STUDENT ARTICLES

REGULATING GENETICALLY MODIFIED PRODUCTS AND PROCESSES: AN OVERVIEW OF APPROACHES

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INTRODUCTION

Biotechnology is rapidly changing agricultural practices and posing a significant challenge to policymakers worldwide. Although the first genetically engineered foods were marketed only a few years ago, about thirty to thirty-five percent of soybeans and twenty-five percent of corn grown in the United States in 1998 were from genetically-modified (GM) seeds, with total acreage in GM crops exceeding thirty million.[1] Around sixty percent of packaged foods in supermarkets contain genetically modified organisms (GMOs).[2] Despite the many benefits attributed to genetic engineering of crop—such as increased yields and reduced pesticide inputs—scientists, the public, and governments are divided as to the ecological and health risks posed by GMOs.

Though selective breeding techniques have been implemented for centuries, the advent of recombinant DNA technology has greatly expanded the extent to and rapidity with which plants can be manipulated for desired traits. Researchers can now remove genes from microorganisms, animals, and plants and

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[1] *See* Natalie Pargas, *Next Generation Biotech Products Will Face Traditional Labeling Issues in U.S., Maryanski Notes*, 40 Food Chemical News (Information Access Co.) No. 21 (July 13, 1998), *available in* 1998 WL 10981464; Charles W. Schmidt, *Natural Born Killers*, 106 ENVTL. HEALTH PERSP. A432 (1998).

[2] *See* Gerard Aziakou, *Farm Biotechnology: Panacea or Dangerous Science?*, AGENCE FRANCE PRESSE, Dec. 16, 1998, *available in* DIALOG, File No. 614; *World News Tonight* (ABC television broadcast, Nov. 9, 1998), *available in* 1998 WL 7293309.

insert them into crops to produce traits such as increased yield or quality.[3] These new techniques have solved many of the problems that historically plagued breeders, such as specificity of trait selection and sexual compatibility. For example, tomatoes have been engineered to ripen at a slower rate to increase shelf life.[4] Inherent disease resistance has been introduced into maize by inserting Bacillus thuringiensis (Bt) genes, a virus coat protein, into the genetic material of the maize plant whereby it receives the ability to resist certain insects and viruses.[5] Cotton and soybeans have been given bacterial genes, allowing the plants to tolerate herbicide applications, the primary example of this enhanced seed system being Monsanto's Roundup Ready soybeans.[6]

Biotechnology provides a promising means to increase the yields derived from existing farmed acreage, an attractive alternative to expanding operations into uncultivated habitat. However, the concern is that the ecological and human health effects of biotechnology and GMOs are largely unknown, and the situation is further complicated by potentially troubling social and ethical implications of GMOs. Using GMOs without further knowledge of their effects may be a more serious threat to our ecosystems and biodiversity than the risks of not using GMOs during this time.[7] Opponents of GMOs believe the precautionary principle should serve as a guide in the face of so much scientific uncertainty. Proponents feel the tangible benefits of GMO use outweigh the speculative risks of future environmental crises.[8]

Given the disagreement about the benefits and potential risks of GM crops, it is no surprise that nations have taken varying approaches with respect to the regulation of foods and food products derived from genetic modification. The United States,

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[3] *See* Mary Jane Angelo, *Genetically Engineered Plant Pesticides: Recent Developments in the EPA's Regulation of Biotechnology*, 7 U. FLA. J.L. & PUB. POL'Y 257, 262 (1996).

[4] *See* Sara M. Dunn, Comment, *From Flav'r Sav'r To Environmental Saver? Biotechnology and the Future of Agriculture, International Trade, and the Environment*, 9 COLO. J. INT'L ENVTL. L. & POL'Y 145, 146 (1998).

[5] *See id.* at 151-52.

[6] *See id.* at 151.

[7] *See* Julia Flynn et al., *Seeds of Discontent*, BUS. WK., Feb. 2, 1998, at 62.

[8] *See* Thomas P. Redick et al., *Private Legal Mechanisms for Regulating the Risks of Genetically Modified Organisms: An Alternative Path Within the Biosafety Protocol*, 4 ENVTL. L. 1, 15 (1997).

the world's largest producer of GM food,[9] and European Union (EU) regimes illustrate the tension between competing approaches. The first genetically-engineered crops were produced in the United States in 1994 and have been relatively well-received domestically. Due in part to more traditional agricultural practices and greater consumer resistance to GMOs, the EU and its member states have been less receptive to the introduction of GM crops into their markets.

The most recent embodiment of the GMO debate focuses on whether requiring labeling of products derived from GMOs complies with international trade agreements. The United States has complained to the World Trade Organization (WTO) concerning EC Regulation 1139/98, which requires the labeling of genetically-modified corn and soybeans.[10] The United States views this measure as protectionist and not based on science as required by the WTO Agreement on Sanitary and Phytosanitary Measures (SPS Agreement).[11]

The labeling issue illustrates the broader concerns at the forefront of international trade discussions since the Uruguay Round and in the wake of the WTO summit in Seattle, including: the balance between national and multilateral policies, harmonization of environmental standards, discouragement of unilateral trade measures, and distinguishing production and process methods from end products.[12] The concern of proponents of trade liberalization is that health and environmental regulations can have protectionist effects by blocking the market access of exporting countries.[13] If a United States complaint is formally brought before the WTO dispute settlement body, the challenge will be to determine if the EU's mandatory labeling regulations constitute a legitimate effort to protect environmental and health standards or if they are impermissible restrictions of trade.

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[9] *See* Marie Woolf, *Revealed: How US Bullies Nations Over Genetic Food*, INDEPENDENT, Nov. 22, 1998, at 14.

[10] Council Regulation 1139/98, 1998 O.J. (L 159) 4.

[11] Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS: THE LEGAL TEXTS, at 69; *available in* 1994 WL 761483 [hereinafter SPS Agreement].

[12] *See* Scott Vaughan, *Trade and Environment: Building the Revolutionary Framework* (visited Aug. 28, 2000) <http://www.unep.ch/t&e/ieo.html>.

[13] *See id.*

I
THE COMPETING ASSESSMENTS OF GENETICALLY MODIFIED FOOD AND LABELING REQUIREMENTS

A. *Proponents of Genetic Modification*

1. *Genetic Modification Processes are Safe*

Proponents of GMOs remind skeptics that ecosystems and gene pools fluctuate with or without genetic modifications. As a Monsanto research technician said, "[w]hat we do is the same as Mother Nature."[14] Breeding practices have long involved traditional sex-crossing, selection, and breeding. The use of genetic modification speeds these processes,[15] allows for the development of new crosses,[16] and makes it possible to avoid undesired traits.[17] GM seeds may promise higher yields per unit area, lower pesticide use and costs, and result in crops that tolerate drought and salty soil.[18] The use of pesticides may be drastically reduced by engineering crops to develop their own resistance to predatory insects and diseases, or by selecting and strengthening biological predators of insect or microbial pests.[19]

Problems leading to the development of "super-weeds" and ecosystem disruption are as likely, if not more likely, to arise with the introduction of non-GM exotic species who lack natural predators in the new environment. This disruption is unlikely to occur if the agricultural GMOs such as soy and corn already exist in an area and are domesticated to an extent that makes them unlikely to survive without cultivation.[20] In most cases, hybrids produced from crossing a domesticated crop and a weed will demonstrate sterility or reduced fitness, making the transgenic characteristic unlikely to establish itself in wild populations.[21]

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[14] Stan Grossfeld, *Genetic Engineering Debate Shifting to America*, BOSTON GLOBE, Sept. 23, 1998, at A1.

[15] *See* John H. Barton, *Biotechnology, the Environment, and International Agricultural Trade*, 9 GEO. INT'L ENVTL. L. REV. 95, 106 (1996).

[16] *See id.*

[17] *See* James H. Maryanski, *U.S. Food and Drug Administration Policy for Foods Developed by Biotechnology*, in GENETICALLY MODIFIED FOODS: SAFETY ISSUES at 12, 12-13 (Karl-Heinz Engel et al. eds. 1995).

[18] *See* Barton, *supra* note 15, at 106.

[19] *See* Barton, *supra* note 15, at 99-100; Flynn et al., *supra* note 7, at 5.

[20] *See* Barton, *supra* note 15, at 107.

[21] *See* Schmidt, *supra* note 1, at A435.

Opponents of GMOs are fearful of the risk that genetic material will cross over into wild strains and reduce biodiversity by crowding out other plants. But banning or discouraging the use of GMOs, proponents argue, may require agricultural producers to develop more acreage. This expansion could cause the extermination of desired plant varieties.[22] Long delays in the implementation of these technologies could actually impede sustainable development and result in a loss of biodiversity.[23]

Meanwhile, biotech companies claim that the risks associated with the development of pest resistance and "super-pests" are easily controlled with their voluntary risk management policies.[24] For example, by planting traditional varieties near the GMOs, farmers can create buffer zones or refuges for non-resistant insects that will dilute the resistance built up by insects in the GMO crop. This will postpone the development of resistance for an estimated thirty years, at which point other pesticidal proteins can be engaged.[25] As a last resort, germplasm banks, like the one established in the United States, can prevent a plant from being eradicated by a disease.[26]

2. *Genetically Modified Products are as Safe as Conventionally-Bred Counterparts*

Genetically modified crops may offer retailers and consumers lower-cost products that taste good, are easy to transport, have increased shelf life and nutritional value, and to date, pose no clearly demonstrated health or safety problems. There are many available tests to screen transgenic proteins for allergenic properties, and "there is no evidence that transgenic plants . . . have inadvertently introduced any new allergens into the marketplace thus far."[27] Although imperfect, the existing tests have prevented the introduction of new allergens into the market.[28] In addition, direct benefits to the consumer will soon be realized, with products such as salad oils with lower levels of saturated

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[22] *See* Redick et al., *supra* note 8, at 18-19.

[23] *See* Redick et al., *supra* note 8, at 18-19.

[24] *See* Redick et al., *supra* note 8, at 13.

[25] *See* Michael Pollan, *Playing God in the Garden*, N.Y. TIMES, Oct. 25, 1998, § 6 (Magazine), at 50.

[26] *See* Redick et al., *supra* note 8, at 8.

[27] Schmidt, *supra* note 1, at A434.

[28] *See* Schmidt, *supra* note 1, at A434.

fat.[29] By developing and using genetically modified crops, we can keep apace of a growing global population while keeping natural areas free from conversion to agriculture.

3. *Product Labels Should Not Be Required*

Given the costs associated with the identification, separation, and labeling of GMOs, coupled with the absence of demonstrated health risks, it is impracticable to request manufacturers to label every product containing GMOs. It is also unclear whether providing this information would truly assist consumers or merely confuse them, given "consumers' generally naïve understanding of the environment, the lack of clear standards regarding relationships between human activities and the environment, and the difficulty of verifying many environmental claims."[30]

The fact that a product is produced by genetic engineering is by no means a perfect indicator of increased environmental externalities or adverse health effects.[31] In fact, it may be that a GM crop required significantly fewer chemical inputs or was grown on otherwise infertile land—environmental benefits that may be reflected in a lower price. Until consumers understand the benefits of genetic engineering, labels will cause undue alarm and misconception. Given our complex system of environmental regulation, price is an effective proxy for environmental impacts and resource costs because it reflects many factors.[32]

A labeling requirement based solely on the consumers' desire to know violates the right not to speak.[33] In *International Dairy Foods Association v. Amestoy,* dairy manufacturers challenged the constitutionality of a Vermont law requiring labels for products derived from cows treated with bovine growth hormones.[34] The Court of Appeals for the Second Circuit held that consumer concern alone was not sufficient to constitute a sub-

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[29] *See Continuing Gulf Between US and EU Over Biotech*, AGRA EUROPE, July 3, 1998, at A3.

