., dissenting).

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