Genetically Modified Organisms and International Trade: Precaution or Protectionism?

Lucy Khairy*

Man's ability to alter his environment has developed far more rapidly than his ability to foresee with certainty the effects of his alterations. It is only recently that we have begun to appreciate the danger posed by unregulated modification of the world around us, and have created watchdog agencies whose task it is to warn us, and protect us, when technological 'advances' present dangers unappreciated or unrevealed - by their supporters. Such agencies, unequipped with crystal balls and unable to read the future, are nonetheless charged with evaluating the effects of unprecedented environmental modifications, often made on a massive scale. Necessarily, they must deal with predictions and uncertainty, with developing evidence, with conflicting evidence, and, sometimes, with little or no evidence at all.[1]

Introduction

Globalization is the term used to refer to a world economy – one in which capital, commodities, consumer goods and credit flow across apparently seamless trading networks. In 1994, the passage of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) in United States and other countries, along with the parallel establishment of the World Trade Organization (WTO), thrust globalization to the forefront of the economic landscape and brought with it change as dramatic as the Industrial Revolution.[2] Several divergent areas of debate developed as a result of the concerted push toward globalization – standardization of monetary and educational systems, economic and job stability, and the strain on natural resources and the environment to mention a few.[3] However, in recent years, biotechnology moved beyond debate and emerged as a serious fissure on the façade of the touted successes

---

* Lucy Khairy is corporate counsel for Brylane Inc., part of the French conglomerate Pinault-Printempms-Redoute (PPR). The views expressed herein are the author's own and do not reflect the views of Bryland, PPR, or their associates.

1 *Ethyl Corp. v. EPA* , 541 F.2d 1, 6 (D.C. Cir. 1976).

2 Jerry Mander, *Facing the Rising Tide*, in Jerry Mander and Edward Goldsmith (eds.), *The Case Against the Global Economy*, 1996, pp. 3-19, at pp. 3-4.

3 Id., at p. 4 -12.

European Journal of Law Reform, Vol. V, No. 1/2, 2003, pp. 241 - 274

of globalization. More specifically, the de facto moratorium, since 1998, by six members of the European Union – France, Denmark, Italy, Greece, Austria and Luxembourg – has created tension between the two giant trading partners – the United States (U.S.) and the European Union (EU).[4] The moratorium is against the importation of any new biotechnologically altered foods, plants or other organisms based on the uncertainty of potential risks to the environment or to the health and safety of it citizens.[5] Fueled by the resistance of these countries to the importation of genetically altered foods and organisms, the concomitant loss of revenue to exporters, and growing consumer stigma associated with genetically altered substances, the producers of genetically modified organisms (GMOs) have pulled away from the negotiating tables.[6] Although this resistance motivated the U.S. to file non-compliance charges against the EU, it had held that action in abeyance, in large part to avoid further aggravation of its European allies regarding the March 2003 invasion of Iraq.[7] However, on 13 May 2003, shortly after President G.W. Bush declared an end to the conflict in Iraq, the U.S. requested WTO consultations to air its frustration with stalled GMO applications and approval.[8] The U.S. announced the failure of the consultations immediately after their close on 18 August 2003 and demanded the WTO to convene a Panel to judicially resolve their challenge to the EU's moratorium on GMO imports.[9] The WTO Panel will determine whether the EU is violating international trade law by its moratorium and its introduction of specific laws[10] designed to address consumer demands regarding the safety of GMOs for human health and the environment.[11]

---

4 Nuala Ahern, *Europe Must Face US Down Over GM Foods,* The Irish Times, 13 June 2003, at p. 16.

5 Frances Williams, *U.S. Fires First Shot at EU Biotech Policy WTO Move,* Financial Times (London), 19 August 2003. Although it is outside of the scope of this paper, it is worthwhile mentioning that there has been significant resistance to biotechnology-derived foods in the United States as well. See, e.g., Paul S. Naik, *Biotechnology Through the Eyes of an Opponent: The Resistance of Activist Jeremy Rifkin*, 5 Va. J.L. & Tech. 5 (2002).

6 Andrew Osborn, *U.S. Escalates GM Food Dispute with Europe,* The Guardian (London), 19 August 2003; *U.S. to Seek WTO Ruling on Biotech Goods Ban,* Los Angeles Times, 20 June 2003; Amy Becker and Lee Egerstrom, *U.S. Use of Genetically Modified Crops Sparks International Food Fight,* St. Paul Pioneer Press, 13 September 2003.

7 *Frankenfood Challenge to Europe Postponed,* Acres USA, April 2003, at p. 5.

8 *European Commission Regrets the Request for a WTO Panel on GMOs,* 2003 Rapid, 18 August 2003.

9 Id. and Williams, supra note 5. The U.S. was joined by Canada and Argentina in its demand to convene the WTO Panel. See Will Beacham, *US, Canada, Argentina Stick with Call for WTO Probe on GMOs*, Chem. News & Intel., 18 August 2003.

10 *EU Support for GMO Rules,* Morgenavisen Jyllands-Posten, 3 July 2003 (hereinafter Morgenavisen).

11 See Ahern, supra note 4.

Based upon WTO Panel and Appellate Body decisions of the recent past, certain observers predict that the U.S. is likely to prevail in this conflict.[12] These observers base their predictions on the application of the 'scientific approach,' required by the WTO/GATT, trumping the 'precautionary principle' defense, embodied in the BioSafety Protocol of Cartegena and invoked by the EU, and the EU's newly adopted laws regulating traceability, labeling and marketing of GMOs and GM-derived food and feed products.[13] This paper contends that while the WTO's so-called 'scientific approach' may possibly trump the precautionary approach when advancing the precautionary principle as customary law – as borne out by previous EU attempts[14] – it may not necessarily be the case if the precautionary principle is used as a procedural standard in international environmental law.

Part I describes the development of genetically modified organisms including the risks and benefits that opponents and proponents of this technology commonly recite to support their positions. Part II sets forth the heart of the controversy between the major trading partners and points out that it is based in large part on their divergent approaches to biotechnologically modified substances. Moreover, this part highlights the different aims that these giant trading partners wish to achieve regarding the acceptance of such substances. Part III presents details of the relevant laws and treaties that could be used to settle this dispute. Part IV discusses the status of the precautionary principle: customary law or procedural standard? It concludes that the precautionary principle can be applied more successfully when used as a standard through which the EU could advance its position, possibly to prevail in the current clash of wills being played out between the EU and the US regarding GMOs.

I. Background

A. Development of Genetically Modified Organisms

Genetic manipulation is not new. Although used for centuries as a technique to enhance preferred or favorable traits of agricultural products and in animal husbandry,[15] the Austrian monk and botanist, Gregor Mendel is credited with founding modern

---

12 Herbert Smith, *US Prepares for WTO Battle on GM Moratorium,* All Regions (Intellectual Property; Legislation & Regulation Section), 7 February 2003.

13 *Europe Completes Laws Governing Transgenic Food and Feed,* Environment News Service, 23 July 2003.

14 Charles W. Smitherman III, *Comment: World Trade Organization Adjudication of the European Union-United States Dispute Over the Moratorium on the Introduction of New Genetically Modified Foods to the European Common Market: A Hypothetical Opinion of the Dispute Panel,* 30 Ga. J. Int'l. & Comp. L. 475, 498 (2002).

15 Sara M. Dunn, *From Flav'r Sav'r to Environmental Saver? Biotechnology and the Future of Agriculture, International Trade, and the Environment,* 9 Colo. J. Intl. Envtl. L. & Policy, 145, 148 (1998).

genetics in 1865.[16] However, with the advent of biogenetic engineering, the once relatively simple process of influencing natural selection by cross-breeding within members of the same species, has developed into a sophisticated process of genetic material crossing both genera, families, orders, classes, phyla, and kingdoms.[17]

The discovery of the ladder-like, double helix structure of DNA in 1953 by James Watson and Francis Crick, laid the foundation essential to the exploration of biotechnology.[18] Two decades later, researchers Stanley Cohen and Herbert Boyer devised a methodology for transferring genetic data from one living organism to another by breaking genetic molecules and recombining them with other genetic material.[19] Their procedure came to be known as 'recombinant DNA technology.' In the 1980s, researchers began testing this methodology with biotechnologically-derived foods.[20] The first FDA-approved, biogenetically engineered food was the Calgene FalvrSavr® tomato – approved in 1994 – which had been genetically altered to give consumers a more flavorful tomato with a longer shelf life.[21] Soon thereafter, bioengineers began experimenting with corn and soybean crop varieties. The advent of 1996 saw scientists biogenetically incorporating a gene from Brazil nuts into soybeans to enhance the soybeans' protein content.[22] Likewise, scientists 'enhanced' corn by transferring the Bacillus thuringiensis (Bt) gene from soil bacterium into corn plant tissue to make the plant resistant to certain types of insects.[23] Such was the birth of genetically modified organisms (GMOs).

---

16 *The History of Biotech*, available at http://www.dupont.com/biotech/intro/history/1865.html (last visited 13 March 2003).

17 John Charles Kunich, *Mother Frankenstein, Doctor Nature, and the Environmental Law of Genetic Engineering*, 74 S. Cal. L. Rev. 807, 811 (2001).

18 *The History of Biotech*, supra note 16, available at http://www.dupont.com/biotech/intro/history/1953.html (last visited 13 March 2003).

19 See id., available at http://www.dupont.com/biotech/intro/history/1973.html (last visited 13 March 2003).

20 See id., available at http://www.dupont.com/biotech/intro/history/1980.html (last visited 13 March 2003).

21 See Naik, supra note 5, at n. 214. The Flavr Savr tomato was

> 'genetically modified through a process called antisense technology in which the deoxyribonucleic acid (DNA) sequence of one of its genes was reversed. Reversing the DNA sequense of a gene that codes for the enzyme polygalacturonase reduces the amount of the enzyme produced by the plant cells. Because polygalacturonase is required for the synthesis of ethylene, a compound that is necessary for the degradation of pectin and the initiation of ripening, the rate of ripening in the Flavr Savr tomato slowed down. As a result, this GM tomato may be picked red off the vine, yet it remains firm and ripe for many weeks after harvest.'

Sheldon Krimsky and Nora K. Murphy, *Epidemiology and Science: Biotechnology at the Dinner Table: FDA's Oversight of Transgenic Food*, 584 Annals 80, 81 (2002).

22 Ved P. Nanda, *Genetically Modified Food and International Law – The BioSafety Protocol and Regulations in Europe*, 28 Denv. J. Intl. L. & Policy 235, 237 (2000).