[30] Peter S. Menell, *Structuring a Market-Oriented Federal Eco-Information Policy*, 54 MD. L. REV. 1435, 1445 (1995) (citations omitted).

[31] *Cf. id.* at 1451 (discussing a comparative study of polystyrene versus recycled paperboard cups and noting the numerous factors that must be considered in evaluating a product's externalities).

[32] *See id.* at 1455.

[33] *See* International Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 71-72 (2d Cir. 1996).

[34] *See id.*

stantial state interest, and thus the mandatory labeling was found to be an unjustifiable restriction of commercial speech in violation of the First Amendment.[35] Any other result would theoretically require that a vast array of consumer concerns be addressed on product labels. A more rational and feasible option is to encourage consumers to buy "GMO-free" products, while recognizing the limited utility of such a label when it comes to health or environmental implications.[36]

B. *The Precautionists*

1. *The Process of Genetic Modification May Be Unsafe*

Although biotech companies like Monsanto depict GM as no different from other human modifications of natural processes,[37] it is erroneous to conclude that what has been safe in the past will be safe in the future, without considering relevant factors such as new combinations being produced across phyla[38] and increasingly disturbed habitats. Precautionists are wary of the proclamation that GM crops are as safe as conventional breeds since there is no way to predict all of the effects of genetic manipulation, especially when field tests are conducted under tightly controlled conditions. Also skeptical of the political influence of multinational chemical companies, opponents note that GMOs are geared toward large-scale farming, which will reinforce monocultural agriculture and its attendant risks, such as reduced genetic and biological diversity.[39] Development of herbicide-resistant crops may also lead to an increase in herbicide application and a reduced emphasis on the development of other more sustainable agricultural practices.[40]

Although biotech companies speak of the benefits of GM technology for addressing the problem of world hunger, skeptics identify increasing shareholder profits as the principal motivation

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35 *See id.* at 74.

36 *See, e.g.*, Frederick H. Degnan, *The Food Label and the Right-to-Know*, 52 FOOD & DRUG L.J. 49, 59 (1997).

37 *See* Pollan, *supra* note 25, at 48.

38 *See* Pollan, *supra* note 25, at 48 ("The introduction into a plant of genes transported not only across species but whole phyla means that the wall of that plant's essential identity—its irreducible wildness, you might say—has been breached").

39 *See* Consumers International, *Genetically Modified Foods: Magic Solution or Hidden Menace?* (last modified July 31, 1999) <http://www.consumersinternational.org/campaigns/biotech/briefing.html>.

40 *See id*.

of these GMO developers.[41] For example, one argument is that large agricultural chemical companies entered the market so they can develop GM seeds that are tied to a particular chemical product, thus enabling the company to insure a continued market for its chemicals.[42]

Another concern surrounding GMOs involves the competing tension between the goal of transferring genes on the one hand, and, on the other hand, the effort to preclude gene flow once the transfer has occurred in order to minimize the dilution of species diversity.[43] There is a substantiated fear that pesticide-resistant genes engineered into seed crops could outcross into other sexually compatible plants surrounding the crop.[44] This transfer of genetic material may then confer the superior trait, such as insecticidal properties, to the wild relatives, giving them a competitive edge over other plants. The effects could be particularly damaging in a crop's origin country. For example, for corn, Mexico is the center of diversity, for soya beans, China.[45] The gene transfer, also referred to as "genetic pollution," may also extend to soil microbes and other locations on the food web. A related risk is that the genetically modified crops themselves can become weeds as a result of their new vigor.[46]

Containment of transgenic plants is an impractical goal. Governments and industry should proceed on the assumption that the transgenes will escape their intended locations. A lack of data establishing environmental risk should not be taken as evidence of no risk, but as an indication that research is needed in that area. Otherwise, biological pollution may indeed become "the environmental nightmare of the 21st century."[47] The theory that exotic species that have not co-evolved possess a greater potential to disrupt ecosystems is an argument for the regulation of

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41 *See, e.g.*, J. Madeleine Nash, *Grains of Hope,* TIME, July 31, 2000, at 41 (stating that consumers view the fact that GM seeds are produced by the same multinational corporations that produce agricultural pesticides with suspicion).

42 *See* Neil D. Hamilton, *Plowing New Ground: Emerging Policy Issues in a Changing Agriculture,* 2 DRAKE J. AGRIC. L. 181, 190 (1997).

43 *See* Barton, *supra* note 15, at 99; Nash, *supra* note 41, at 45.

44 *See* Barton, *supra* note 15, at 99.

45 *See* Schmidt, *supra* note 1, at A436.

46 *See* David J. Earp, *The Regulation of Genetically Engineered Plants: Is Peter Rabbit Safe in Mr. McGregor's Transgenic Vegetable Patch?*, 24 ENVTL. L. 1633, 1654 (1994).

47 Pollan, *supra* note 25, at 50, *quoting* Andrew Kimrell, director of the Center for Technology Assessment in Washington, DC.

both exotic species *and* GMOs, not for the dismissal of GMO regulation as unnecessary.[48]

There is evidence that beneficial insects—natural predators of insect pests—may be killed as unintended targets of the genetically engineered seeds containing pesticides, introducing weakness in the food web.[49] A recent and controversial study released by Cornell University researchers demonstrated that pollen from Bt-corn can kill monarch butterfly larvae.[50] The pollen of Bt-corn can be carried beyond the field by the wind, landing on other plants that comprise food sources for various insects.[51]

Another danger is the likelihood that over time, pests are likely to build up resistance to the pesticidal toxins in GM plants (also referred to as "plant-pesticides"). This could lead to an increase in pesticide use, a phenomenon GMOs have been proclaimed to reduce. Of particular concern is resistance to Bt, an externally applied defense mechanism favored by organic farmers, which researchers have now engineered into crops. Bt-based plant-pesticides have been adopted at a rate three times as fast as estimates by the United States Environmental Protection Agency (EPA) had predicted.[52] The fear is that insect resistance to externally-applied and plant-pesticide Bt will develop, putting an end to the effectiveness of this method of pest defense.[53] Greenpeace International (Greenpeace), the International Federation of Organic Agricultural Movements (IFOAM, with more than 650 member organizations representing farmers, processors and retailers in one hundred countries), the Center for Food Safety, and more than seventy other plaintiffs filed a suit against the EPA in February 1999, alleging the violation of several environ-

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48 *See* Barton, *supra* note 15, at 116.

49 *See* Nigel Williams, *Agricultural Biotech Faces Backlash in Europe*, 281 SCIENCE 768, 770 (1998).

50 *See* Blaine P. Friedlander, Jr., *Toxic Pollen From Genetically Modified Corn Kills Monarch Butterflies, Researchers Find in Lab Tests*, CORNELL CHRON. (visited Jan. 27, 2000) <http://www.news.cornell.edu/Chronicles/5.20.99/toxic_pollen.html>.

51 *See id.*

52 *See* United States Environmental Protection Agency, Office of Pesticide Programs, *Status Report for the PPDC: Resistance Management For Bt-crop* (last modified Dec. 31, 1998) <http://www.epa.gov/oppfead1/cb/ppdc/resistbt.htm>.

53 *See* Pollan, *supra* note 25, at 48.

mental laws and regulations in allowing Bt plants to be marketed.[54]

Labeling may be an inconvenience to agribusiness, but it seems a small sacrifice for gaining increased trust from consumers while acknowledging the novelty of the technology. Industry should counter opposition not with resistance to labeling, but with consumer education about the benefits of biotechnology and the safety of the products, to the extent such information is available and truthful. Industry could even view a GMO label as a marketing tool, an "eco-label." It could demonstrate that the GMO-derived product has been developed and marketed with concern for the environment and sustainability.[55] A GMO product's life cycle and resulting environmental impacts could put it ahead of a traditionally derived product on an overall scale of environmental soundness.[56]

2. *Genetically Modified Products May Be Unsafe*

There are demonstrated health risks associated with genetically altered food as well as considerable uncertainty as to other possible negative health effects. Allergenicity is one of the primary health concerns.[57] Due to a lack of predictive models for testing allergens, it may be difficult to assess the toxicity of transgenic substances and to determine the sensitized portions of the populations.[58] Given the increased risk of allergen presence in GM foods, labels should be required. For example, in 1996, individuals who unsuspectingly consumed soy with inserted Brazil nut genes suffered from serious allergic attacks.[59]

Another problem with plant-pesticides like Bt-maize is the potential for resistance to antibiotics. For example, through the insertion of Bt and "marker" genes, Ciba developed a European corn borer-resistant hybrid that controls the insect from within the plants.[60] Although the marker permits engineers to determine if a gene has been successfully injected into a plant and

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[54] *See* Greenpeace v. Browner, No. 99-389 (D.D.C. filed Feb. 18, 1999).
[55] *See* Redick et al., *supra* note 8, at 68.
[56] *See* Redick et al., *supra* note 8, at 73-74.
[57] *See* Schmidt, *supra* note 1, at A434.
[58] *See* Schmidt, *supra* note 1, at A434.
[59] *See* Aziakou, *supra* note 2.
[60] *See, e.g.,* Abigail Salyers, *Genetically Engineered Plants Are Safe—and Necessary Bioextremist Forces Have Created Unwarranted Public Anxiety*, CHRISTIAN SCI. MONITOR, Jan. 28, 1997, at 18.

helps to distinguish genetically engineered from traditional varieties, it also may be resistant to the common antibiotic ampicillin.[61] Resistance to ampicillin is not a troublesome characteristic for corn, but there is concern about the ramifications to consumers further along the food chain,[62] such as antibiotic resistance in humans, livestock, and bacteria. Highly contested research by a scientist at the Rowett Institute also indicates significant negative effects of GM potatoes on the immune systems of rats.[63]

3. *Product Labels Should be Required for Product and Process Risks*

While some groups advocate a total ban on GMO products, labeling is viewed as a less comprehensive but important first step to protecting human health and the environment in the face of risk and uncertainty.[64] While product safety and health concerns are a major factor in the push for mandatory labeling, many consumer and environmental groups also advocate labels on the basis of environmental concerns and the consumer right-to-know doctrine.[65]

Critics of biotechnology do not correlate the lack of consumer resistance with meaningful acceptance, but rather with well-funded education campaigns launched by the biotechnology industry.[66] Even with such campaigns, it is likely that the low level of consumer resistance is due to ignorance of the fact that some of the products they are consuming are derived from GMOs.[67] Labels may be able to provide information where the market does not. Price alone is not sufficient to inform consumers about a product's life cycle and externalities. Although price may in part reflect the environmental costs of production—for example, higher costs in areas with more pollution and possibly more stringent controls as a result—it is not clear that our system of environmental regulation captures the full cost of the regu-

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61 *See* Consumers International, *supra* note 39.

62 *See e.g.,* Consumers International, *supra* note 39.

63 *See, e.g., GM Foods: Half-Baked*, ECONOMIST, Oct. 16, 1999, at 85.

64 *See, e.g.* MATTHEW STILWELL & BRENNAN VAN DYKE, AN ACTIVIST'S HANDBOOK ON GENETICALLY MODIFIED ORGANISMS AND THE WTO 6-7 (2d ed. 1999).

65 *See* Philip L. Bereano, *The Right to Know What We Eat*, SEATTLE TIMES, Oct. 11, 1998, at B7.

66 *See* Aziakou, *supra* note 2.

67 *See* Pollan, *supra* note 25, at 45.

lated activity or precludes evasion of the law.[68] For example, Roundup Ready soybeans might cost less than a traditionally-bred variety. This cost savings could result from a variety of factors, from reduced labor needs to being able to indiscriminately spray the crop with herbicides while not being held accountable for the resulting increase in non-point source pollution. Consumers may not yet be sophisticated enough to incorporate "downstream costs" and product quality into their decision-making process without the assistance of labels and other supplemental information.[69]

In addition, many environmental costs, such as biodiversity reduction, are not as amenable to monetary valuation as, for example, are energy inputs or transportation costs. However, these costs need to be considered. For example, although hotly contested, a recent study conducted at Cornell has received a great deal of press for its discovery of the negative effects of Bt-corn *pollen* on monarch butterflies.[70]

Even with the overall high level of "acceptance" of GMOs, opposition is mounting in the United States. Some lawsuits have been brought, such as the 1998 action brought by the Alliance for Bio-Integrity, the International Center for Technology Assessment, twenty-two individuals, and one synagogue against the Secretary of the Department of Health and Human Services and the FDA's Lead Deputy Commissioner. The suit alleges current food policy regarding bio-engineered foods violates federal statutory mandates to protect public health and inform consumers.[71]

Many of the individual plaintiffs who are religious leaders claim that the defendants are also violating their religious freedom and placing a burden on individuals who follow religious dietary laws.[72] The plaintiffs are challenging thirty-six genetically modified whole foods now being sold in the United States, arguing that lack of safety testing and refusal to require labeling makes it "difficult or impossible to comply with religious dietary

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[68] *See* Menell, *supra* note 30, at 1452.

[69] *See* Menell, *supra* note 30, at 1464 (explaining how "intelligent" use of a price system depends in large part on consumers engaging in comparative shopping that accounts for use and disposal costs as well as product quality in their initial purchasing decisions).

[70] *See* Friedlander, *supra* note 50.

[71] *See Safety, Religious Concerns Cited in Suit Against FDA Over New Foods,* 66 U.S.L.W. No. 47, at 2753 (June 9, 1998).

[72] *See id*. at 2754.

laws."[73] The defendants maintain that "[t]here is no scientifically valued distinction between the safety of genetically enhanced food and food grown by traditional methods."[74]

More recently, Greenpeace, IFOAM and twenty-two U.S. farmers filed a suit against the EPA on February 18, 1999.[75] The plaintiffs allege that EPA violated federal laws and the agency's own regulations in approving Bt-crops.[76] Abroad, Friends of the Earth has recently challenged the U.K. government's consent for increased GM oil seed rape trials.[77] In addition, news coverage of the protests in Seattle at the WTO trade summit brought international attention to the food labeling and safety debate. The media attention may escalate the level of attention American consumers give to GMOs and result in more widespread rejection and distrust of GMO products than has previously been the case.

II
Regulation of Genetic Modification and its Products in the United States

A. *General Acceptance of Genetic Modification and its Products*

The reason for the United States government and biotech industry's opposition to the EU regulations concerning the mandatory labeling of GMOs becomes clearer after examining the relevant regulatory mechanisms. The United States system for regulating GM plants and their products seeks to determine their safety to humans and the environment. Three federal organizations figure significantly in the regulation of GM plants: the United States Department of Agriculture (USDA), the EPA, and the Food and Drug Administration (FDA).

The roles of the various organizations are outlined under the Coordinated Framework developed in 1984.[78] The Framework is comprised of existing statutes and is expected to evolve in accord

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[73] *Id*. at 2753.
[74] *Id*. at 2754.
[75] *See* Greenpeace v. Browner, No. 99-389 (D.D.C. filed Feb. 18, 1999).
[76] *See id.*
[77] *See* Peta Firth, *U.K. Government Announces Plan to 'Robustly' Defend GMO Approval*, 22 Int'l Env't Rep. (BNA) No. 18, at 719 (Sept. 1, 1999).
[78] *See* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (1986).

with the experiences of industry and the agencies.[79] All three organizations have reached the conclusion that fear of GM plants is, for the most part, misplaced and are in the process of relaxing regulations and simplifying approval procedures.[80] Resolving labeling issues for foods and food products, including those derived from GMOs, is the responsibility of the FDA.[81] The FDA and USDA are participating in international efforts to harmonize food safety and labeling requirements[82] and some U.S. policymakers have indicated support for self-regulation and voluntary risk management.[83]

B. *Regulation of Genetically Modified Foods and Labeling Requirements*

1. *The Process and Raw Product are Safe*

a. *The USDA Regulation of Genetically Modified Plants and Their Offspring*

Under the authority of the Plant Protection Act of 2000,[84] the USDA regulates GM plants, primarily through the Animal Plant Health Inspection Service (APHIS). It is the permitting organization for the import, interstate movement and field testing of GM plants.[85] Since concluding that transgenic plants are generally safe, APHIS has simplified its procedures for introduction of GM plants, resulting in many plants being introduced after following the "notification" procedure. This procedure requires a plant to meet various criteria and also requires assurance of containment of the plant and its offspring.[86] In addition, plants may be deregulated after an Environmental Assessment is

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[79] *See* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23,302.

[80] *See* Judith E. Beach, *No "Killer Tomatoes": Easing Federal Regulation of Genetically Engineered Plants*, 53 FOOD & DRUG L.J. 181, 182 (1998).

[81] *See generally id.*, at 184-87 (considering the FDA's authority to regulate GM products).

[82] *See* Bruce Silverglade et al., *International Harmonization of Food Safety and Labeling Standards: Threats and Opportunities for the U.S. Food and Drug Administration and the U.S. Department of Agriculture* (visited Sept. 1, 2000) <http://www.cspinet.org/reports/codex.htm>.

[83] *See* Redick et al., *supra* note 8, at 50.

[84] Pub. L. No. 106-224, 114 Stat. 358 (2000).

[85] *See* United States Trade Representative for Agricultural Affairs, *U.S. Regulation of Products Derived From Biotechnology* (last modified June 29, 1998) <http://www.ustr.gov/reports/bioreg.pdf>.

[86] *See, e.g.,* 7 C.F.R. §§ 301, 318, 319, 340 (1999).

prepared detailing the risks of no longer regulating a plant, and after a Determination concludes the plant does not threaten to become a pest.[87] One example of a deregulated GMO is the Flav'r Sav'r tomato, considered to be as safe as conventionally-produced tomatoes.[88]

b. *EPA Regulation of Genetically Modified Plants with Characteristics of Pesticides*

GM plants with characteristics of pesticides (also known as "plant pesticides") are regulated by the EPA. The EPA regulates the testing, sale and use of bio-engineered pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)[89] and has permit authority under the Federal Food, Drug, and Cosmetic Act (FDCA).[90] Experimental Use Permits (EUPs) are required before field testing of pesticide-plant crops that will eventually be used as food or feed.[91] Before the sale or distribution of a crop, the plant pesticide rule requires the developer to register the new plant-pesticide and seek a tolerance or tolerance exemption.[92] The registrant must comply with various conditions, including conditions on sale or distribution, resistance management and monitoring for adverse effects.[93] All registered pesticides must comply with risk-reduction labeling requirements.[94] Recognizing that typical pesticide labels may not be meaningful on plant pesticides—for example, seeds saved from previous seasons will not bear labels—the EPA is attempting to adapt the regulatory process to the unique issues posed by plant pesticides.[95]

The EUP rule exempts those plant pesticides that the EPA believes pose a low probability of risk and are unlikely to cause unreasonable adverse effects if not regulated.[96] Some of the low risk categories identified by the EPA are: plant pesticides that are normally a component of the plant; plant-pesticides that act

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87 *See* Beach, *supra* note 80, at 183-84.
88 *See* Beach, *supra* note 80, at 185.
89 7 U.S.C. § 136-136y (1994).
90 21 U.S.C. §§ 301-395 (1994).
91 *See* 7 U.S.C § 136c.
92 *See* 7 U.S.C. § 136.
93 *See* Schmidt, *supra* note 1, at A436.
94 *See* 40 C.F.R. § 172.6 (1999).
95 *See* Angelo, *supra* note 3, at 296.
96 *See* Angelo, *supra* note 3, at 297-98.

to inhibit a pest from physically attaching to the plant or penetrating its tissues; coat proteins from plant viruses that confer viral coat protein-mediated resistance (not toxic to humans or animals); residues of nucleic acids; plant-pesticides from plants closely related to the recipient plant; and plant-pesticides that would not result in significantly different exposures.[97]

2. *The FDA and Food Products*

GM food safety issues are primarily handled by the FDA under the FDCA[98] and the Public Health Service Act (PHSA).[99] In 1992, the FDA clarified its regulatory approach regarding products derived from new plant varieties and provided industry guidance for conducting food safety assessment.[100] According to the FDA, the extensive history of safety of plant varieties developed through agricultural research generally renders it unnecessary to review the safety of foods derived from new plant varieties.[101] The same safety standards applied to food and food ingredients derived from traditional plant breeding are applied to products derived from genetic engineering:

> The regulatory status of a food, irrespective of the method by which it is developed, is dependent upon objective characteristics of the food and the intended use of the food (or its components). The method by which food is produced or developed may in some cases help to understand the safety or nutritional characteristics of the finished food. However, the key factors in reviewing safety concerns should be the characteristics of the food product, rather than the fact that the new methods are used.[102]

A food substance or food component that is the result of plant genetic modification and whose composition is so altered that the substance is not "generally recognized as safe" (GRAS), and that is otherwise not exempt, is subject to regulation, including pre-market review and approval, as a "food additive" under

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97 *See* Angelo, *supra* note 3, at 297-98; Beach, *supra* note 80, at 190-91.

98 21 U.S.C. §§ 301-395 (1994).

99 42 U.S.C. §§ 201-300 (1994).

100 *See* Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984 (1992).

101 *See* Maryanski, *supra* note 17, at 15.

102 Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. at 22,984-5.

FDCA section 409.[103] The FDA expects that the substances or components that are the products of genetic engineering—proteins, carbohydrates, fats and oils—will be the same as or substantially similar to those already present in traditional foods and so are not likely to warrant pre-market review and approval as food additives.[104] The FDA "recommends" pre-market consultation for all products that are bio-engineered or considered GRAS, but ultimately leaves the decision to company discretion.[105]

The FDA also monitors foods to ensure that pesticide tolerances set by the EPA are not exceeded.[106] The FDA generally exempts whole foods such as grains from the pre-market approval process,[107] while imposing obligations, under FDCA section 402(a), on developers to ensure that their products are safe to consumers.[108] The FDA retains the authority to pull products that it determines pose a health risk.[109] The FDA's 1992 policy statement includes a "decision tree" analysis to guide developers through the process of product review.[110]

3. *FDA Does Not Require Specific Product Labels For GMO Products or Processes*

The toxins produced by plant pesticides—genetically modified plants with pesticidal characteristics like the Bt toxin—are not considered foods or food additives and so are exempt from regulation by the FDA.[111] They are treated instead as pesticides and are therefore subject to regulation by the EPA.[112] However, if the plant pesticide is a food or food product, it comes under the jurisdiction of the FDA.[113] But whereas the EPA would require

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103 *Id.*; 21 U.S.C. § 348; *see also* United States Trade Representative for Agricultural Affairs, *supra* note 85.

104 *See* Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. at 22,990.

105 *See* Beach, *supra* note 80, at 185-86.