23 See Dunn, supra note 15, at p. 151.

The two primary focal points of biotechnology research in the plant and micro-organism areas are enhanced seed systems and transgenic seeds.[24] Enhanced seed systems are those in which the seed and the chemical that 'enhances' it work together by design, such as, Monsanto's Roundup Ready soybeans, which are glyphosate-resistant.[25] In practical terms, enhanced soybean seeds allow farmers to use Roundup Ultra herbicide on their fields without killing the soybeans that genetically contain the antidote to the herbicide.[26] Transgenic seeds function differently. They operate by producing plants that contain their own 'built-in' insecticides designed to kill plant predators or to enhance certain already existing properties, such as oil or sugar content, as well as to resist a normally deadly herbicide.[27] The Bt corn described above allows it to be resistant to certain insects such as the European Corn Borer by internally assembling certain proteins that kill the targeted predator without having any seeming effect on humans, livestock, wildlife or beneficial insects.[28]

The commercial planting of genetically modified (GM) seed crops began in 1995.[29] The rapid increase in acreage planted with GM crops demonstrated their acceptance in farming, particularly in the United States, where in 1997, 20.3 million acres of GM crops were planted.[30] That figure more than doubled in 1998, topping 50.2 million acres, and in 1999 reached over 70 million acres.[31] However, GM crops are not limited to the United States. Other major agricultural producers are Canada, Argentina, Australia, Chile, China, and Uruguay and to some extent Japan and the EU.[32]

B. The Benefits and Risks of GMOs

1. Benefits

Proponents of GMOs claim numerous benefits from this biotechnology. They include, but are not limited to: (1) the inherent efficiency – mostly speed – and error reduction of genetically transferring new and favorable characteristics into new

---

24 See Susan Boensch Meyer, *Land and Resource Management: Genetically Modified Organisms*, 1998 Colo. J. Int'l Envtl. L. Y.B. 102 (1998).

25 See Dunn, supra note 15, at pp. 150-151. Glyphosate is a chemical found in Monsanto's Roundup Ultra herbicide.

26 Id., at p. 150.

27 Ronald E. Yates, *Genetic Engineering Moves into Corn, Soy Beans, "Breakthrough" Seeds Likely to Boost Yields, Transform Industries*, Chi. Trib., 17 March 1996, at p. 1.

28 See Dunn, supra note 15, at p. 150.

29 Kunich, supra note 17, at p. 812.

30 Id.

31 Id. See also, Kirsten N. Jabara, *The BioSafety Protocol*, 8 U. Balt. J. Envtl. L. 121, 126 (2001).

32 Henrique Freire de Oliveira Souza, *Genetically Modified Plants: A Need for International Regulation*, 6 Ann. Surv. Intl. & Comp. L. 129, 141 (2000). The United States is, nevertheless, the largest of GM crop producers, with an estimated 75 percent of all GM crops being grown there. Id.

plants;[33] (2) the increase in crop yields per acre of farm land, thereby allowing more land for the development and protection of biodiversity;[34] (3) the higher profits from higher yields;[35] (4) the improvement of food quality;[36] (5) the decrease in the need for costly and environmentally harmful chemical pesticides;[37] (6) the conservation of natural resources such as fossil fuels used to produce chemical pesticides and fertilizers, as well as fuels used to operate farm equipment that distributes those chemical products;[38] (7) the replenishment of the world's scarce living resources;[39] and (8) the prolonged post-harvest shelf life.[40]

Some examples of these benefits follow. Traditional breeding practices, in contrast with biotechnological genetic modifications, often require growing numerous generations of a substance – up to 12 years – in order to achieve one desired characteristic.[41] Biogenetic- engineering can achieve the same results immediately. The increasing popularity and consumption of fish has steadily depleted the world's fisheries.[42] By using GM fish, reproduction rates are increasing and the fish are engineered to be more resistant to factors contributing to their depletion such as disease and weather changes.[43] Bt corn not only eliminates the need to use costly and dangerous insecticides, but it can thereby contribute to a more than 200 percent return on investment for producers.[44] Likewise, the decreased use of insecticides, herbicides, and fungicides could take the strain off of contaminated air, soil, water and food.[45] Moreover, GM crops that are herbicide resistant, can tolerate higher doses, which adds to increased crop yields and ultimately to increasing the world's food supplies to feed growing populations.[46] With GM crops that produce higher yields per acre, there should be less of a need to expand tillable land requiring the use semi-arid or marginally erodable areas that could threaten destruction of many natural

---

33 See Smitherman, supra note 14, at p. 480.

34 John H. Barton, *Biotechnology, the Environment, and Intellectual Agricultural Trade,* 9 Geo. Intl. Envtl. L. Rev. 95, n. 1 (1996).

35 David J. Earp, *The Regulation of Genetically Engineer Plants: Is Peter Rabbit Safe in Mr. McGregor's Transgenic Vegetable Patch?,* 24 Envtl. L. 1633, 1635 (1994).

36 Carrie F. Walter, Beyond the Harvard Mouse: Current Patent Practice and the Necessity of Clear Guidelines in Biotechnology Patent Law, 31 Intell. Prop. L. Rev. 195, 196 (1999).

37 Karen L. Werner, *Increased Yields, Reduced Use Seen as Result of Use of Engineered Crops,* 22 Intl. Envtl. Rep. (BNA) 626 (21 July 1999).

38 Smitherman, supra note 14, at p. 481.

39 Darren Smits and Sean Zaboroski, *Trade and Genetically Modified Foods: GMOs: Chumps or Champs of International Trade,* 1 Asper. Rev. Intl. Bus. & Trade L. 111, 113.

40 Kunich, supra note 17, at p. 810.

41 Kara-Anne Yaren, *Trade and Genetically Modified Foods: Frankenfears: A Call for Consistency,* 1 Asper Rev. Intl. Bus. & Trade L. 149, 150.

42 See Smits and Zaboroski, supra note 39, at p. 113.

43 Id.

44 See Jabara, supra note 31, at p. 124.

45 See Smits and Zaboroski, supra note 39, at p. 113.

46 See Nanda, supra note 22, at p. 236.

habitats.[47] Destruction of such habitats in turn undermines the earth's biodiversity.[48] GM foods can be manipulated to ripen more slowly, be resistant to frost, and manifest more pleasing colors and tastes to achieve greater consumer acceptance while remaining on the shelves longer.[49] Finally, there is the promise of agri-pharmaceuticals – foods containing drugs or vitamins, such as bananas containing hepatitis vaccines or beta-carotene producing 'golden rice' that converts its beta-carotene into vitamin A in humans to ward off blindness.[50] The promise of these biotechnological benefits needs to be balanced with a number of significant risks.

2. Risks

On the other side of the GMO equation, there are significant ecological, economic, ethical, health and safety risks. From the ecological standpoint, there is the concern that GMOs might disrupt or even destroy natural ecosystems through their intentional release or accidental escape.[51] For example, in England, a test field of GM herbicide-resistant rape-seed oil plant successfully pollinated nearby 'natural' fields,[52] or the revelation in Nature Magazine that claimed native maize in Mexico had been contaminated, across vast distances, by GM pollen.[53] Left unchecked, many fear such pollination might create a new breed of 'superweeds' with the same herbicide resistant genes capable of overtaking and displacing other plant life.[54] This could become a particularly devastating situation for endangered plant species as well as a threat to the biodiversity of a given area and within a given gene pool leading to monoculture.[55] Additionally, it is feared that 'the right to eat GM-free food will be severely compromised if GM crops are grown [on] a large scale.'[56]

GMOs threaten biodiversity in another way. Farmers, attracted by higher yields and lower expenditures for herbicides and insecticides, may come to rely on

---

47 See Yaren, supra note 41, at p. 151.

48 Id., at p. 152.

49 See Nanda, supra note 22, at p. 236. It should be noted that in today's market, often the quality of the colors and tastes of food are created through advertising.

50 See Yaren, supra note 41, at p. 152.

51 Kunich, supra note 18, at p. 816.

52 Id., at pp. 817-818.

53 George Monibot, *The Fake Persuaders: Corporations are Inventing People to Rubbish their Opponents on the Internet*, The Guardian, 14 May 2002.

54 See Kunich, supra note 17, at pp. 817-818. It should be noted that the British government destroyed this test field once they realized that the involuntary pollination had occurred.

55 Id., at p. 819. 'If the transgenic strains crowd out the native varieties, biodiversity would be diminished, with concomitant reduction in the raw material available for future natural selection. With reduced biodiversity comes lessened flexibility to respond to new and different evolutionary pressures, and diminished overall vigor of the ecosystem.' Id. at pp. 819-820.

56 *Europe Completes Laws Governing Transgenic Food and Feed*, Environment News Service, 23 July 2003.

only a few GMO varieties of plants.[57] Canada is a prime example of this type of threat. In its western provinces, farmers first planted GMO canola in 1995, and by 1998 70% of these canola fields contained GMO canola.[58] There are also ecological concerns surrounding the effect of GM plants on the insect world. For example, some laboratory studies have shown that monarch butterfly larvae die when fed GM corn pollen.[59] This not only depletes the Monarch butterfly population, but impacts more generally on the entire ecological balance. Moreover, there is the possible risk that widespread use of GMO seeds and plants may contribute to development of more resistant insects.[60]

The economic concerns are equally chilling. Traditionally, farmers used the inexpensive technique known as 'seed saving' to propagate seeds from one year's crop to produce plants for the next year's crop.[61] Large corporations engaged in seed biotechnology prefer to license the 'patented' seeds to the farmers rather than selling them as they had prior to the time of GM seeds.[62] This creates significant influence and control over agriculture by large companies whose primary motivations are profits and shareholder accountability,[63] not to mention the loss of a millennia old, cost effective system of food propagation. The higher price of 'patented' GMO seeds may adversely affect the survival of smaller family farms and favor the larger corporate agribusinesses whose focus is primarily profit rather than a livelihood.[64] More significantly, however, widespread use of GMOs could undercut major exports of developing countries.[65] Economies of emerging countries that have relied on specific cash crops such as saffron, vanilla, cocoa or coffee, may be severely threatened when, through genetic engineering, these crops can be grown in different countries with previously inhospitable climates.[66] Destroying the fragile and often meager

---

57 See Smits and Zaboroski, supra note 39, at p. 114.

58 Id. Not to mention the danger and fragility of cultivating only one or two varieties as was demonstrated with the potato famine in Ireland in the nineteenth century.

59 Julia Klimova, *Ecological Revolution: Economics, Technology and the Global Environment*, in Laura DePaola, (ed.), *GMO Foods: The Next Ecological Revolution*, Symposium 30 July 2001, available at http://www.geocities.com/portfolio23015/gmo_foods.htm (last visited on 24 March 2003). This study was conducted at Cornell University and found that 'migrating Monarch butterflies were being killed in great numbers because the pollen that was blowing off the genetically modified cornfields onto the nearby milkweed' off which the butterflies fed.

60 *Insects Thrive on GM Pest-Killer Crops*, Acres USA, May 2003, at p. 6. Recently published research results from a study completed by scientists at Imperial College London and the Universidad Simon Rodrigues in Caracas, Venezuela suggest that pests designed to be killed by Bt engineered crops actually thrive on them, growing bigger and faster with a 56 percent higher growth rate.