106 *See* 21 U.S.C. § 346a; *see also* Maryanski, *supra* note 17, at 13.

107 *See* James H. Maryanski, *Safety Assurance of Foods Derived by Modern Biotechnology in the United States* (last modified May 11, 2000) <http://vm.cfsan.fda.gov/~lrd/biojap96.html>.

108 *See* 21 U.S.C. § 342.

109 *See* Maryanski, *supra* note 17, at 15; *see also* Maryanski, *supra* note 107.

110 *See* Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. at 22,985 figs. 1-2.

111 *See* Pollan, *supra* note 25, at 50.

112 *See* Pollan, *supra* note 25, at 50.

113 *See* Pollan, *supra* note 25, at 50.

labeling of a pesticide to be externally applied, the FDA generally does not require the labeling of foods containing plant pesticides.[114] Nor are labels required for other transgenic plants that are ultimately consumed, unless they contain known allergens or are substantially different from their non-transgenic counterparts.[115]

Furthermore, no food label is required simply because genetic modification was used in its production.[116] If an allergen is introduced, if the nutritional content of the food product is substantially altered in structure, or if a unique issue is presented about which the public should be informed, then a label may be required.[117]

The FDCA requires a food producer to reveal all material facts relating to representations suggested by the label or to consequences of the product's use.[118] However, unless there is a safety or usage issue, the FDA does not consider the process used to develop a product to be "material," that is, information requiring disclosure.[119] There are no guidelines on negative labeling such as "does not contain GMOs," other than the requirement that such statements be factual and not suggest superiority over GMO products.[120] Although the FDA requires food labels to disclose processing changes—for example if a food is irradiated, frozen, homogenized or pasteurized[121]—it does not believe genetically-modified foods, absent other characteristics of concern, warrant labels:

> The Act . . . requires that all labeling be truthful and not misleading. The Act does not require disclosure in labeling of information solely on the basis of consumers' desire to know. The Act does require that a food be given a common or usual name, and that the label disclose information that is material to representations made or suggested about the product and consequences that may arise from the use of the product.[122]

The exemption from labeling is based on a determination that foods derived from biotechnology are no less safe or differ-

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114 *See* Pollan, *supra* note 25, at 51.
115 *See* Pollan, *supra* note 25, at 51.
116 *See* Pargas, *supra* note 1, at 5.
117 *See* Pargas, *supra* note 1, at 5.
118 *See* 21 U.S.C. 343(a).
119 *See* Angelo, *supra* note 3, at 274; Maryanski, *supra* note 17, at 16.
120 *See* Pargas, *supra* note 1, at 5.
121 *See World News Tonight*, *supra* note 2.
122 Maryanski, *supra* note 17, at 20.

ent as a class than traditionally bred foods.[123] The United States feels this approach is scientifically justifiable and consistent with international conclusions, based on its review of the scientific literature and reports on foods derived from biotechnology of such bodies as the United States National Academy of Sciences, the United States. National Research Council, the World Health Organization (WHO), the Food and Agriculture Organization (FAO), and the Organization for Economic Cooperation and Development.[124] According to the FDA, all foods are subject to the same stringent standards.[125] The FDA has not required labels for other methods of plant breeding such as chemical and radiation induced mutagenesis or cell culture and sees no reason to distinguish gene splicing;[126] therefore why should DNA methods be any different? Of course, a developer can always voluntarily label a product as developed from genetic engineering, as Calgene has done with the Flav'r Sav'r tomato.[127] However, any requirements above and beyond existing regulations must be scientifically and legally sound.[128]

III
European Union GMO Regulation and Policy

A. *Product and Process Concerns*

While GMOs have met with virtually no resistance in the United States, consumer groups in Europe have actively pursued stringent regulation of genetically-modified crops for several years. For support, they cite to the scientific uncertainty surrounding the environmental effects of the process of genetic engineering as well as the health effects of the foods produced by it.[129]

For example, in 1996, an alliance between the European Parliament Greens and EuroCommerce, an organization representing retail, wholesale and international trade interests, sought a

123 *See* Beach, *supra* note 80, at 186.
124 *See* Beach, *supra* note 80, at 186.
125 *See* Maryanski, *supra* note 17, at 21.
126 *See* Maryanski, *supra* note 17, at 16.
127 *See* Maryanski, *supra* note 17, at 20.
128 *See* Maryanski, *supra* note 17, at 17.
129 *See* Williams, *supra* note 49, at 770.

wholesale ban on genetically modified soybeans.[130] The alliance claimed that soybeans from the United States could be found in 30,000 foods and sixty percent of processed foods sold in markets represented by EuroCommerce and that consumers were wary of such products and the paucity of information provided to them in order to make informed choices.[131] Recently leaked, an internal report from Monsanto revealed that opposition to GMOs is on the rise, from thirty-five to fifty-one percent since 1997, despite a $1.67 million advertising campaign over the past summer.[132] Even the Prince of Wales has publicly expressed his rejection of genetically altered crops.[133]

Trade associations and leading retailers in the EU member states have heeded consumer sentiment and decided that they support giving consumers the opportunity to make an informed choice.[134] Some EU countries, such as Austria and Luxembourg, have banned genetically-modified crops from being planted in their fields even though the crops have been approved by the EU, citing for support the EC Council Directive 90/220 on the deliberate release of GMOs.[135] Article 16 of this Directive allows EU member nations to provisionally restrict or prohibit the use and sale of GMOs for environmental or health reasons.[136]

The difference in consumer reaction in the EU as compared with the United States has been attributed to the public distrust of the food industry after scares from bovine spongiform encephalopathy (mad cow disease); the fact that while risks are taken by consumers, the benefits often go to U.S.-owned agricultural biotechnology companies; and the small-scale nature of farming practices in Europe relative to those in the United

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130 *See* Nyaguthii Chege, Comment, *Compulsory Labeling of Food Produced from Genetically Modified Soya Beans and Maize*, 4 COLUM. J. EUR. L. 179, 180 (1998).

131 *See id.*

132 *See* Aziakou, *supra* note 2.

133 *See* Pollan, *supra* note 25, at 50.

134 *See Europeans Renew Push for Labeling of Genetically Modified Soybeans*, 25 Pesticide & Toxic Chemical News (Information Access Co.) No. 32 (June 4, 1997), *available in* 1997 WL 9738506.

135 *See* European Commission Directorate General, *Commission Proposes to Repeal National Bans on GMO Maize in Austria, Italy and Luxembourg*, EC Doc. No. IP/97/784 (Sept. 10, 1997); Council Directive 90/220, art. 16, 1990 O.J. (L 117) 15, 20.

136 *See* Council Directive 90/220, art. 16, *supra* note 135, at 16; Williams, *supra* note 49, at 768.

States.[137] The use of genetic engineering in the medical field has not been challenged, perhaps due to the distinction between risk takers and beneficiaries in that forum.[138]

The European Commission believes public concern is focused primarily on the novelty of this method of genetic modification and the desire to make informed choices about whether or not to consume GM foods.[139] The fear is that current perceptions of safety are erroneous. In the face of such uncertainty, the European Commission says the public wants full implementation of the precautionary principle.[140]

B. *Regulation of Genetically Modified Foods and Labeling Requirements*

1. *The Process*

Approval of viable GMOs for release and commercialization in EU member states is governed by EC Council Directive 90/220, regulating the deliberate release of GMOs into the environment.[141] The Directive does not apply to those organisms obtained through certain GM techniques that have been conventionally used in a number of applications and have a long safety record.[142]

Researchers are charged with carrying out environmental risk assessments prior to a GMO release, for example, prior to a field test for product development.[143] In addition, no product containing or consisting of GMOs and intended for deliberate release can be marketed without the completion of satisfactory field testing.[144] Directive 90/220 defines an "organism" as "any biological entity capable of replication or of transferring genetic material."[145] A GMO is defined as an organism whose genetic

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137 *See* Williams, *supra* note 49, at 768-69.

138 *See* Williams, *supra* note 49, at 769.

139 *See* Directorate General of the European Commission, *The European Commission Approves the Labelling of Genetically Modified Organisms*, Doc. No. IP/97/528, 1997-06-18, at 2-3 [hereinafter Directorate General].

140 *See id*. at 2-3.

141 *See* Council Directive 90/220, *supra* note 135. The Directive is currently under review for amendment. *See e.g*., Wybe Th. Douma & Mariëlle Matthee, *Towards New EC Rules on the Release of Genetically Modified Organisms*, 8 REV. OF EUR. COMMUNITY & INT'L ENVTL. L. 152 (1999).

142 *See* Council Directive 90/220, Preamble, *supra* note 135, at 15.

143 *See* Council Directive 90/220, art. 5, *supra* note 135, at 17.

144 *See* Council Directive 90/220, art. 5.2(a)(2), *supra* note 135, at 17.

145 Council Directive 90/220, art. 2.1, *supra* note 135, at 16.

material has been altered in such a way that did not naturally occur through natural recombination or reproduction.[146] The Directive interprets "deliberate release" as "any intentional introduction into the environment of a GMO or a combination of GMOs without provisions for containment, such as physical barriers or a combination of physical barriers together with chemical and/or biological barriers used to limit contact with the general population and the environment."[147]

The notification and prior consent procedures for GMO products intended for marketing are more extensive than those required for research and development releases. The manufacturer or importer of a product containing GMOs must submit a notification to the proper authority of the relevant state.[148] The notification for marketing releases must include information on human health and environmental impacts collected in the research and development stages.[149] In addition, marketing notification must contain the notifier's proposed labeling of the product, including the names of GMOs the product contains.[150] The competent authority, however, has the ultimate say with respect to the labeling.[151]

2. *The Product*

After submitting a notification, the manufacturer or importer of a GMO must receive written consent prior to releasing or marketing the product.[152] Consent to market the product may only be granted if written consent was secured during the research and development stages, or if the Directive's risk analysis requirements have been met.[153] First, the national authority may either reject the proposed release or forward the notification to the European Commission, recommending a favorable decision.[154] The Commission then circulates the notification to the

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146 *See* Council Directive 90/220, art. 2.2, *supra* note 135, at 16.

147 Council Directive 90/220, art. 2.3, *supra* note 135, at 16.

148 *See* Council Directive 90/220, art. 5.1, *supra* note 135, at 17.

149 *See* Council Directive 90/220, arts. 15-16, *supra* note 135, at 20. *See also Genetic Engineering: France Under Fire for Non-Compliance with GMO Directive*, EUR. REP., Oct. 10, 1998, *available in* 1998 WL 19803480.

150 *See* Council Directive 90/220, art. 11.1, *supra* note 135, at 18-19.

151 *See* Council Directive 90/220, art. 11.1, *supra* note 135, at 18-19.

152 *See* Council Directive 90/220, art. 6.4, *supra* note 135, at 18.

153 *See* Council Directive 90/220, art. 10.1, *supra* note 135, at 18.

154 *See* Council Directive 90/220, art. 12.1, *supra* note 135, at 19.

EU member states, which have sixty days to object.[155] Once the notification and written consent requirements are met, the product may be used throughout the EU, subject to safe use conditions established by the competent authority of the notifying state.[156] No member state may impede the marketing of the GMO-containing products that are in compliance with Directive 90/220, unless it has a justifiable reason to believe the product poses a risk to human health or the environment.[157]

Whereas Directive 90/220 does not expressly cover non-viable products derived from GMOs, Council Regulation 258/97 on Novel Foods established a pre-market approval system and additional labeling requirements for all novel foods including foods consisting of, containing or produced from but not containing GMOs.[158] The novel foods regulation adopts by reference many of the provisions of Directive 90/220. Before being marketed, novel foods must undergo an environmental risk assessment to ensure environmental safety similar to that required by Article 10 of Directive 90/220.[159] A simplified approval procedure is applied to those novel foods and novel food ingredients which are "substantially equivalent" to existing foods or ingredients or derived from traditional propagating or breeding practices with a history of safe use.[160]

The individual wishing to market a GMO food or ingredient must submit a request to the relevant member state.[161] The Commission carries out an initial assessment.[162] Either consent is given to market the product without delay, for example when the product is found to be substantially equivalent and no reasoned objection is made by the Commission or a member state, or an authorization decision is required.[163] A member state may suspend trade in the novel foodstuff if in possession of detailed grounds for believing it poses a danger to human health or the environment.[164]

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155 *See* Council Directive 90/220, arts. 13.1-13.2, *supra* note 135, at 19.
156 *See* Council Directive 90/220, art. 13.5, *supra* note 135, at 20.
157 *See* Council Directive 90/220, art. 15, *supra* note 135, at 20.
158 *See* Council Regulation 258/97, arts. 1.2, 8.1, 1997 O.J. (L 43) 1, 2-3.
159 *See* Council Regulation 258/97, arts. 4, 6, *supra* note 158, at 4.
160 *See* Council Regulation 258/97, arts. 1.2(e), 3.4, *supra* note 158, at 2-3.
161 *See* Council Regulation 258/97, art. 4, *supra* note 158, at 4.
162 *See* Council Regulation 258/97, art. 6, *supra* note 158, at 4.
163 *See* Council Regulation 258/97, art. 4.2, *supra* note 158, at 2.
164 *See* Council Regulation 258/97, art. 12.1, *supra* note 158, at 6.

Soya beans and maize were not covered by the novel foods regulation because it did not apply retroactively to products introduced for sale in the EU before May 15, 1997.[165] Soya beans and maize continued to be regulated under the older Council Directive 90/220. EC Council Regulation 1139/98 of May 26, 1998 (1998 Regulation) fills this gap by regulating the marketing and labeling of GM maize and soya beans.[166]

EC Commission Decision 96/281 formalized consent for the United Kingdom to handle non-viable soya bean fractions during import and before and during storage and processing, but not during sowing.[167] The preamble concludes that there is no reason to believe there will be adverse human health or environmental effects of introducing the pesticide-resistant soya nor any safety reason for requiring its segregation from other soya.[168] In this Decision, it was also found that there was no safety reason for labeling to indicate that the product results from genetic modification. However, as provided for in Directive 90/220, if new information becomes available, additional safeguards such as labeling may be instituted.[169]

EC Commission Decision 97/98 gave France permission to market GM maize which carries the insecticidal properties of the Bt-endotoxin gene that confer increased resistance to the herbicide glufosinate ammonium.[170] Based on the risk assessment conducted, the Decision concluded that there is no reason to believe there will be any adverse human health or environmental effects.[171] The Commission expressly stated that the possibility of insect-pest resistance to the insecticidal properties is not an adverse environmental effect since "existing agricultural means of controlling such resistant species of insects will still be available."[172]

As with the soya consent decision, Decision 97/98 concluded that there is no reason to mention that the product is obtained from genetic modification techniques, but that the label on seed

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165 *See* Council Regulation 258/97, art. 1.2, *supra* note 158, at 2-3. GM rapeseed has since been approved.

166 *See* Council Regulation 1139/98, art. 1.1, 1998 O.J. (L 159) 4, 6.

167 *See* Commission Decision 96/281, Preamble, art. 1, 1996 O.J. (L 107) 10, 10-11.

168 *See id.* Preamble, at 10.

169 *See id.* Preamble, at 10.

170 *See* Commission Decision 97/98, 1997 O.J. (L 31) 69.

171 *See id.* Preamble, at 69.

172 *Id.*

should indicate that the plant has an increased tolerance to the herbicide glufosinate ammonium and protects itself against corn borers.[173] Additional products, such as rapeseed, have received research and development consent in some countries.

3. *Product Labels Required*

a. *Labels Required for Foodstuffs "No Longer Equivalent" to Conventional Counterparts*

Article 8 of Regulation 258/97 on Novel Foods contains additional labeling requirements for foodstuffs that, as determined by scientific assessment, are "no longer equivalent"[174] to conventional foodstuffs. A food is "no longer equivalent" if the assessed characteristics are outside the "accepted limits of natural variations for such characteristics."[175] Consumers are to be informed of the modified characteristics or properties and the method that effected such change.[176] This may be viewed as either a regulation requiring the identification of the products of genetic modification or of the process of genetic modification, depending on whether one views the "no longer equivalent" standard as a valid proxy for product safety issues or simply as a method of isolating and differentiating those products derived from the genetic modification process.

The model for labeling requirements for "no longer equivalent" foodstuffs is EC Council Regulation 1139/98 concerning compulsory labeling of certain foodstuffs produced from genetically modified organisms or particulars.[177] The 1998 Regulation went into effect September 3, 1998.[178] It requires mandatory labeling of GMO products that have already been

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[173] *See id.* art. 1.3, at 70. This Decision was immediately challenged by consumer and environmental groups as well as the European Parliament, which by a vote of 407 to two condemned the Decision and called for its suspension while further investigations were conducted. EU member states also supported the development of clear regulations governing the labeling of genetically modified soya and maize. *See* Chege, *supra* note 130, at 181.

[174] *See* Council Regulation 258/97, art. 8.1(a), *supra* note 158, at 5.

[175] Council Regulation 258/97, art. 8.1(a), *supra* note 158, at 5.

[176] *See* Council Regulation 258/97, art. 8.1(a), *supra* note 158, at 5.

[177] Council Regulation 1139/98, *supra* note 166. General labeling requirements for all products are set out in Council Directive 79/112 on the Approximation of the Laws of the Member States Relating to the Labelling of, Presentation and Advertising of Foodstuffs for Sale to the Ultimate Consumer. *See* Council Regulation 1139/98, Preamble, *supra* note 166, at 4.

[178] Council Regulation 1139/98 repealed and replaced Commission Regulation 1813/97. *See* Council Regulation 1139/98, Preamble, *supra* note 166, at 4-5.

granted consent to be marketed in the EU, namely soya beans (*Glycine max*. L.) with increased tolerance to the herbicide glyphosate[179] and maize (*Zea mays* L.) with the insecticidal properties of Bt-endotoxin gene and increased tolerance to the herbicide glufosinate ammonium.[180] As a result, GMOs marketed before and after the Novel Foods Regulation became effective must comply with the same requirements. The 1998 Regulation details the requirements for two specific GMOs and will likely serve as the model for future GMO marketing and labeling regulations.

The prior regulations, namely Council Directive 90/220, indicated a lack of safety grounds to require labeling of GM soya beans or maize and did not expressly cover non-viable products derived from GMOs.[181] EU member states filled in these gaps with varying levels of food labeling. The lack of harmony between the various member states led the EC to pass the 1998 Regulation to facilitate the trade of these food products and ingredients among EU member states.[182] Environment Commissioner Ritt Bjerregaard expressed satisfaction at the new labeling regulations, considering labels on GMOs as information for the consumer and not a warning.[183] Bjerregaard noted that the labeling makes a strong difference in whether or not EU member states approve GMOs.[184]

The preamble of the 1998 Regulation explains the necessity of informing the final consumer about food characteristics and properties that render a food or food ingredient *no longer equivalent* to an existing food or food ingredient.[185] Therefore, foods and food ingredients produced from GM soybeans or maize which are no longer equivalent to conventional breeds should be subject to labeling requirements.[186] These requirements will be based on "scientific evaluation"[187] using "common

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179 *See* Commission Decision 96/281, 1996 O.J. (L 107) 10.

180 *See* Commission Decision 97/98, *supra* note 170.

181 *See* Council Directive 90/220, *supra* note 135.

182 *See* Council Regulation 1139/98, Preamble, *supra* note 166, at 4.

183 *See* Directorate General of the European Commission, *The European Commission Approves the Labelling of Genetically Modified Organisms* (visited Aug. 30, 2000) <http://europa.eu.int/rapid/start/cgi/guesten.ksh?p_action.gettxt=gt&doc=IP/97/528|0|AGED&lg=EN>.

184 *See id*.

185 *See* Council Regulation 1139/98, Preamble para. 9, *supra* note 166, at 5.

186 *See* Council Regulation 1139/98, Preamble para. 9, *supra* note 166, at 5.

187 Council Regulation 1139/98, Preamble para. 10, *supra* note 166, at 5.

scientifically validated testing methods"[188] resulting in labels that are "no more burdensome than necessary but sufficiently detailed to supply consumers with the information they require."[189]

As the Commission's goal is to have coherent labeling throughout the food and production chains, legislation is being proposed for animal feed and seed. The Commission intends to integrate this "food chain" approach into its proposals for revision of Council Directive 90/220.[190]

b. *The Issue of What Constitutes an Equivalent Product*

The presence of protein or DNA from genetic modification triggers the labeling requirement.[191] A threshold for detection will be set, considering the possibility of a de minimis level of DNA or protein from genetic modification.[192] Food and food ingredients from GM maize or soya beans where DNA or protein from genetic modification is present are not considered equivalent products and are compelled to wear informing labels.[193] However, if DNA or protein resulting from genetic modification is destroyed or reduced to an undetectable level in successive stages of processing, the labeling requirements do not apply.[194] This exemption from the labeling requirement suggests that it is not purely the *process* of GM that the EU is regulating, but rather the final products of the process which have retained the DNA or protein from genetic modification.

In addition, though products produced in whole or part from GM soya beans or maize are subject to the labeling requirements, the 1998 Regulation expressly excludes food additives, food flavorings or extraction solvents used in foodstuff production from its coverage.[195]

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188 Council Regulation 1139/98, Preamble para. 11, *supra* note 166, at 5.

189 Council Regulation 1139/98, Preamble para. 12, *supra* note 166, at 5.

190 *See* Directorate General of the European Commission, *The European Commission Agrees on an Orientation for EU Labelling of GMO Products* (visited Aug 30, 2000) <http://europa.eu.int/rapid/start/cgi/guesten.ksh?p_action.gettxt=gt&doc=IP/97/700|0|AGED&lg=EN>.

191 *See* Council Regulation 1139/98, Preamble para. 13, *supra* note 166, at 5.

192 *See* Council Regulation 1139/98, Preamble paras. 14-15, *supra* note 166, at 5.

193 *See* Council Regulation 1139/98, Preamble para. 16, *supra* note 166, at 5.

194 *See* Council Regulation 1139/98, art. 2.2, *supra* note 166, at 6.