61 Klimova, supra note 59, at p. 9.

62 Id. Monsanto, until fairly recently used 'terminator' genes in their seeds so that the next generation of seeds produced from the plants of the previous seed would be rendered infertile – preventing farmers from saving seeds. See Nanda, supra note 22 , at p. 241.

63 Id.

64 See Smits and Zaboroski, supra note 39, at p. 115.

65 Id.

66 Id.

competitive advantage enjoyed by these emerging economies could contribute to their downfall,[67] and thus to their increased dependence upon richer nations. The result could also be the destruction of agricultural diversity as a whole and the creation of a virtual monopoly for the few large agribusiness giants.[68] Along with these social and economic risks, there is the political risk of depriving citizens of 'meaningful control over technologies that could transform their lives.'[69]

Viewing GMO's risks from an ethical standpoint, there is the question of whether tampering with nature to such an extent is tantamount to 'playing God.'[70] GMO critics refer to these substances as 'Frankenfoods' recalling Mary Shelley's novel about Frankenstein in which the narrative conveys the dangers of tinkering with life's secrets.[71] Biogenetic engineering represents a new level of human dominance and control over nature, not only from the standpoint of speed, but also breadth of manipulation solely for the benefit of mankind without much consideration of potential long-term effects on other species.[72] Furthermore, the issue of non-disclosure of genetic co-mingling of plant and animal products, raises ethical, moral, and religious concerns for individuals espousing vegetarianism. Without properly labeling GM foods, how is a vegetarian to know the tomatoes or strawberries he eats contain genetic material from arctic fish to enhance their resistance to frost.[73]

Finally, health and safety risks include concerns about unanticipated nutritional changes, unanticipated production of toxins or anti-nutritional factors, and introduction of allergens into foods. Unanticipated changes are possible because genes do not act in isolation, but rather their expression is influenced by the genetic background of the organism in which they function. Thus a gene isolated and introduced into a different organism may cause unexpected changes to occur beyond the production of the compound coded for by that specific gene.[74]

---

67 Id.

68 See Klimova, supra note 59, at p. 3. The three giants of GM seeds and agribusiness are Monsanto, DuPont, and Novartis. Id.

69 Sheila Jasanoff, *Product, Process or Programme: Three Cultures and the Regulation of Biotechnology*, in Martin Bauer (ed.), *Resistance to New Technology: Nuclear Power, Information Technology, and Biotechnology*, 1995, pp. 311 et seq., at p. 313.

70 See Smits and Zaboroski, supra note 39, at p. 114.

71 John S. Applegate, *The Prometheus Principle: Using the Precautionary Principle to Harmonize the Regulation of Genetically Modified Organisms*, Sustainable Development, Agriculture, and the Challenge of Genetically Modified Organisms (Symposium), 9 Ind. J. Global Leg. Stud. 207, 213 (2001).

72 See Klimova, supra note 59, at p. 3. Klimova questions the oft-touted GMO benefit of increasing the world's food supply by stating that it is not food supplies that are lacking but effective distribution of those supplies. Id., at pp. 3-4.

73 Id., at pp. 3-4.

74 See testimony of Dr. Margaret E. Smith, Associate Professor, Dept. of Plant Breeding, Cornell Cooperative Extension, Cornell University, *Testimony for New York Assembly Hearing on Genetically Engineered Crops and Foods Produced from these Crops* (27 September 2000). Recently published research results from a study completed by scientists at Imperial College London and the Universidad Simon Rodrigues in Caracas, Venezuela suggest that pests designed to be killed by Bt engineered crops actually

The concerns of allergy risks include, for example, the protein enhancement of soybeans via introduction of genetic material from Brazil nuts.[75] Tests demonstrated that allergies to Brazil nuts could be triggered by ingestion of such protein-enhanced soybeans.[76] Another health risk is that enhancing protein or any other nutritional element could create internal dietary or assimilation imbalances given that all nutrients work together rather than in isolation.

Distribution mistakes in the recent past have highlighted safety concerns of GMOs. One such incident in Canada was the massive recall of canola seeds by Monsanto because the wrong gene had mistakenly been spliced into them.[77] This is an example of the sort of error the large GMO producers claimed could not occur because of strict testing guidelines,[78] but which could occur with greater frequency as the production and use of GMOs take on global proportions. Another similar incident occurred when GM corn, known as 'Starlink' and specifically modified for use in cattle feed, was mixed with human corn supplies.[79] The 'Starlink' corn that was not approved for human consumption appeared in Taco Bell taco shells and many other food products in the U.S. as well as in food products in Japan even though that country had banned its import.[80] There were massive recalls as well as a switch to the use of white corn, which itself turned out to be contaminated through cross-pollination.[81]

GMO producing and exporting countries focus on their benefits; the importing and smaller or non-producing countries are keenly aware of GMO risks. In the current era of global free trade, the two camps are polarized around two major issues.

---

thrive on them because they are able to digest and utilize the toxin and may be using it as a supplementary food, adding that the presence of the poison 'could have modified the nutritional balance in plants' for them. *Insects Thrive on GM Pest-Killer Crops*, Acres USA, May 2003, at p. 7.

75 Peter N. Spotts, *The Brave New World of Biotechnology and Beyond*, Christian Sci. Monitor, 28 October 1999, at p. 17.

76 Id.

77 *Seed Recall Raises Biosafety Questions*, available at http://www.mtholyoke.edu/courses/jgrosssho/archives/monsanto-canola.html (last visited 30 September 2003).

78 Klimova, supra note 59, at p. 7.

79 Holly Birch, *Corn Not yet OK'd for Use in Food*, The Daily Illini, 28 September 2002.

80 Stephanie Strom, *Gene Modified Corn Turns Up in U.S. Exports To Japan*, N.Y. Times, 25 October 2002, available at http://www.ngin.tripod.com/9.htm (last visited 30 September 2003).

81 Klimova, supra note 59, at p. 8.

II. The Roots of the Controversy: Divergent Standards and Goals

The exuberance and promise accompanying the introduction of GMOs induced their early acceptance in world markets. In 1996, European imports of U.S corn and soybeans, including GM and conventional varieties, reached an all-time high of nearly $3 billion.[82] However, with increasing concern over the potential risks, that figure declined to $1 billion in 1999[83] primarily because of the European Union's de facto failure to authorize import or use of any new GMO products as of March 1998.[84] Since the EU moratorium on importing GMOs, other countries have followed suit.[85] The two central players in this biotechnology standoff are the two largest trading partners in the world today, namely the United States and the European Union.[86] The U.S. claims the EU is using health and safety to disguise a trade barrier; the EU contends the uncertainty of unknown risks warrants application of the precautionary principle to protect its citizens and its environment.[87] The heart of the controversy consists of two major issues: (1) whether and to what degree sovereign nations may control the importation of GMOs based on precautionary standards that constitute an acceptable level of risk of exposure to them; and (2) to what extent the WTO will recognize and accept those standards as legitimate precautions rather than illegitimate protectionism. Underlying the second issue is the question of the extent to which a government can subordinate its social and political policies to an international law promoting free trade while remaining viable and relevant as a representative of its citizens.

These complex issues revealed a hardening of positions on each side and have their roots in a difference between standards and paradigms, as well as a difference between goals and objectives. The differing standards and paradigms are reflected in the respective laws, utilized and developed by the two major trading partners, to regulate GMOs. The divergent goals and objectives demonstrate the purposes behind the treaties promoting trade of GMOs as opposed to treaties promoting protection of the environment and citizens' health against the risks of GMOs. The current conflict is rooted in these differences. The United States, on one side, is armed with the GATT/WTO treaties, championing the continued dominance of trade through the spread and exportation of genetically modified organisms. The European Union, on the other side, is confident that the precautionary principle – lynch-pin of

---

82 See David Barboza, *In the Heartland, Genetic Promises*, N.Y. Times, 17 March 2000, at p. C6.

83 Id.

84 Sean D. Murphy, *Biotechnology and International Law*, 42 Harv. Int'l L.J. 47, 79-81.

85 Conn Hallinan, *Food Bully*, at http://www.counterpunch.org/hallinal07292003.html (last visited 30 September 2003). In Japan, Brazil, Mexico and South Korea, for example, products containing GMO's are required to be labeled as such causing an effective moratorium because consumers in those countries prefer non-GMO products. See also, Nanda, supra note 22, at p. 239.

86 See Amy Becker and Lee Egerstrom, supra note 6.

87 Id.

the Cartagena Protocol on Biosafety, and embodied in EU GMO release laws as well as the EU's newest tracking, labeling and marketing laws – will ensure human health, environmental safety, and decrease consumer uncertainty, all in accord with WTO law.[88]

A. Different Standards

The United States and the European Union approach food safety and health from different perspectives; therefore, the respective laws governing their regulation manifest divergent approaches.[89] The U.S., through a White House committee under the auspices of the Office of Science and Technology Policy, issued the Coordinated Framework for the Regulation of Biotechnology granting three U.S. agencies the responsibility for controlling biotechnological products.[90] The master principle of this framework is that 'techniques of genetic engineering are not inherently risky and that genetic engineering should not be regulated as a process, but rather that the products of biotechnology should be regulated in the same way as products of any other technology.'[91] This approach is one of identifying individual products as safe or unsafe based on their apparent characteristics through measures developed for more conventional products.

Markedly distinct from the decentralized, product-oriented U.S. approach to GMOs is that of the EU. The EU approach focuses on the processes used to derive these products and maintains a comprehensive regulatory framework to monitor them.[92] The EU's approach is one designed to ensure human health by unifying its members around the common goal of maintaining solidarity with regard to its diverse political views and historical attitudes toward food alteration.[93] The two-pronged approach to GM product regulation includes both pre-marketing safety assessments and a centralized clearance procedure that allows the EU to subsist as a single market for GM products.[94]

1. U.S. Regulatory Approach

The Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA) regulate and approve the use

---

88 See Rapid, supra note 8.

89 See generally Marsha A. Echols, *Food Safety Regulation in the European Union and the United States: Different Cultures, Different Laws,* 4 Colum. J. Eur. L. 525 (1998); see also Souza, supra note 23, at pp. 142-143.