195 *See* Council Regulation 1139/98, art. 1.2, *supra* note 166, at 6.

c. *Label Appearance, Content, and Placement*

The 1998 Regulation specifies that the genetic modification information must be placed in the list of ingredients in parentheses immediately after the ingredient is listed or is to appear prominently (at least in the same sized typeface as the list) in a footnote to the list relating to an asterisk after the named ingredient.[196] The information "produced from genetically modified soya" or "produced from genetically modified maize" may also appear clearly on the product label if no list of ingredients exists.[197] If an ingredient is represented as a category, the information may consist of "produced from genetically modified maize/ starch."[198]

The 1998 Regulation does not affect the right to voluntarily place labels stating "GMO-free" or "contains GMOs" where not scientifically demonstrated but indicated by other evidence so long as such labels comply with other EC law.[199] However, acceptance of the European Commission proposal by the Parliament and member states hinged on the omission of the "may contain" provision.[200] The Commission wanted the "may contain" option to protect small businesses from having to bear the cost of testing raw materials, but most member states, backed by producers, retailers, consumer groups and the food industry, did not want the uncertainty of such a label, feeling it would impose costs while not significantly informing consumers.[201]

d. *Implementation of the 1998 Regulation*

Acting with the intent to protect biodiversity and human health in the face of unknown consequences until further research can be completed, the EU member states will apply the 1998 Regulation universally to genetically-modified soya and maize.[202] The 1998 Regulation provides for a six month transi-

196 *See* Council Regulation 1139/98, art. 2.3, *supra* note 166, at 6.
197 Council Regulation 1139/98, Preamble para. 19, *supra* note 166, at 5.
198 Council Regulation 1139/98, art. 2.3, *supra* note 166, at 6.
199 *See* Council Regulation 1139/98, art. 2.4, *supra* note 166, at 6.
200 *See EU Ministers Approve New Liability Rules for Genetically Engineered Soy and Corn*, 26 Pesticide & Toxic Chemical News (Information Access Co.) No. 31 (May 28, 1998), *available in* 1998 WL 11008931.
201 *See id.*
202 *See Environmental Group Criticizes Loophole in EU Labeling Rules for Genetically Modified Foods*, 6 Food Labeling News (Information Access Co.) No. 50 (Sept. 23, 1998), *available in* 1998 WL 12497907.

tional period for industry to comply with the new requirements.[203]

When the European food industry realized it was losing the labeling battle, it changed its approach and began to use labeling as a positive indicator of quality, a high level of testing and environmental benefits such as reduced pesticide use.[204] Several supermarket chains have decided to avoid genetically modified ingredients in their own brand products or to label products as containing GMOs if avoidance is not possible.[205] In addition, several biotechnology companies, including Monsanto, have made guarantees to assuage GMO consumer safety and environmental concerns, such as ensuring that GMOs are labeled throughout the processing stages.[206] The concessions came after EU Environment Ministers agreed on a moratorium on GMO applications until amendments to Council Directive 90/220 on the Deliberate Release of GMOs are adopted.[207] The United Kingdom reached a voluntary agreement with the biotechnology industry, postponing any commercialization of GMOs or marketing decisions until after large-scale trials are completed in 2002.[208]

IV
CRITICISM OF THE EUROPEAN UNION'S 1998 REGULATION

A. *The United States and Agribusiness*

The United States stands firmly behind its view that the safety and equivalency of GM maize and soybeans have been scientifically demonstrated, rendering the EU's ban scientifically unsound and motivated by a protectionist desire to give EU

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203 *See* Council Regulation 1139/98, art. 4, *supra* note 166, at 6.

204 *See* Pargas, *supra* note 1.

205 *See No Genetic Alterations, Asda Tells Food Firms Amid Concern*, YORKSHIRE POST, Oct. 14, 1998, *available in* 1998 WL 8182833; *Information Unlimited: All the Facts You Need to Avoid Heartache No. 16 Genetically Modified Food*, INDEPENDENT (LONDON), Nov. 30, 1998, at 9 [hereinafter *Information Unlimited*].

206 *See* Joe Kirwin, *Leading Biotechnology Firms Offer to Make Environment Guarantees on GMOs*, 22 Int'l Env't Rep. (BNA) No. 23, at 904 (Nov. 10, 1999).

207 *See id.*

208 *See* Peta Firth, *U.K., Biotech Sector Agree No Decision on Marketing GMOs to be Made Before 2002*, 22 Int'l Env't Rep. (BNA) No. 23, at 912-13 (Nov. 10, 1999).

farmers a competitive advantage. Based on the data, FDA has found no basis to disagree with the developers' determinations that neither product was significantly altered from varieties of soy and corn with a history of safe use, and that both products are safe for introduction into the marketplace. The agency has received no additional data that would cast doubt on that assessment.[209]

The United States exports twenty-five percent of its soya bean crop to the EU.[210] Sixty percent of products on supermarket shelves would require additional labeling.[211] The effort to segregate GMO from non-GMO products would be impractical.[212] Developing a system of segregation would be incredibly costly in terms of time and money. Therefore, industry strongly opposes the EU's GMO labeling requirements. Several United States agricultural and trade officials have expressed policy concerns. For example, Secretary of Agriculture Dan Glickman "warn[ed] that the dispute between the U.S. and EU over the safety of genetically modified crops could become the 'battle royale' of the 21st century world agriculture," and that "segregating crops and processed products on the basis of GMO characteristics is scientifically unfounded and commercially impossible."[213]

The USDA notes that the EU has fallen behind relative to other parts of the world in terms of research and development of genetically modified crops, partially due to its restrictive and time-consuming regulations.[214] The USDA also criticizes existing EU regulation of products developed with genetic engineering as not applied in a predictable or transparent manner.[215] The agency believes these delays are the result of political con-

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209 *See* Arhur Whitmore, *FDA Evaluation of Bioengineered Soybean and Corn Varieties* (visited Sept. 1, 2000) <http://vm.cfsan.fda.gov/~lrd/tpbioeng.html>.

210 *See* Chege, *supra* note 130, at 181.

211 *See* Chege, *supra* note 130, at 181.

212 *See* Chege, *supra* note 130, at 181.

213 Beach, *supra* note 80, at 187. *See also EU Makes GMO Labels Compulsory*, 5 Food Ingredient News (Information Access Co.) No. 7 (July 1, 1997), *available in* 1997 WL 9030868.

214 *See* United States Department of Agriculture, *Europe Inching Towards Lighter Regulation of Genetically Modified Crop Plants* (visited Sept. 1, 2000) <http://www.accessexcellence.org/AB/IWT/European_Attitudes.html>.

215 *See* United States Department of Agriculture, Office of Agricultural Affairs, U.S. Mission to the European Union, *Genetically Modified Foods / Novel Foods* (last modified Aug. 9, 2000) <http://www.useu.be/agri/GMOs.html>.

siderations rather than legitimate health or safety concerns.[216] The EU regulations appear to be encouraging biotech firms to look to Africa and other areas where they can operate under fewer restrictions.[217]

In 1997, then-president David Erickson of the American Soybean Association (ASA) expressed concern that "implementation of the [EU Agricultural Commissioner] Fischler proposal would result in major market disruptions, high price discounts to U.S. farmers, and could potentially restrict access for U.S. agricultural exports to the European Union."[218] The ASA maintains its position that the labeling requirements are not based on science and are unnecessary, but it is willing to negotiate with the EU and its member states if the alternative is losing that market.[219] ASA would prefer a voluntary "GMO-free" label, which would require scientific verification, to a mandatory "contains GMOs" label.[220]

One commentator offered insight into industry reaction to the labeling regulations: "If the Americans refuse to segregate, it is true that we can't legally enforce that, but the Americans will one day wake up to the fact that market pressures—the thing they understand—will probably force segregation."[221] Monsanto, the leading U.S. agricultural biotechnology company and producer of Roundup Ready soybeans, has recently changed its stance and decided to support the labeling of GMO products exported to the EU.[222] Behind this is a view that Monsanto is willing to do what it takes to ensure its European consumers are comfortable with purchasing Monsanto's products. It still considers GM products the equivalent of traditional varieties but is willing to provide the GMO information to European consumers

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216 *See id.*

217 *See* Thomas Hirenee Atenga, *Biotech Firms Have Their Eyes on Africa, Euro MPs Say*, INTER PRESS SERVICE, Oct. 14, 1998, *available in* 1998 WL 19900988.

218 American Soybean Association, *ASA Alerts U.S. Officials to Potential Non-Tariff Trade Barriers* (visited Sept. 1, 2000) <http://www.amsoy.org/documents/biotech.htm>.

219 *See id.*

220 *See* Kathleen Hart, *Monsanto Changes Stand on Labeling Genetically Modified Food in European Union*, 26 Pesticide & Toxic Chemical News (Information Access Co.) No. 28 (May 7, 1998), *available in* 1998 WL 11008899; American Soybean Association, *supra* note 218.

221 Jackie Storer, *Ministers Press EU on Food Labelling*, PRESS ASS'N LIMITED, Nov. 12, 1998, *available in* LEXIS, Press Ass'n Newsfile.

222 *See* Hart, *supra* note 220.

if it will lead to education about, and acceptance of, genetically modified products.[223]

Monsanto's reluctance to support labeling grew out of the concern that the label identifies the GM products as different even though the resulting foods are the equivalent of traditional varieties. The Monsanto spokesman from Belgium explained his view that the logic of labeling GM foods is seriously flawed because "once you say process has validity, where do you stop? Do you label a product as using union truckers? What about the amount of gasoline used in production?"[224] The biotech industry and the USDA are even concerned that the "organic" label's exclusion of GMOs will be seen by trading partners as evidence of safety concerns about bio-engineered products.[225]

Questions remain about what the threshold standard will be to declare a product GMO-free as well as what analytical methods will be used to determine what requires labeling. The 1998 Regulation has also been criticized as ambiguous, leading to some inconsistent outcomes. For example, while a genetically modified "ingredient" has to be labeled, an "additive" does not.[226] In spite of the remaining questions, the EU regulations have led to the creation of an industry for testing crops and food products for the presence of modified DNA or proteins. John Fagan, a scientist with Genetic ID in Iowa, has said that GMO-free foods can be achieved most effectively by designing a system to ensure "a production, shipping, storage and manufacturing chain" that is GMO-free.[227] He stated that not only can this be done in the future, but it has been done for over twelve years by companies shipping certified organic soybeans to Europe and Japan.[228] This fact has been confirmed by individuals in the industry. However, many indicate that there will be a high cost. Mark Berg, former president of the American Soybean Association, emphasizes that there is no difference between GMO and tradi-

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223 *See* Hart, *supra* note 220.

224 Hart, *supra* note 220.

225 *See* Leora Broydo, *Organic Engineering; US Dept of Agriculture Memo Favors Biotech Firms Over the Organic Food Industry in Rules-making*, MOTHER JONES, May 15, 1998, at 25; Paul Schmelzer, *Label Loophole: When Organic Isn't*, PROGRESSIVE, May 1, 1998, at 28.

226 *See* Pargas, *supra* note 1.

227 Kathleen Hart, *Scientists Consider Testing Techniques to Detect Modified DNA in Foods*, 40 Food Chemical News (Information Access Co.) No. 21 (July 13, 1998), *available in* 1998 WL 10981483.

228 *See id.*

tional crops from a safety and health viewpoint and that separating them would be very difficult, but "[i]f Europeans are willing to pay a premium, producers will rise to the occasion."[229]

B. *Environmental and Consumer Groups*

Environmental groups, such as Greenpeace and Friends of the Earth, believe the 1998 Regulation is under-inclusive and not a victory for consumers.[230] Products containing derivatives of soya or maize which may be regarded as "additives" will be exempt, as will those products that derive from GMOs but have undetectable amounts of modified DNA or protein.[231] Therefore, the majority of products derived from GMOs will go unlabeled. Among the exempted products are vegetable protein, hydrolyzed vegetable protein and protein isolate found in such foods as sausage, soups, coffee creamer, bacon and frozen dessert; lecithin used to make such foods as chocolate, margarine and bread; vegetable oil, vegetable fat and hydrogenated vegetable oils found in products like chips, crackers, cookies and fast food; soya flour, soya milk, tofu and textured vegetable protein.[232]

Greenpeace has developed a policy on labeling in the EU to "inform consumers about the production process and to allow an informed choice between genetically engineered and conventional food products."[233] Two requirements are proposed. First, the required label would read "Genetically Manipulated" and would apply to products and their components that consist of or contain GMOs, whether or not currently detectable.[234] It would extend to additives, animal products derived from animals fed with GMO grain, GM animals and GM animal fodder.[235] Second, food products would bear the statement "Produced with

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[229] Hart, *supra* note 220. *See also U.S. Growers Fear Jeopardizing European Business*, 25 Pesticide & Toxic Chemical News (Information Access Co.) No. 32 (June 4, 1997), *available in* 1997 WL 9738522.