90 See Kunich, supra note 17, at p.823.

91 Id., at pp. 823-824.

92 See generally Council Directive 2001/18/EC repealing Council Directive 90/220/EEC (2001).

93 See Becker and Egerstrom, supra note 6.

94 See Smitherman, supra note 14, at p. 486.

of GMOs.[95] Laws and regulations within the framework of these three agencies control GMO releases because the U.S. has 'no special laws that specifically apply to GM foods.'[96]

The EPA regulates pesticides, and therefore it has jurisdiction over pesticides derived from biotechnology.[97] The EPA applies three statutes to regulating the release of GMOs.[98] The Federal Fungicide, Insecticide and Rodenticide Act (FIFRA) requires manufacturers of pesticide-enhanced plants and seeds to register them with the EPA before selling them in the U.S.[99] Under the Federal Food, Drug and Cosmetic Act (FFDCA), the EPA establishes maximum tolerance levels for pesticide residues in food.[100] Through the Toxic Substances Control Act (TSCA) which the EPA administers, a producer of new microorganisms, including transgenic organisms, must provide the EPA with prior notification of the 'unreasonable risk' these substances pose to health and environment.[101]

The FDA has jurisdiction over food safety. Through the FFDCA, it regulates GMOs just as it regulates conventional food under the provisions dealing with adulteration or food additives.[102] As a 'food,' GMOs are 'presumed safe and the FDA must, in order to deem them adulterated, show that the food contains a poisonous or deleterious substance which may render it injurious to health.'[103] Because the FDA has the burden of showing that GMO's would be unsafe, the FDA's policy statement on GMOs was that they 'are not inherently dangerous and, except in rare cases, should not require [...] regulation.'[104] It would be difficult, if not impossible for the FDA to prove GMOs unsafe because the nature of their testing standards does not include long-term, synergistic effects of such substances and ignores the element of uncertainty in the absence of such long-term tests.[105] The result is that foods containing GMOs are not considered adulterated unless the substances they contain or attributes they exhibit are not usual for the food product in which they reside and only then are treated as additives.[106] Treated as additives, GMOs in food can be relieved from testing requirements by the 'generally recognized as safe' exemption.[107] Nevertheless, the FDA may require pre-market review if it learns through

---

95 See Nanda, supra note 22, at p. 243.

96 Id.

97 See id., at p. 244.

98 Id.; see also Kunich, supra note 17, at p. 824.

99 See Nanda, supra note 22, at p. 244.

100 Id.

101 See Kunich, supra note 17, at p. 824.

102 See id. at p. 842; Nanda, supra note 22, at p. 246; 21 U.S.C. 342 (1994).

103 Gail Kachadurian McCallion, *From the Source to the Mouth: What Can You Reasonably Expect to Find in Your Food*, 5 Fordham Envtl. L.J. 189, 195-96 (1993).

104 Kunich, supra note 17, at p. 843, referring to Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984 (29 May 1992).

105 See Lucy Khairy, *Food: Hazardous for Your Health: Is the FDA Really Ensuring Safe Food?* (upublished thesis, on file with author), at pp. 28-37.

106 See id.

107 See Steven M. Drucker, *Advisory on U.S. Law and Genetically Engineered Food*, Alliance for Bio-Integrity at http://www.biointegrity.org/Advisory.html (last visited 5 February 2002). The GRAS category of substances is exempt from the FDA premarket

discussions with producers that a new product raises health concerns.[108] One way of dealing with such concerns, should they come to light, is through labeling. The FDA requires labeling of GMO-containing food products if it believes that the transgenic material is capable of causing allergies, or if the nutritive value of the GMO differs from what consumers would reasonably expect.[109] The new labeling requirements also allow non-GMO food or seeds to be labeled as such.[110]

Animal and plant agriculture fall within the jurisdiction of the USDA. Its regulation of GMOs falls under the Animal and Plant Health Inspection Service (APHIS). APHIS regulates GM substances through a procedure of notification and permits for their movement, importation and field-testing.[111] These regulations include a petition process allowing a GMO producer to seek a 'non-regulated status,' which once determined, relieves a GMO from APHIS review.[112] Between 1992 and 1998, the USDA, through APHIS, granted non-regulated status to 36 GMOs.[113] However, along with the USDA's attempt to set up a national 'organic' standard, it proposed strict rules prohibiting GM ingredients in products with 'organic' labels, although there is no general requirement for labeling products containing GMOs.[114]

2. The EU Approach

The EU legislation dealing with GMOs consists of four coordinated components.[115] These are: Deliberate Release Directive,[116] the Novel Foods Regulation,[117] the Commission Directive amending the Deliberate Release Directive[118] and the Council Regulation for labeling requirements.[119]

---

approval requirement, and the rigors of the Delaney Clause because of a prior history of safe use. See Stuart M. Pape, *Legislative Issues in Food Safety Regulation*, in Eugene Bardach and Robert A. Kagan (eds.), *Social Regulations: Strategies for Reform*, 1982, pp. 161 et seq., at p. 168.

108 See Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,991 (29 May 1992).

109 See Jonathan Adler, *More Sorry than Safe: Assessing the Precautionary Principle and the Proposed International Safety Protocol*, 35 Tex. Intl. L.J. 173 (2000).

110 H.R. 3377, 106th Congress, 1st Session, 16 November 1999, Sec. 2, para. (3).

111 7 U.S.C. § 150m et seq. (1999).

112 See id.

113 T. Morath, *U.S. Regulation of Products Derived from Biotechnology*, Office of U.S. Trade Representative 1998, p. 1. The number of non-regulated GMOs is expected to increase in the future. See, Smitherman, supra note 14, at p. 485.

114 See *New Rules on Organic Foods*, N.Y. Times, 9 March 2000, at p. A28.

115 See Ruth MacKenzie and Sylvia Franceson, *The Regulation of Genetically Modified Foods in the European Union: An Overview*, 8 N.Y.U. Envtl. L.J. 530, 534-35 (2000).

116 See Council Directive 2001/18/EC (2001), supra note 92.

117 Commission Regulation 258/97 (1997).

118 Commission Directive 97/35/EC (1997).

119 See id., preamble, para. 4, 9.

The Deliberate Release Directive, as the centerpiece of GMO legislation in the EU, mandates pre-market approval of GM products.[120] The goal of this directive is to approximate GMO environmental release laws of Member States and 'ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or the placing on the market of GMOs.'[121] Prior to market introduction of a GMO in the EU, this directive requires: (1) the competent member state authority of the release location receive notification of the release;[122] (2) the notification contain a risk assessment evaluating foreseeable risks posed by the GMO to human health, safety and the environment all of which the EU Commission communicates to other member states;[123] (3) the appropriate labeling and packaging describing the presence of all GMOs except where technically unavoidable traces have already been authorized;[124] (4) the state's evaluation and written consent as a prerequisite to release;[125] and (5) a safeguard clause in the event of severe risk based upon new information.[126] The notable difference between the 2001 Council Directive and its repealed predecessor is that the current Council Directive plainly states its commitment to the precautionary principle and the Cartagena Protocol on BioSafety (BSP) to the Convention on Biological Diversity.[127]

The Novel Foods Regulation applies to foods not previously used for human consumption 'to a significant degree' in the EU.[128] The definition used for novel foods includes foods produced by, though not containing, GMOs and food containing new or intentionally modified molecular structures.[129] The significant aspect of this regulation is that the approval procedures, similar to the Deliberate Release Directive, require scientific assessments and product labeling.[130]

Commission Directive 97/35/EC requires labeling of GM products informing the consumer whether the product consists of GMOs or possibly contains them.[131] Council Regulation No. 1139/98, attempting to harmonize the various state laws on GM labeling, covers labeling for GM products not covered by the Novel Foods Regulation that would include GM corn and soybeans.[132] This directive is the EU's

---

120 See Council Directive 2001/18/EC, supra note 92, art. 1.
121 Id., art. 4.
122 Id., art. 13.
123 Id., art 14.
124 Id., art. 21.
125 Id., art. 19.
126 Id., art. 23.
127 See id., para. 13 of the Preamble, and Annex II that is essentially a detailed definition of the precautionary principle and the methodology used in assessing environmental risk assessment.
128 See Commission Regulation 258/97, art. 1(2) (1997).
129 See id., art. 1.
130 See id., art. 6(1), 8(1), 8(1)(a), and 8(1)(d).
131 See Commission Directive 97/35 (1997).
132 See id., preamble, para. 4, 9.

response to citizens' demands for their right to 'freedom of choice' through prior notification and thus prior consent to consume GMOs.[133]

In furtherance of this four-pronged approach, on 3 July 2003, the EU parliament voted to introduce a new set of rules designed to fine tune the labeling and traceability legislation of GM products.[134] These new rules are set to take effect by the end of the year after negotiations between the EU parliament and individual EU governments occur.[135] The new rules allow a tolerance of 0.9 percent for accidental GMO contamination in foods.[136] Anything over that tolerance will necessitate labeling to indicate the presence of GMOs.[137] The rules also require that all GM feed be labeled as well.[138] The new rules include a three-year transitional period to achieve a zero tolerance of GMOs that have not met the risk assessment tests for entry into the EU.[139]

B. Different Goals

1. Profit and Economic Well-Being

With the formation of the World Trade Organization, the General Agreement on Tariffs and Trade, which until the 1994 round of talks in Uruguay functioned as an international contract regulating world trade through setting quotas and tariffs, moved beyond its traditional regulatory role.[140] Starting in 1986, negotiators of the Uruguay Round, supported by large transnational corporations, pushed for an agenda of globalization that would maximize global economic liberalization, resulting in widely prophesized, broad-based economic and social benefits for all trading partners.[141] The goal of achieving such economic well-being through expanded trade growth and global development was first promoted in corporate circles but ultimately reverberated as official government policy.[142] Nevertheless, the Uruguay Round established 'comprehensive international rules about which policy objectives [...] countries are permitted to pursue and which means a country might use to obtain [...]

---

133 See Becker and Egerstrom, supra note 6.

134 See Morgenavisen, supra note 10.

135 See Ahern, supra note 4, at p. 16.

136 Id.

137 Id.

138 *Europe Completes Laws Governing Transgenic Food and Feed*, Env. News Serv., 23 July 2003.

139 See Ahern, supra note 4, at p. 16, and *Lift Rules on Biotech Crops: U.S. Tells WTO,* Toronto Star, 19 August 2003, at p. C02.

140 Ralph Nader and Lori Wallach, *GATT , NAFTA, and the Subversion of the Democratic Process*, in Jerry Mander and Edward Goldsmith (eds.), *The Case Against the Global Economy*, 1996, pp. 92-107, at p. 96.

141 Id., at p. 95.

142 Joseph Kahn, *Swiss Forum has Its Focus on Memories from Seattle,* N.Y. Times, 29 January 2000, at p. 1C; David E. Sanger, *Senate Approves Pact to Ease Trade Curbs; A Victory for Clinton*, N.Y. Times, 2 December 1994, at p. 1A.

GATT-legal objectives.'[143] The result, which received only limited recognition by Congressmen before passage of the GATT/WTO treaty, is that in the United States, congressional and presidential approval of GATT gave the agreements the status of U.S. federal law. Thus, GATT rules trump U.S. state and local laws as a matter of U.S. constitutional jurisprudence. In addition, the WTO trumps provisions in pre-existing international agreements, including environmental treaties that conflict with trade rules.[144]

The situation is similar for the EU, for as the WTO text states, 'Each Member shall ensure the conformity of its laws, regulations and administrative procedures with its obligations as provided in the annexed agreement.'[145] Therefore, every member nation's laws must conform – and this particularly impacts laws dealing with health, safety and the environment – to the WTO and to each other's laws, or risk violation of GATT rules.[146] Moreover, in the context of this discussion, it is interesting to note that the WTO constitution mentions the environment only cursorily in its preamble, whereas nowhere in the GATT mandate annexed to it does the word 'environment' appear.[147] In fact, GATT contains provisions requiring harmonization of environmental as well as other national standards to its standards.[148] Thus, the GATT/WTO objective, with the mostly unconscious and in some cases reluctant compliance of its member states, places the free movement of goods, money and services across international borders above any other objective including sovereign national objectives such as environmental protection and protection of citizens' health and safety.[149] At the same time, the GATT/WTO places the interests of transnational corporations, prevalent in the most powerful, developed and largest nations and which benefit most from the 'no borders' trade, above all else.[150] It is not surprising, therefore, that the United States as the most powerful and commercially developed nation in the world today, backed by its large transnational corporations with vast and far-flung financial/commercial interests, would be at the forefront, despite the obvious domestic drawbacks, of supporting and implementing the GATT/WTO treaty.[151] It is also important to mention in this regard that, while there continues to be some opposition to the WTO/GATT,[152] the majority of the U.S. citizenry appears to accept the treaty without understanding what the long-term safety, health, economic and environmental consequences might be.

---

143 See Nader and Wallach, supra note 140, at p. 96.
144 Id.
145 See Nader and Wallach, supra note 140, at p. 104.
146 Id.
147 Edward Goldsmith, *Global Trade and the Environment*, in Jerry Mander and Edward Goldsmith (eds.), *The Case Against the Global Economy*, 1996, pp. 78-91, at p. 90.
148 See Nader and Wallach, supra note 140, at p. 106.
149 See id., at pp. 95-106.
150 See id., at p. 103.
151 See Kahn, supra note 142, at p. 1C and Sander, supra note 119, at p. 1A.
152 See Kahn, supra note 142, at p. 1C.

2. Concern for Health, Safety and Environment

On the other side of the commercial playing field is the European Union. Despite an initial acceptance of GMOs, an intense and vocal resistance to them developed quickly throughout Europe. There are several reasons for this strong reaction against GMOs but it is mostly associated with the Europeans' perceptions of safety based on real and potential health problems arising from imported foods.[153] First and foremost is the 1996 appearance of mad cow disease that ravaged herds in Britain, caused a European ban on British beef,[154] and wreaked financial havoc among British and French cattle farmers, not to mention the toll of human lives.[155] Next came the 1999 hoof and mouth disease crisis, also affecting British herds and raising fresh fears of their effect on human health.[156]

In addition to these crises, the television broadcast of a January 2000 scientific research study in Aberdeen, Scotland, finding that GM potatoes were responsible for harming healthy rats by stunting their growth and damaging their immune systems, seemed to confirm the alarm surrounding imported foods.[157] Reacting to public alarm surrounding GMOs in Britain, Prime Minister Blair, in February 2000 acknowledged the harm of GMOs to human safety and the environment.[158] Strict testing and labeling of GM foods was required to satisfy British consumers, as was the halt on commercial growing of GM crops.[159] Similar crises that undermine public confidence have not taken place in the United States, and the ones that have occurred have not received as much publicity as those in Europe. Other factors that influenced the European position vis-à-vis GMOs include the results of the Monarch Butterfly study showing that pollen from Bt corn poses a threat to their larvae,[160] and continuing reports coming from a variety of sources showing that potential risks of GMOs have not been completely studied.[161]

---

153 See Becker and Egerstrom, supra note 6.

154 Warren Hoge, *World Briefing Europe: Deadline for France in Beef Dispute*, N.Y. Times, 28 June 2002, at p. A11.

155 Mark Johnson and John Fauber, *Human Prints on Animal Crisis*, Milwaukee J. Sentinal (Wisc.), 3 November 2002, at p. 01A.

156 See Smitherman, supra note 14, at p. 478.

157 See Joel Bleifuss, *No Small (Genetic) Potatoes: A British Researcher Raises Doubts about Genetically Engineered Food*, These Times, 10 January 2000, at p. 2; Geoffrey Lean, *Exposed: Blair's Hypocrisy Over GM*, Independent (London), 5 March 2000, at p. 13.

158 See Nanda, supra note 22, at p. 238.

159 Id., at pp. 238-239.

160 See www.greenpeace.org/geneng/reports/gmo/gmo011.htm for findings of Cornell University study on the effect of Bt corn on the Monarch butterfly.

161 Just to mention a few reports: GM corn is being investigated for causing false pregnancies in sows; over-planting of Roundup Ready Soy (described in Part I, A above) is being credited with the recent appearance of superweeds resistant to the herbicide Roundup in at least five states in the U.S; reports from India reveal that non-GM rice can withstand harsher conditions than current GM varieties. Eco-Update, News from around the World, Acres USA, March 2003.

National and cultural distinctions also account for the resistance to GMOs in the EU because different countries have different perceptions and attitudes toward risk-taking particularly when it comes to food, its sources and freshness.[162] Europeans often want to know where their food is grown, who the farmer was, and how fresh it is before they will purchase it. It is part of their heritage to discuss these factors with the grocers or butchers before deciding to purchase. An extension of this attitude coupled with the alarm over tainted beef has led to the establishment of 'beef passports' in Britain. The beef cattle are marked with a registry and identification number so that anyone who wants to know may determine the cattle's cradle to grave whereabouts and thereby be assured of the safety and quality of the beef.[163]

EU citizens are also concerned about the testing methodology used to arrive at the determination of safety for GMOs. Primarily, they point to the fact that in the U.S. testing is conducted by the companies who produce the GMOs, in accordance with FDA regulations.[164] This is seen as a conflict of interest, self-serving, and ultimately not trustworthy. Nevertheless, most of the EU concern is voiced over the fact that there are no long-term studies regarding the effects of GMO consumption on agriculture, and that no assessments have been made of their potentially adverse future impact on human health and the environment.[165] Such concerns are understandable when one realizes that significant negative consequences could lie dormant for several years as the case with mad cow disease proved.[166] In short, EU citizens are highly sensitized to the real and potential dangers lurking in imported GMOs and have yet to be convinced otherwise. The result is that their governments, without any acceptable data to the contrary, are responding to these concerns – to do otherwise would be political suicide. The EU has turned to the precautionary principle embodied in the BioSafety Protocol of Cartagena to stave off further trade encroachments of GMOs by halting food imports at their 1998 levels and GM seed imports at their 1999 levels.[167] Notwithstanding such concerns, the United States views the EU's 'safety' measures to control the release of GMOs as a cover-up for trade barriers.[168]

---

162 See Becker and Egerstrom, supra note 6.

163 Michael McCarthy and Colin Brown, *Exactly What's What in the Quarrel about British Cattle,* The Independent (London), 12 November 1999, at p. 4.

164 See Smits and Zaboroski, supra note 39, at p. 119.

165 Id.

166 Id. Similarly in the U.S. it took thirty years before it was realized that the over-use of antibiotics, particularly through non-prescription sources such as is obtained from meat and poultry fed on antibiotic enhanced feed was lowering human resistance to viruses. See Ross Hume Hall, *Food For Naught: The Decline in Nutrition* (Vintage Books 1976), at p. 92; Mike Burros, *Farmers Who Raise Poultry Lowering Use of Antibiotics,* Indianapolis Star, Feb. 10, 2002, at p. A7.

167 See Part II, A, 1, b discussing the incorporation of the BioSafety Protocol into EU's Deliberate Release Directive 2001/18/EC.

168 See Peter W.B. Phillips and William A. Kerr, *The BioSafety Protocol and International Trade in Genetically Modified Organisms,* Can. Agrifood Trade Research Net, Paper 2000-03, March 2000, at p. 7, available at http://www.eru.ulaval.ca/catrn.

III. Laws Controlling the GMO Issue – Treaties

Although the EU has implemented laws controlling the release of GMOs in its Member States, the WTO/GATT treaty, as mentioned above, requires conformity of its signatories' laws with the obligations of GATT. GATT therefore disfavors national laws – even sanitary and phytosanitary laws – that might be used to protect domestic goods at the expense of imports. This pro-trade, seemingly anti-environmental, stance of GATT resulted in growing international concern relating to the uncertainties and unforeseen risks to human health, safety and the environment among consumers, farmers, and activists worldwide. Such concern led to over 130 countries adopting the BioSafety Protocol (BSP) in 2000 to address specifically the use, handling and trade of GMOs through the application of the precautionary principle.[169] The juxtaposition of the respective positions during the BSP negotiations and since its adoption with regard to how it would be implemented in conjunction with GATT and other WTO agreements reflects the essence of the controversy in the current U.S.-EU standoff with regard to GMOs particularly since the BSP is often seen as conflicting with GATT treaties.[170]

A. The World Trade Organization (WTO)

The creation of the WTO at the end of the Uruguay Round of talks established a new dispute resolution mechanism significantly altering and strengthening adjudication processes of international trade disputes.[171] The new Dispute Settlement Body (DSB) consisting of Panels and an Appellate Body to carry out this new role have made the WTO a permanent governing structure 'with the kind of 'legal personality' enjoyed by the U.N., the World Bank, and the I.M.F.'[172] Thus, when one treaty member challenges another with regard to trade regulations, it begins a three-stage process to resolve charges.[173] The stages are: (1) consultation, (2) Dispute Settlement Panel (DSP)

---

169 Sabrina Safrin, *Treaties in Collision? The BioSafety Protocol and the World Trade Organization Agreements,* 96 A.J.I.L. 606 (2002); see also Jabara, supra note 20, at pp. 121-122.

170 See generally Adler, supra note 109.

171 John Stephen Fredland, *Unlabel Their Frankenstein Foods!: Evaluating a U.S. Challenge to the European Commission's Labeling Requirements for Food Products Containing Genetically-Modified Organisms,* 33 Vand. J. Transnat'l L. 183, 194 (2000).

172 See General Agreement on Tariffs and Trade – Multilateral Trade Negotiations (the Uruguay Round): Understanding on Rules and Procedures Governing the Settlement of Disputes, 15 December 1993, 3 I.L.M. 112, 114, art. 2.1; see also Nader and Wallach, supra note 116, at p. 102.

173 See General Agreement on Tariffs and Trade – Multilateral Trade Negotiations (the Uruguay Round: Agreement Establishing the Multilateral Trade Organization, 15 December 1993, 33 I.L.M. 13, 17, art. 4.4 (hereinafter GATT). No private parties may bring an action under the WTO because only WTO member states have standing to bring such grievances. However, when a private party believes that a government may have violated WTO/GATT rules it will mount a campaign to convince its home state

hearing; and (3) Appellate Body hearing.[174] Once a panel, consisting of three individuals selected from a pre-set list, has been chosen, it has six months to conclude and render a decision.[175] The DSB then adopts the panel decision unless one of the parties appeals it or all members of the board block it. Blockage of a panel report requires consensus of the board members.[176] After adoption of a panel decision, the DSB monitors its implementation or, in the event a member state does not implement the decision, the DSB will automatically sanction that member.[177]

The final resort for a member state is the DSB's Appellate Body consisting of seven members, three of whom sit to hear an appeal.[178] This group reviews issues of law and legal interpretation dealing with inconsistencies between members' actions and one of the WTO agreements. Typically the Appellate Body recommends the conformity of trade measures with appropriate WTO agreements or overturns the decision of the Panel.[179] The following WTO-administered agreements potentially apply to GMOs and could be employed by a Dispute Settlement Panel or the Appellate Body in a challenge regarding them.