[230] *See Genetic Engineering: GMO Labelling Regulation Comes into Force*, EUR. REP., Sept. 2, 1998, *available in* 1998 WL 19803259.

[231] *See id*. S*ee also Environmental Group Criticizes Loophole in EU Labeling Rules for Genetically Modified Foods*, Food Labeling News, *supra* note 202.

[232] *See Information Unlimited*, *supra* note 205, at 9.

[233] *See* Greenpeace, *Policy Concerning the Labelling and Declaration of Genetically Engineered Food Products* (visited Sept. 1, 2000) <http://www.greenpeace.org/~comms/97/geneng/policy.html>.

[234] *See id.*

[235] *See id.*

Genetic Engineering" in the list of ingredients if produced with the help of production processes operating with GMOs or if or containing or produced with additives produced or derived from GMOs.[236]

C. *Other Countries*

New Zealand and Australia have decided that all GM crops should be labeled as such, providing the consumer with the ultimate choice of what to buy.[237] This decision of the health ministers was contrary to the recommendation of the Australian and New Zealand Food Authority (ANZFA), the national food authority.[238] Opponents of the labeling requirements say this opens the countries up to WTO complaints similar to those filed by the United States and Canada against the EU regulations.[239] The United States has been accused of "bullying" foreign governments to protect the American biotech industry.[240] New Zealand cabinet documents reveal that the U.S. indicated the regulatory and labeling scheme threatens a potential free-trade agreement with New Zealand.[241]

India and Norway now mandate labeling of all genetically modified food, while Japan only requires labeling for some genetically modified foods.[242] Brazil, Argentina, and Chile have sided with the United States against mandatory labeling of genetically modified food, but the South American nations are also sensitive to the views of the EU, often approving GM crops the day after the EU does so.[243]

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[236] *See id.*

[237] *See* Laren Martin, *Gene Food Must Carry Labelling*, SYDNEY MORNING HERALD, Dec. 18, 1998, at 2.

[238] *See, e.g.,* Ben Hills, *Labelling of Gene Food Put to the Test*, SYDNEY MORNING HERALD, Dec. 17, 1998, at 7.

[239] *See* Katrina Willis, *All Genetically Modified Food to Be Labelled*, AAP NEWSFEED, Dec. 17, 1998.

[240] *See* Marie Woolf, *Revealed: How U.S. Bullies Nations Over Genetic Food*, INDEPENDENT, Nov. 22, 1998, at 14.

[241] *See id.*

[242] *See* Merrill Goozner, *Multicultural March Protests Genetically Altered Food, WTO Policies*, CHI. TRIB., Dec. 3, 1999, at 29.

[243] *See* Kathleen Hart, *Biosafety Protocol Could Impede Biotech Trade*, 40 Food Chemical News (Information Access Co.) No. 39 (Nov. 16, 1998), *available in* 1998 WL 10981949.

Japan is considering legislation that would create legally binding guidelines for growing GMO crops.[244] The guidelines would provide for much more detailed analysis of GMOs than the current voluntary guidelines contemplate. The current voluntary guidelines ask growers to conduct a forty point examination of their crops before engaging in commercial production. The main differences expected from the coming legislation are its binding nature and focus on possible gene proliferation resulting from GMOs.[245]

V
The World Trade Organization and International Agricultural Trade Dispute Settlement

A. *The Role of the WTO*

The primary forum for resolving disputes involving agricultural trade is the World Trade Organization (WTO), the new embodiment of the General Agreement on Trade and Tariffs (GATT) as reorganized by the 1993 Uruguay Round.[246] The 1993 Uruguay Round contained two agreements with a direct bearing on the GMO debate and other measures taken to protect human, animal and plant life and health and the environment: the Agreement on Technical Barriers to Trade (TBT Agreement)[247] and the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement),[248] binding on all WTO member nations. Both encourage member nations to participate in the development and adoption of international food safety and labeling standards, making it unclear whether a WTO

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244 *See* Toshio Aritake, *Japan Weighs Safety Guidelines for Production of GMO Crops*, 22 Int'l Env't Rep. (BNA) No. 18, at 719 (Sept. 1, 1999).

245 *See id.*

246 *See* Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, Results of the Uruguay Round of Multilateral Trade Negotiations: The Legal Texts 6 (1994), 33 I.L.M. 1144 (1994) [hereinafter WTO Agreement].

247 Agreement on Technical Barriers to Trade, Apr. 15, 1994 WTO Agreement, Annex 1A, Results of the Uruguay Round of Multilateral Trade Negotiations: The Legal Texts, at 138; 1994 WL 761483 [hereinafter TBT Agreement].

248 Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, WTO Agreement, Annex 1A, Results of the Uruguay Round of Multilateral Trade Negotiations: The Legal Texts, at 69; 1994 WL 761483 [hereinafter SPS Agreement].

decision-making body would resolve the GMO debate under the TBT, SPS, or both agreements.

WTO dispute settlement procedures encourage the resolution of disputes through formal consultations. If unable to reach an acceptable bilateral solution, other means of resolution can be used. Under the dispute settlement process of the WTO, an international panel of three trade experts, nominated by the secretariat of the WTO, would review the EU regulation to determine if it violates a WTO Agreement, calling upon experts and international organizations if needed.[249] Panel decisions are reviewable by the WTO appellate body.[250] If the appellate body finds that a WTO Agreement has been violated, it will recommend measures that the losing party shall take to come into compliance.[251] However, if the party fails to come into compliance, the appellate body has the power to order that compensation for loss be made.[252] A nation may choose not to comply with a WTO panel or appellate body decision, but, if the winning party is the United States, the nation must compensate the United States in other ways or be subject to retaliatory tariffs or other punitive trade sanctions.[253]

B. *Relevant WTO Agreements and Cases*

1. *Process Safety: The Shrimp-Turtle Case*

The EU's GMO regulations may be seen as discriminating against a production process that does not alter the product. A similar issue was faced in the dispute between the United States and Mexico concerning the incidental taking of sea turtles in the process of shrimp harvesting.[254] The Appellate Body in this case addressed whether Section 609 of the United States' Marine Mammal Protection Act[255] unjustifiably discriminated between

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[249] *See* Understanding on Rules and Procedures Governing the Settlement of Disputes, Apr. 15, 1994, WTO Agreement, Annex 2, RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS: THE LEGAL TEXTS, at 404; 1994 WL 761484 [hereinafter DSU].

[250] *See id.* art. 17, at 417-19.

[251] *See id.* art. 19, at 420.

[252] *See id.* art. 22, at 422-25.

[253] *See* Barton, *supra* note 15, at 104.

[254] WTO Appellate Body, United States—Import Prohibition of Certain Shrimp and Shrimp Products, WT/DS58/AB/R (1998) [hereinafter Shrimp-Turtle].

[255] 16 U.S.C. §§ 1361-1384 (2000).

countries where the same conditions prevail, thereby violating Article XX of GATT 1994.[256] Article XX states in relevant part:

> Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures: . . . (b) necessary to protect human, animal, or plant life or health; . . . (g) relating to the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption . . .[257]

The Appellate Body held that the United States measure served an objective that was legitimate under Article XX. It complied with the requirements under Article XX(g) because the sea turtles at issue constituted "exhaustible natural resources," Section 609 was a measure "relating to" the conservation of an exhaustible natural resource, and Section 609 was a measure made effective in conjunction with the restrictions on domestic harvesting of shrimp.[258] However, the Appellate Body ultimately concluded that Section 609 did not comply with Article XX.[259] The three standards set forth by the Appellate Body were (1) arbitrary discrimination between countries where the same conditions prevail; (2) unjustifiable discrimination between countries where the same conditions prevail; and (3) disguised restrictions on international trade.[260] In scrutinizing the measure under these standards, the Appellate Body stated:

> Perhaps the most conspicuous flaw in this measure's application relates to its intended and actual coercive effect on the specific policy decisions made by foreign governments, Members of the WTO. Section 609, in its application, is, in effect, an economic embargo which requires *all other exporting Members,* if they wish to exercise their GATT rights, to adopt *essentially the same* policy (together with an approved

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256 *See* Shrimp-Turtle, *supra* note 254, at 42.

257 General Agreement on Tariffs and Trade, art. XX, Oct. 30, 1947, 61 Stat. A-11, T.I.A.S. 1700, 55 U.N.T.S. 194 [hereinafter GATT].

258 Shrimp-Turtle, paras. 130, 142, 149-50, 152-53, *supra* note 254, at 48-49, 55, 58-59.

259 *See* Shrimp-Turtle, para. 195(c), *supra* note 254, at 82.

260 *See* Shrimp-Turtle, para. 158, *supra* note 254, at 61-62.

> enforcement program) as that applied to, and enforced on, United States domestic shrimp trawlers.[261]

Another flaw in the measure identified by the Appellate Body was that shrimp caught using identical methods were excluded from the U.S. market because they were caught in the waters of countries not yet certified by the United States. This undercuts the purported objective to conserve sea turtles and instead indicates a desire to influence WTO Members' regulatory regimes.[262] The Body stressed that the lack of serious attempts to conclude bilateral or multilateral agreements for the conservation of sea turtles prior to the enforcement of the import prohibition weighs heavily in any determination of justifiability.[263]

The EU's GMO labeling regulations are not prohibitions on imports. However, whether or not the regulations are necessary to protect human, animal or plant life or relate to the conservation of exhaustible natural resources is less clear. There is an argument that biodiversity protection could fall under conservation of an exhaustible natural resource. If the labeling regulations do fall under one of these Article XX exceptions, there remains the application of the requirements. Although applied across the board to all imports and domestic products, one could argue that the EU measures are disguised restrictions on trade. In addition, according to the United States view of product equivalence, the measures may be viewed as discrimination between countries with the same conditions.[264]

2. *Product Safety: The TBT Agreement, SPS Agreement and their Application in the Beef-Hormone Case*

Both the TBT and SPS Agreements bear on the GMO labeling debate. The TBT Agreement aims to ensure that "technical regulations and standards, including packaging, marking and labelling requirements, and procedures for assessment of conformity with technical regulations and standards do not create unnecessary obstacles to international trade."[265] It allows countries to take measures to ensure the quality of its exports; to protect human, animal or plant life or health; to protect the

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261 Shrimp-Turtle, para. 169, *supra* note 254, at 68.
262 *See* Shrimp-Turtle, para. 173, *supra* note 254, at 70-71.
263 *See* Shrimp-Turtle, para. 174, *supra* note 254, at 71.
264 *See generally infra* Part II.
265 TBT Agreement Preamble.

environment; or to prevent deceptive practices, at levels it considers appropriate.[266] However, measures must not be applied so as to constitute arbitrary or unjustifiable discrimination between countries where the same conditions prevail. Nor may the measure be a disguised restriction on international trade.[267]

Agricultural products are expressly covered by the TBT Agreement unless the measures are sanitary or phytosanitary, in which case they fall under the SPS Agreement.[268] With respect to food issues, labeling requirements, nutrition claims and related regulations are normally subject to the TBT Agreement.[269] However, the WTO acknowledges that labeling requirements may also fall under the SPS Agreement for regulations related to health concerns or food safety:

> [R]egulations which address microbial contamination of food, or set allowable levels of pesticide or veterinary drug residues, or identify permitted food additives, fall under the SPS Agreement. Some packaging and labelling requirements, if directly related to the safety of the food, are also subject to the SPS Agreement.[270]

While labeling of GMOs is likely to be covered by Annex A1 of the SPS Agreement as discussed below, the two agreements have parallel provisions. For example, neither TBT nor SPS measures may be adopted to create unnecessary obstacles to international trade, the measures may be no more restrictive than necessary to meet a legitimate objective, and international standards should be used when available and appropriate to address the legitimate objectives of the measures.[271] Many environmental groups argue that the TBT Agreement is the relevant text under which labeling regulations designed to respect a consumer's ethical and religious convictions or a consumer's right-to-know about the genetically modified nature of their product should be analyzed.[272] The SPS Agreement does not on its face appear to extend beyond food safety issues to encompass the

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266 *See id.*

267 *See id.*

268 *See id.* arts. 1.3, 1.5.