B. The GATT Agreements

Under the umbrella of the WTO, Articles III and XI of GATT prohibit discrimination against imports based upon measures that affect either the qualities of imported products or their importation, respectively; Article XX contains the general exceptions allowed by a regulating member in order to maintain that regulation or be in violation of GATT.[180] However, it is in Article XX that the WTO allows certain defenses that include protection and preservation of the environment as long as the domestic laws enacted are 'necessary to protect human, animal or plant life or health.'[181] Nevertheless, any action by a member state taken for such purposes remains subject to Article XX's requirements which prohibit means that are: '(1) arbitrary, (2) unjustifiable discrimination between countries where the same conditions prevail, or (3) a disguised restriction on international trade.'[182] In the current conflict, it is likely the EU will be able to withstand an attack under the first two

---

to act on its behalf. Additionally, 'disputes are not decided by democratically elected officials or their appointees but by secret tribunals of foreign-trad bureaucrats from a preset roster [...] State and local government representatives (such as a state attorney general), citizens, and the press are locked out.' Nader and Wallach, supra note 140, at p. 102, enumerating the problematic traits of the WTO dispute resolution system.

174 See GATT, supra note 173, art. 4.4.

175 See GATT, supra note 173, art. 11. 9.

176 See id., art. 16.4.

177 See id., art. 21.3 and 22.

178 See id., art. 17.1-17.2 and 17.4.

179 See id., art. 17.2, 17.6, 19-19.1.

180 See General Agreement on Tariffs and Trade, 30 October 1947, 61 Stat. A-ll, T.I.A.S. 1700, 55 U.N.T.S. 194, art. III, XX, and XI.

181 See GATT, supra note 173, art. XX.

182 Id.

requirements, but it is the third requirement which is most likely to cause difficulty. As prior decisions by the Dispute Settlement Panel (DSP) indicate, the DSP has placed more weight on the benefits gained from international trade than on the benefit to the environment.[183] The message that reverberates is one of trade above all else.

1. Sanitary and Phytosanitary Agreement

The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) is a set of rules specifically designed to allow the WTO to regulate trade in agricultural products in such a way that health and safety measures mandated by member states will not constitute a barrier to trade. As such, it is the main set of regulations that covers the trade of GMOs.[184] Compliance with the SPS is presumptively compliance with Article XX of GATT. The WTO allows member states to set their own health and safety standards to the extent they are based upon 'accepted scientific principles.'[185] Article 3 of the SPS acts to require conformity of a member state's health and safety measures along international standards, guidelines or recommendations.[186] The sanitary and phytosanitary measures mandated by member nations are, under the WTO, to be used in the least restrictive manner, must be uniformly applied, and must not to be used as a trade weapon.[187] The result is that while member states have a sovereign right to protect their citizens' health and the environment, the regulations are subject to the overarching requirements of WTO's SPS which is a minimal standard whose goal is to favor trade.

What happens when a member state institutes health and safety measures at a level higher than those of the SPS? Under Article 5 of the SPS, such measures may only be utilized based upon scientific justification or risk assessments working in tandem with the scientific evidence requirement of Article 3 that are 'an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health.'[188] When undertaking risk assessments, member states must rely on 'available scientific evidence, relevant processes and production methods; [... and] relevant ecological and environmental conditions.'[189] Nevertheless, Article 5.7 makes

---

183 See Smitherman, supra note 14, at p. 491.

184 See Smits and Zaboroski, supra note 39, at p. 121, citing *Understanding the WTO Agreement on Sanitary and Phytosanitary (SPS) Measures* (May 1998), available at the World Trade Organization, http;//www.wto.org/English/tratop_ e/spsund.htm.

185 Id.

186 See Smitherman, supra note 14, at p. 492.

187 See Agreement on the Application of Sanitary and Phytosanitary Measures, 69, (hereinafter SPS) art. 5.4 and 5.5 as part of the General Agreement on Tariffs and Trade, 30 October 1947, 61, Stat. A-11, T.I.A.S. 1700, 55 U.N.T.S. 194, as modified by Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, [WTO Agreement] Legal Instruments-Results of the Uruguay Round vol. 1, 33 I.L.M. 1154 (1994).

188 See id., at art. 3 and 5.1.

189 See id., at art. 5.2.

allowances for situations where there is insufficient scientific evidence.[190] In such circumstances, health and safety measures may be adopted by member states 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.'[191] The taking of such measures remains subject to future objective risk assessments made within a reasonable period of time.[192] In terms of the U.S.-EU GMO dispute, certain aspects of SPS Articles 3 and 5 could be used to exclude and clash with or to include and harmonize with the use of the precautionary principle of the BioSafety Protocol depending on the facts of a case. These are: (1) the 'international standards,' (2) 'scientific justification' language in Article 3.3, (3) the risk 'assessment, as appropriate to the circumstances,' (4) 'scientific evidence' and (5) 'relevant economic factors' language in Article 5.1, 5.2, and 5.3 respectively.

2. Technical Barriers to Trade Agreement

The Agreement on Technical Barriers to Trade (TBT) applies mainly to the issue of labeling.[193] The TBT like the SPS restricts the use of Article XX defenses. The TBT allows packaging, labeling and marketing requirements to the extent that they do not create unnecessary or disguised barriers to international trade or unjustifiably or arbitrarily discriminate against imports.[194] Only GMO-labeling requirements that are determined not to be sanitary or phytosanitary measures falling under the SPS would be subject to the TBT.[195] This agreement clearly reflects the U.S. regulatory approach to labeling GMOs. The important factor under the WTO/GATT regime is that the U.S. and its GM producing allies need to prove only that no scientific evidence demonstrates that use or consumption of GMOs is harmful. The EU, on the other hand, must prove that scientific evidence demonstrates that GMOs are harmful. The precautionary principle of the BioSafety Protocol would reverse the burden of proof.

C. BioSafety Protocol

The Cartagena BioSafety Protocol, the goal of which was to establish an international system to manage the transboundary movement of GMOs intended for environmental release or entry into the food chain, falls under the United Nations Environmental Program's Convention on Biological Diversity.[196] It reflects the international

---

190 See id., at art. 5.7.
191 Id.
192 Id.
193 See Agreement on Technical Barriers to Trade, 15 April 1994, WTO Agreement, supra note 162.
194 Id.
195 Id.
196 See *Treaty on Trade in Biotech Organisms to Become Law*, 13 June 2003, available at http://www.mindfully.org/GE/200e/Cartagena-Protocol-Biosafety 13jun03.htm.

community's 'historic attempt to reconcile economic and trade policies with environmental concerns' – a position that received minimal attention in the WTO/GATT treaty.[197] Negotiations for the BSP took place between 1996 and 2000. The BSP came into force on 11 September 2003 – ninety days after the fiftieth signatory ratified it.[198] The United States, although a significant actor in the negotiations, has neither signed nor ratified the BSP.[199] The European Union has both signed and ratified the treaty.[200] Nevertheless, the BSP does not contain a release from WTO/GATT requirements.[201] Aside from labeling, the BSP does not regulate the safety of pharmaceuticals containing GMOs or products such as GMO corn and soybeans processed for use as food or feed.[202] The BSP does take into account risks to human health in the context of the transboundary movement of covered GMOs without mitigation, unlike the SPS, which considers such risks 'as appropriate to the circumstances.'[203]

The centerpiece of the BSP is the Advance Informed Agreement ('AIA') as set forth in Articles 8 through 10 and 12.[204] This, along with sustainable development and the precautionary principle, forms the three-pronged approach to bridge the environmental gap resulting from the divergence of WTO/GATT regimes and member state regulatory measures.[205] The AIA procedure requires exporters shipping seeds for planting, fish for release and microorganisms for bioremediation to obtain prior consent from an importing country.[206] The AIA establishes the necessity of informed consent along with the importer's right to refuse entry of the GMO.[207] Indeed, the majority of the BSP is procedural rather than rule-based in nature – a point that raises concerns regarding its efficacy as a defense against what some consider indiscriminate transboundary movement of GMOs.[208] Nevertheless, the BSP mandates labeling requirements that cover GMOs 'intended for direct use as food or feed, or for processing' and specifies that such labeling clearly identify that these items 'may contain' GMOs.[209] The labeling mandate of the BSP is significant in so far as some observers

---

197 See Nanda, supra note 22, at p. 251.

198 See *Global Treaty on GMOs Takes Effect*, Hermes Database, 11 September 2003. Notably, the U.S. has not signed or ratified the United Nations Convention on Biological Diversity.

199 See *Treaty on Trade in Biotech Organisms to Become Law*, supra note 196.

200 See CBD, supra note 175.

201 See Applegate, supra note 71, at p. 244. For a thorough discussion of the 'savings clause' issue in the BioSafety Protocol see generally Safrin, supra note 169.

202 See Cartagena Protocol on BioSafety to the Convention on Biological Diversity, 29 January 2000, reprinted in Secretariat of the Convention on Biological Diversity, *Cartagena Protocol on Biosafety to the Convention on Biological Diversity: Text and Annexes* 3 (2000) (hereinafter BSP).

203 Id., at art. 1.

204 Id., at art. 7.

205 See Applegate, supra note 60, at p. 241.

206 See BSP, supra note 202, at art. 8-10, and 12.

207 Id.

208 Sonia Boutillion, *Note: The Precautionary Principle: Development of an International Standard,* 23 Mich. J. Int'l. Law, 429, 437-440 (2002).

209 See BSP, supra note 202, at art 18.

see the current standoff between the U.S. and the EU as potentially resolving around a labeling issue.[210] However, for the purposes of this discussion the most relevant aspect of the BSP is the precautionary principle that deals with the role of uncertainty and the lack of scientific information in the risk assessment process relating to an importer's decision.

IV. The Precautionary Principle – Customary Law?

The precautionary language of the BSP dealing with uncertainty and lack of scientific information states:

> 'Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking into account risks to human health, shall not prevent the Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question [...] in order to avoid or minimize such potential adverse effects.'[211]

Perhaps in anticipation of the emergence of the BSP, the EU argued, in a challenge before the WTO Appellate Body, that its restriction on importing U.S. and Canadian beef injected with hormones was justifiable under the SPS on the basis of the precautionary principle as a customary international rule.[212] The Appellate Body did not rule on whether it considered the precautionary principle as a general customary rule of international law; nevertheless its comments on the relationship between the SPS and precautionary principle leave open the possibility of reconciliation between the two.[213] These comment were: (1) the principle is not in the SPS as a ground for justifying what would otherwise be inconsistent with members' obligations under the agreement; (2) the principle is reflected in Article 5.7 of the SPS – in the case of insufficient scientific evidence a precautionary approach can be taken; (3) the principle is reflected in Article 3.3 of the SPS – allowing governments to adopt their own standards based on scientific justification; (4) SPS Articles 5.7 and 3.3 did not exhaust the use of the principle; and (5) a panel considering a member state's SPS measure should keep in mind that representative governments commonly act based on prudence and precaution when dealing with risk to health.[214] Such comments may not predict any position the Dispute Settlement Panel or Appellate Body may take on a WTO/GATT trade issue, nevertheless they leave open the possibility of

---

210 See *Frankenfood Challenge to Europe Postponed*, supra note 7, at p. 5.

211 See BSP, supra note 202, at art. 10.6.

212 See Yaren, supra note 41, at p. 159, and Smitherman, supra note 14, at p. 496.

213 *EC Measures Concerning Mean and Meat Products (Hormones*), Report of the Appellate Body, para. 123 (16 January 1998) WT/DS26/AB/R, available online at WESTLAW.

214 Id., at para. 124.

applying the precautionary principle as something other than customary international law.

For nearly fifteen years there has been an international debate over whether to consider the precautionary principle as customary law .[215] State practice – behavior – along with opinio juris generally determines a custom. Examples of this would be grant of immunity to foreign diplomats, non-interference with sovereign vessels on the high seas, or not engaging in law enforcement in the territory of another state.[216] Nevertheless, with the proliferation of treaties focused on environmental issues, numerous scholars today consider those treaties to be a preeminent international law-making method that tends to diminish the role of customary international law.[217] Such scholars focus their attention on whether a norm evident in international environmental law has achieved the status of customary law.[218] Their focus points out the difference between what is the 'traditional,' more empirical method of determining customary law and the 'declarative' method that is more normative – or the difference between what states do and what states say.[219]

Analyzing the precautionary principle – the duty to prevent transboundary harm – based on how states behave, one would likely conclude that it is not customary law. This is because transboundary pollution or other environmental harm 'seems to be more the rule than the exception in interstate relations. Pollutants continuously travel across most international borders through the air and by rivers and ocean currents. In a few cases, states have undertaken efforts to reduce these pollution flows – generally, through treaties.'[220]

The declarative method, on the other hand, rather than observing behavior, collates texts 'to see whether a critical mass of authority exists in support of a given norm.'[221] In the context of international environmental law and transboundary harm, the collating began with *Trail Smelter* – still the only case where one state was held responsible for transboundary harm to another state.[222] The precautionary principle in the same context first appears in 1972 in Principle 21 of the Stockholm Declaration.[223] From that point, scholars cite the 1982 U.N. World Charter for Nature, the

---

215 For differing views see generally James Cameron and Juli Abouchar, *The Precautionary Principle: A Fundamental Principle of Law and Policy for the Protection of the Global Environment*, B.C. Int'l. & Comp. L. Rev. 1 (1991) and Daniel M. Bodansky, *Scientific Uncertainty and the Precautionary Principle*, 33 Environment 4 (1991).

216 See Daniel Bodansky, *Customary (and not so Customary) International Environmental Law*, 3 Ind. J. Global Leg. Stud. 105, 108, 112 (1995).

217 Id., at p. 106.

218 Id., at p. 107.

219 Id., at pp. 108-112.

220 Id., at p. 111 and n. 28.

221 Id., at p. 114.

222 *U.S. v. Canada*, 1941, U.N. Rep. Int'l Arb. Awards 1905 (1949); Bodansky, supra note 216, at p. 114.

223 See *Stockholm Declaration on the Human Environment*, princ. 21, Report of the United Nations Conference on the Human Environment, Stockholm, 5-16 June 1972, U.N. Doc. A/CONF.48/14/Rev.1, U.N. Sales No. E.73.II.A.14, pt. 1, ch.1 (1973) reprinted in 11 I.L.M. 1416 (1972).

1985 Vienna Convention for the Protection of the Ozone Layer, and then successively numerous regional and international instruments such as the charter of the European Union, the Bamako Convention on Hazardous Waste in Africa, the Convention on Biological Diversity, the Stockholm Convention on Persistent Organic Pollutants, the Rio Declaration, and the BioSafety Protocol.[224] The value of the declarative law method is that it collects a quantitative mass of legal data indicating how states speak to one another and how states should conform their behavior to a given norm rather than how the states actually behave.[225] Therefore, the declarative method does not determine international customary law. What value, then, could this method have in the arena of international environmental law, if it is not determinative of customary law?

In third party control systems – courts and arbitral tribunals – where one party can convince the judges or arbiters that a norm such as the precautionary principle represents law, then that norm may be applied and enforced.[226] This is precisely the approach the EU attempted before the Appellate body in the Beef Hormone case, when it invoked the justification of stricter sanitary and phytosanitary measures based upon the precautionary principle as customary law; nevertheless, the EU did not prevail.[227] Had it prevailed, the precautionary principle would have achieved the legal status of a norm and greatly enhanced its influence. Therefore, the use of a norm formulated via the declarative method requires validation – third party validation. Thus, the fact that the precautionary principle has not been used extensively by international courts or arbiters points to its weakness as a substantive rule.[228] But, if the precautionary principle is not customary law based on state action or a declarative method of achieving that status, what else could it be?

A. Formulation and Elements of the Precautionary Principle

Notably, throughout the various instruments in which it has appeared, no single formulation of this principle is uniformly found. However, its underlying notion of foresight particularly as it relates to new technologies and in the absence of long-term scientific assessments of risk, is a standard feature of international environmental treaties.[229] Typical formulations of the precautionary principle are in the context of environmental issues – those that affect nature and its resources or human

---

224 See Applegate, supra note 71, at pp. 247-248. Applegate makes reference to an 'exhaustive catalogue' of international and domestic laws that include the precautionary principle in Harald Hohman, *Precautionary Legal Duties and Principles of Modern International Environmental Law* (1994).

225 See Bodansky, supra note 216, at pp. 116-119.

226 Id., at pp. 116-117. Bodansky illustrates this use of the declarative method of 'making law' by citing *Filartiga v. Pena-Irala*, 630 F.2d 876 (1980) where plaintiff convinced the court that customary international law prohibits torture.

227 See supra, Part IV.

228 See Boutillion, supra note 208, at p. 432.

229 See Applegate, supra note 71, at pp. 247-248.

life. Furthermore, enunciation of the principle rarely occurs in isolation, but rather in conjunction with other norms or processes such as risk assessment or scientific evaluation.[230] The emergence of this typical formulation notwithstanding, the content and extent of the actions the principle necessitates have not, up until the BSP, been clearly defined, thereby impacting its legal status.[231] In addition to the principle's contextual link to the environment, risk assessment and scientific evaluation, there are certain elements of the formulation that through time have taken shape and which the BioSafety Protocol embodies.

Certain common elements regularly appearing in the various iterations of the principle have taken shape in the BioSafety Protocol. The BSP, however, also includes a variety of responsibilities that importers and exporters must assume.[232] Therefore, this latest iteration of the precautionary principle may thrust it further along the path of determining its legal status. These elements are: the goal of preventing irreversible harm to the environment; the temporal allocation of that harm, namely, the future, and thus the future allocation of environmental resources implying cost-effectiveness; the need for continuing, ongoing scientific research to dispel uncertainty; and the exchange of information through the BSP's Clearinghouse, to foster dissemination of the scientific research and increase public awareness.[233] These elements can be further reduced and expressed as: (1) environmental risk evaluation; (2) cost/benefit and cost-effectiveness; and (3) on-going scientific research.[234]

The definition of a normative ensemble of actions such as those enumerated above that have been expressed over time in numerous treaties or treaty-like instruments points to the possible formation of a standard.[235] One might even conclude the U.S.'s strong opposition to the precautionary principle is a result of the hardening of its expression into something more than a mere guideline, for in the past, unlike currently, the U.S. was party to instruments that contained the principle.[236]

---

230 See Boutillion, supra note 208, at p. 433.

231 Id.

232 Responsibilities include among others notification, risk assessment, following decision making procedures. See BSP, supra note 202, art. 8-15.

233 See BSP, supra note 202 at art. 1, 12, 23, Annex III.

234 See Boutillion, supra note 208, at p. 447.

235 See id., at pp. 433-439.

236 Id., at p. 444.

B. Toward a Standard

A standard is a type of norm, or formula, a uniformity of behavior. It is a level of conduct that the community demands that is external and objective – a model of all proper qualities that can be adapted from situation to situation.[237] A standard is a means by which judges and arbitrators can gauge actions taking into account risk and the capacity to meet it.[238] The concept of standard contains within it the notion of conformity of past behavior as well as expectation of future behavior.[239] A standard can make reference to other systems such as morals, economics, or science.[240] When applying this ensemble of definitions to the elements of the precautionary principle, the outlines of a standard begin to emerge.

1. Environmental Risk Assessment in the BSP

Annex III of the BSP sets forth the risk assessment procedure and methodology.[241] The BSP's risk assessment objective is to identify and evaluate the potential adverse effects of GMOs on conservation and biological diversity including risks to human health.[242] It enunciates general principles of risk assessment as: (1) scientific soundness; (2) transparency of information and methodology; (3) reliance upon expert advice and guidelines of international organizations; (4) limiting the lack of scientific knowledge or scientific consensus as an indicator of risk; (5) GMO risk considerations as compared with non-GMO risk considerations in the potential receiving environment; and (6) employing a case-by-case basis.[243]

With regard to the limitations on the application of the principle, Annex III para. 4 states: 'Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.'[244] This language appears duplicitous and may tend to undermine the core principle, namely, uncertainty based on lack of knowledge, resulting in a weakening of the principle's effect in the BSP.[245] The net effect of this language, however, is that the risk assessment methodology, which includes risk management, advances to the forefront of the BSP as a clear procedural requirement.[246] That methodology includes: (1) identification of GMOs with characteristics that may adversely effect biological diversity; (2) evaluation of the likelihood of adverse effects

---

237 W. Page Keeton (ed.), *Prosser and Keeton on the Law of Torts*, 2nd ed. 1984 (hereinafter Prosser), at pp. 173-175.
238 Id., at p. 174.
239 See Prosser, supra note 237, at p. 193.
240 See Boutillion, supra note 208, at p. 447.
241 See BSP, supra note 202, at Annex III.
242 Id., at Annex III, para. 1.
243 Id., at Annex III, para. 2-6.
244 Id., at Annex III para. 4.
245 See Boutillion, supra note 208, at p. 439.
246 Id., at p. 438.

being realized and consequences in the event they are realized; (3) recommendations regarding the manageability of the risks; (4) requesting further information or implementing risk management strategies or monitoring of GMOs in the event of the uncertainty of the level of risk.[247]

The features of the precautionary principle's environmental risk assessment methodology have clear earmarks of a standard, namely, a prescribed framework of behavior that is external and objective and can be adapted on a situation-by-situation basis. It contains the notion of conformity of past behavior based on the weight of past treaties, the European Commission use of the principle certain directives, notably the Deliberate Release Directive,[248] and in cases before the European Court of Justice such as the drift-net case and the continuing ban on British beef.[249] More importantly, however, it sets the level of expectation for future behavior.

2. Cost/Benefit and Cost-Effectiveness

An important aspect of the BSP's risk assessment methodology is the possible use of socio-economic considerations. Article 23 states that parties 'may take into account, consistent with their international obligations, socio-economic considerations arising from the impact' of GMOs on conservation and biodiversity.[250] The SPS, in contrast, states that member states 'shall' factor in economic considerations such as loss of production or sales, costs of control/eradication and cost-effectiveness of alternative approaches to limiting risk.[251] This contrast underscores the BSP's commitment to moral obligation and the SPS's commitment to trade. It also emphasizes a potential source of conflict between the BSP and the WTO/GATT regime within their otherwise congruent risk analysis methodologies. Moreover, it accents the plenary and proportional nature of the BSP and the narrow, trade-focused character of the SPS/GATT/WTO regime. Cost/benefit is an important element of the BSP because it allows states to include a much larger array of factors in their decision-making processes – a very necessary aspect of socio-political decision-making. The SPS's cost analysis considers only cost-effectiveness for trade and traders. Nevertheless, as mentioned in Part IV, A, 2(a) above, the BSP limits the application of the precautionary principle thereby increasing the certainty and expectancy of behavior in that regard. Channeling conduct within a prescribed trajectory with reference to other systems – in this case socio-economic – brings the precautionary principle into the domain of a standard.[252] The fact that the SPS adopted a rule that reflects a U.S. industry influenced regulatory approach to cost analysis does not necessarily mean it represents a desired behavior because '[e]ven an entire industry, by adopting [...]

---

247 See BSP, supra note 202, at Annex III, para. 8 (a)-(f).
248 See Part II, A, 1, b. supra.
249 See Boutillion, supra note 208, at pp. 464-465.
250 See BSP, supra note 202, at art. 26.
251 See SPS, supra, note 187, at art. 5.3.
252 See Boutillion, supra note 208, at pp. 448-449.

methods to save time, effort, or money, cannot be permitted to set its own uncontrolled standard.'[253]

3. On-going Scientific Research and Decision Review

Because scientific uncertainty is at the heart of the precautionary principle, on-going research and data gathering is an essential feature that the principle requires.[254] Aspects of this element are that while allowing the principle to operate to halt, in some cases, the introduction of GMOs, it should not be used as an implacable barrier for them. The goal is one of restraint not prohibition and so includes risk management and monitoring – a limited or gradual release – until science can provide better data that would confirm or alter the prior decision.[255] This procedure is a predictable method, a predictable ensemble of behavior that includes review and re-assessment and underscores the standard-like nature of the principle.

The precautionary principle, as elaborated in the BSP, exhibits a few other similarities to a standard. One is that it has a defined set of circumstances under which it is applied or when it is triggered. The main circumstance for triggering the precautionary principle is uncertainty – 'the lack of a definitive cause-and-effect relationship or a quantifiable dose-response relationship.'[256] The trigger aspect, therefore, implies activating the risk assessment methodology, discussed above, in order to ascertain the level of uncertainty. Some commentators have characterized the trigger as 'reasonable doubt' that encompasses social factors such as national culture and public perception of a potential threat rather than uncertainty, but such a characterization would put the principle in direct conflict with the SPS.[257] The other similarity with a standard is the burden of proof aspect of the principle. The BSP clearly states that it is not the importing, regulating state that must prove grave or irreversible risks, but the exporting state that must prove the absence of such, thus shifting the burden of proof from what it is under the SPS.[258] Such burden shifting could be a considerable tension source for applying the precautionary principle under the BSP because of its direct conflict with the WTO/GATT regime. This has led some commentators to conclude that the burden-shifting aspect present in the BSP is not a regular feature of the precautionary principle,[259] while others do not see the burden-shifting aspect as incompatible WTO/GATT regime.[260] Notwithstanding such a conflict, the responsibility of burden is another aspect of the precautionary principle that recommends it as a standard of international law.

---

253 See Prosser, supra note 237, at p. 194.
254 See BSP, supra note 202, at art. 12, para. 1.
255 See BSP, supra note 202, at Annex III, para. 8(f).
256 See Applegate, supra, note 71, at p. 251.
257 See Boutillion, supra note 208, at p. 450.
258 See BSP, supra note 202, at art. 15.2.
259 See Applegate, supra note 71, at p. 252.
260 See Souza, supra note 32, at p. 173.

Undoubtedly, to accord the precautionary principle the status of an international legal standard that can be applied by judges and arbiters is beyond the conception of many. Doing so would raise objections from legal and commercial/industrial quarters alike. Nevertheless, this discussion demonstrates the possibility that the aspects and elements of the principle are more standard-like than they are rule-like and that as a standard the principle could conceivably encounter less resistance from pro-GMO member states than it would as a rule.

C. Value as a Standard

Just prior to 1906 when the Pure Food and Drug Act was passed, Dr. Harvey W. Wiley, first administrator of that organization, set up his renowned 'Poison Squad' experiments with human volunteers to text the effects of food additives.[261] The results were shocking. From that time on the FDA and other food regulatory agencies have attempted to keep pace with the rapid introduction of innovative food production techniques that include additives and now genetically modified organisms.[262] In 1962, Rachel Carson caught the world's attention with the publication, *Silent Spring*, by focusing in detail on the devastating effects of chemical pesticides on the natural environment. These two events are characteristic of how technology and those who create it have proceeded unimpeded by control or regulation until after signs of devastation occur. With time, however, some scientists, concerned citizens, government representatives and others began to realize the value of forestalling and preventing such harms to ensure the sustainability of the environment for future generations – to invoke precaution as a principle of that sustainability. Successive iterations of that environmental precaution have encouraged an increasingly distinct formulation of the principle into a norm with standard-like elements with an eye perhaps to raising its legal status.

As a standard, environmental precaution has delineated a uniformity of responsible environmental stewardship and served as a model of predictable, desired behavior. As a standard, its systematic application can be molded further and yet maintain a flexibility that it might not otherwise enjoy as a rule. As a standard, its holistic parameters can continue gathering legal validity without directly threatening the rigidity of the WTO/GATT regime. As a standard, it can realistically as well as scientifically assess risk by including what is not known into the risk assessment

---

261 See Hall, supra note 166, at pp. 74, 77. 'The nineteenth century manufacturers added such chemicals as borax, salicylic acid, formaldehyde, and benzoic acid as preservatives to many foods. Because business scruples were somewhat lax, manufacturers also resorted to widespread adulteration to improve their competitive position. Much of this adulteration was not necessarily harmful . . . But some widespread commercial practices were more serious: alum was added to flour to make it "finer," sulfuric acid was added to beer to accelerate maturation and reduce storage time, beautiful "green" pickles were colored with copper sulfate, and natural cheese color was provided by lead salts.' Id. at p. 77.

262 See generally Hall, supra note 166.

equation in order to monitor, mitigate or avoid situations like those encountered and described by Rachel Carson, Dr. Wiley, and others throughout the last century. Even though the argument of lack of state behavior can be leveled against its bid as a standard, the necessity of implementing the precautionary standard grows more essential as science reveals new areas of harm that the passage of time reveals. Waiting to accumulate conformity to the precautionary standard may be waiting too long.

Finally, even though the international legal community as a whole does not yet consider the precautionary principle as a standard, the press to have it ripen into one, as proposed in this discussion, can be employed as a political bargaining tool by the negotiators on either side of the major trading blocs facing each other in the recently convened Panel. With the EU poised to impose $4 billion in sanctions against the U.S. for its delay in eliminating tax breaks to major U.S. corporations giving them a trade advantage not open to non-U.S. corporations,[263] the EU may likely push harder for applying the precautionary principle in Dispute Settlement Panel presently set to adjudicate this issue. It may now be more facile than before to point to the precautionary principle as a standard because of its recent incorporation into the risk analysis standards for GM food safety as adopted by the Codex Alimentarius Commission.[264] 'Codex standards are important because they can be used to settle trade disputes ... [and] provide a legal basis under World Trade Organization rules for the European Union's strong safety regulations for genetically modified organisms.'[265] Codex standards are automatically regarded as being based on science; therefore, their reference to traceability of and guidelines for safety of GMOs could enhance the position of EU law on these point.[266] Nevertheless, if the Panel determines that the EU laws now in place to harmonize the procedure for transboundary movement of GMOs constitute a trade barrier, the EU can either comply with the ruling or decide to continue following its laws for labeling, traceability and risk assessment thereby incurring possible sanctions.

Conclusion

The world community founded GATT after World War II as an international contract that set rules for world trade. With trade as their goal, negotiating nations, backed by powerful international commercial interests, created a trading formula that advanced their interests permitting little consideration for the environmental, political and cultural aims of the citizens living within its confines. To counterbalance this limiting approach, aerate the overbearing emphasis on trade *über alles*, and create a framework, procedure and methodology to manage risk for the transboundary release of genetically modified organisms into the environment, the international community

---

263 Patrick Lannin and Richard Waddington, *EU Gets Sanctions Go-Ahead Against U.S.*, Reuters Yahoo! News, at http://story.news.yahoo.com/news (last visited 8 May 2003).

264 *Consumers Union Hails UN Standards on Genetically Engineered Food; Standards Strengthen European Union in Trade Dispute*, AScribe Newswire, 1 July 2003.

265 Id.

266 Id.

reacted by establishing the BioSafety Protocol. The BioSafety Protocol contains the most current and developed formulation of the precautionary principle. The further incorporation of the precautionary principle into EU law regarding transboundary movement of GMOs, and the subsequent development of that law in the areas of traceability, risk assessment and labeling have, at the very least, bought Europe more time to hold back the spread of GMOs.

Constrained by the Sanitary and Phytosanitary Agreement under WTO/GATT from maintaining more restrictive measures to reduce or limit the transboundary release of GMOs, the EU will again be in a position to set forth the precautionary principle as a defense for its actions. The EU has not attempted to use the principle as a standard, but this discussion proposes that doing so has a greater likelihood of acceptance with regard to the WTO/GATT/SPS regime. Advancing the precautionary principle as less than a substantive rule will accord it a more concrete legal status than it currently enjoys, at the same time such an expression will be less threatening to SPS rules and to the EU's trading partners opposing the principle. At the very least, advancing precaution as an international standard in the long-running GMO stalemate may be a political bargaining tool through which the EU can achieve its desired aim.