269 *See id.* Preamble, art. 1.

270 *Understanding the WTO Agreement on Sanitary and Phytosanitary (SPS) Measures* (visited Sept. 2, 2000) <http://www.wto.org/english/tratop_e/sps_e/spsund.htm> [hereinafter *Understanding the SPS Agreement*].

271 *See* TBT Agreement arts. 2.2, 2.4; SPS Agreement arts. 2.2, 3.1.

272 *See, e.g.,* STILWELL & VAN DYKE, *supra* note 64, at 10.

other ethical and consumer right-to-know concerns that GMO labels address. If the TBT Agreement were applied to the GMO labeling debate, it is likely that the EU labeling regulation would have to succeed in satisfying the two-part test mentioned above. First, the regulation must be non-discriminatory, applying equally to all domestic and imported "like" products; and second, it must not be more restrictive than necessary.[273] The difficult aspect of the first prong of non-discrimination would be overcoming the likely U.S. argument that GMOs and traditionally-bred varieties are "like" products, making differential treatment discriminatory. The second prong of "not more trade-restrictive than necessary" is similarly subject to differing interpretations, but a strong argument can be made that the effects of this labeling measure, which fall extremely short of an outright ban, cannot be effectively achieved any other way.

Despite the strength of the arguments for applying the TBT rather than the SPS Agreement, the United States challenge to the EU regulation has focused on disputing the health concerns about GMOs and casting doubt on the EU regulation's basis in science, a standard required by the SPS Agreement.[274] For this reason, the discussion below analyzes both the hurdles the United States would have to overcome to bring a successful challenge to the EU labeling regulation and the burdens the EU would bear in successfully defending against such a challenge.

a. *The SPS Agreement*

Recognizing in its text that a SPS restriction not required for health reasons can be a "very effective protectionist device, and because of its technical complexity, a particularly deceptive and difficult barrier to challenge,"[275] the SPS Agreement aims to protect trade from protectionist measures as well as provide the basis for a challenge of such measures, including those based on product standards.[276]

Generally, nations under the WTO regime have agreed to reduce trade barriers. However, subject to the requirement that measures do not result in arbitrary or unjustifiable discrimination or a disguised trade restriction, Article XX of GATT authorizes a

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273 *See* TBT Agreement arts. 2.2, 2.4; SPS Agreement, arts. 2.2, 3.1.
274 *See* SPS Agreement art. 2.
275 *Understanding the SPS*, *supra* note 270.
276 *See* Barton, *supra* note 15, at 95-96.

nation to impose measures necessary to protect human, animal or plant life or health, or relating to the conservation of exhaustible resources, if made effective in conjunction with restrictions on domestic production or consumption.[277] The SPS Agreement builds on the provisions of the GATT rule to detail the rights and obligations of WTO members with respect to SPS measures. The SPS Agreement qualifies the Article XX exception by clarifying that any such measure must be "based on scientific principles" and not maintained without sufficient scientific evidence unless provisionally adopted on the "basis of available pertinent information," with the Member seeking the additional information within a "reasonable period of time."[278]

In addition, measures may not arbitrarily or unjustifiably discriminate between Members who operate under similar conditions. Article 4 elaborates on the recognition of equivalent measures, stating that the language is met as long as the "exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection."[279] Finally, measures may not be applied so as to constitute a disguised restriction on international trade.[280]

b. *What Are SPS Measures?*

A "sanitary or phytosanitary measure" is defined by the SPS Agreement as any measure applied to protect human, animal or plant life or health within the territory of the Member from risks from pests or diseases, to protect human or animal life or health from risks from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feed and to limit other damage from pests.[281] "Measures" include all relevant laws and procedures, including labeling requirements directly related to food safety.[282] The SPS specifically excepts "[m]easures for environmental protection (other than as defined above), to protect consumer interests, or for the welfare of animals" from coverage, although it states that other WTO Agreements cover these con-

277 *See* GATT art. XX.
278 SPS Agreement arts. 2.2, 5.7.
279 *Id.* art. 4.1.
280 *See id.* art. 2.3; *Understanding the SPS Agreement*, *supra* note 270.
281 *See* SPS Agreement Annex A para. 1(a).
282 *See id.* Annex A para. 1.

cerns—for example the TBT Agreement or Article XX of GATT 1994.[283]

Member states are directed by the SPS Agreement to ensure that their measures are based on assessment of risks to human, animal or plant life or health.[284] Risk assessment is defined as the evaluation of the likelihood of entry, establishment or spread of a pest or disease within an importing Member's territory or the evaluation of the potential for adverse human or animal health effects from additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.[285] In determining risk, the following factors are considered: the risk assessment techniques employed by the relevant international organizations; the objective of minimizing negative trade impacts; the goal of avoiding arbitrary or unjustifiable distinctions resulting in discrimination or disguised trade restriction; the level of voluntary risk exposure by humans; scientific evidence; relevant processes and production methods; relevant inspection and testing methods; the prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment.[286]

Economic factors are to be considered when assessing risk to animal or plant life or health but not human life or health.[287] They include: the potential loss of production or sales, establishment or spread of a pest or disease, the estimated costs of control, and the relative cost-effectiveness of alternative approaches to limiting risks.[288] In addition, economic and technical feasibility may be considered when determining if such measures are more trade-restrictive than required to achieve the appropriate level of protection, also referred to as the acceptable level of risk.[289]

Provisional measures may be adopted based on available pertinent information when relevant scientific evidence is insufficient.[290] However, any Member who believes that a measure is constraining exports and not based on relevant international

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283 *Understanding the SPS Agreement*, *supra* note 270.
284 *See* SPS Agreement art. 2.2.
285 *See id.* Annex A para. 4.
286 *See id.* arts. 5.1-5.2, 5.4-5.5.
287 *See id.* art. 5.3.
288 *See id*. art. 5.3.
289 *See id*. Annex A para. 5.
290 *See id.* art. 5.7.

standards, guidelines or recommendations may request an explanation for the measure from the relevant Member.[291] If a dispute arises, GATT 1994 Articles XXII and XXIII and the Dispute Settlement Understanding apply.[292] For technical and scientific issues, panels are authorized to call upon experts for assistance.[293]

c. *What Is the Definition of "Scientifically-Based"?*

Not surprisingly, the definition of "scientifically-based" is a contested issue likely to be at the heart of any dispute concerning a SPS measure. The requirement that a measure be scientifically-based is directed at ensuring the protection of human, animal and plant health while minimizing negative effects on international trade and use of protectionist measures under the guise of health regulations.[294] The amount of leeway a nation has to choose a "level of protection" or "acceptable level of risk" as addressed in Annex A of the SPS Agreement is currently a subject of debate. There is some tension between this freedom and the goal of global harmonization of standards.[295] No matter what the level of flexibility, the SPS Agreement provides threshold requirements that must be met. As the United States stated in the Beef-Hormone report with respect to determining whether a measure is "based on risk assessment" as required by Article 5.1 of the SPS Agreement:

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[291] *See id*. arts. 5.7-5.8.

[292] *See* DSU art. 3.1.

[293] *See id.* art. 13.2.

[294] *See* SPS Agreement Preamble; United States Trade Representative, *Use of International Standards Under the SPS Agreement* (visited Aug. 27, 2000) <http://www.ustr.gov/reports/stand.pdf> [hereinafter Use of International Standards]; United States Trade Representative, *Preliminary Outline of Issues for Consideration by the Committee As Part of the Triennial Review of the SPS Agreement* (visited Aug. 27, 2000) <http://www.ustr.gov/reports/poutline.pdf> [hereinafter Preliminary Outline].

[295] *See, e.g.,* Barton, *supra* note 15, at 101-102. Barton notes that the United States has interpreted "scientifically based" liberally, and that:

> the requirement . . . would not authorize a dispute settlement panel to substitute its scientific judgment for that of a government maintaining the sanitary or phytosanitary measure . . . [B]y requiring measures to be based on scientific principles . . . (rather than, for instance, requiring an examination of the 'weight of the evidence') the . . . Agreement recognizes the fact that scientific certainty is rare and many scientific determinations require judgments between differing scientific views. The . . . Agreement preserves the ability of governments to make such judgments.

Barton, *supra* note 15, at 102.

> Such a determination does not require a panel to conduct its own risk assessment or substitute its own judgment regarding risks, but only to determine if the measure is "based on" a risk assessment. Under Article 2.2, the question for a panel is not whether it would have come to a different conclusion "based on" the evidence, but rather whether the scientific evidence submitted by the Member maintaining the measure is "sufficient" as a basis for that measure.[296]

In the Beef-Hormone case, the United States challenged the EU's sufficiency of scientific evidence, not its conclusions *per se*.[297] Many criticize the SPS Agreement's allocation of the burden of proving a basis in science on the regulating country rather than the country allegedly endangering public health and the environment, especially when the issue involves an area of great uncertainty, such as manipulation of the DNA sequence.[298]

d. *Encouragement of International Standards and Harmonization*

Under the coordination of the Committee on Sanitary and Phytosanitary Measures (established under Article 12 of the SPS Agreement), the SPS Agreement encourages the harmonization of measures taken by Member nations.[299] Although Article 3 authorizes Members to take measures tailored to protect human, plant or animal life or health, the SPS Agreement states that in other cases, measures should be based on international standards, guidelines or recommendations.[300] Measures that conform receive the benefit of being presumed necessary to protect human, animal or plant life or health.[301] When a Member institutes measures above and beyond the relevant international standards, there must either be a "scientific justification" or the Member's risk assessment pursuant to Article 5 must dictate this

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296 WTO Appellate Body, European Communities—Measures Concerning Meat and Meat Products (Hormones), Jan. 16, 1998, WT/DS26/AB/R, para. 41 [hereinafter Hormones Appellate Body Report].

297 *See id.* para. 43 ("The EC's invocation of a 'precautionary principle' cannot create a risk assessment where there is none, nor can a 'principle' create 'sufficient scientific evidence' where there is none.").

298 *See, e.g.*, *id.* paras. 108-109.

299 *See* SPS Agreement art. 3.5; World Trade Organization, *Report of the Committee on Sanitary and Phytosanitary Measures* (visited Dec. 29, 1998) <http://www.wto.org/wto/goods/spsrp.htm>.

300 *See* SPS Agreement art. 3.1.

301 *See id*. art. 3.2.

higher level of protection.[302] Further expanding on this exception, the SPS clarifies that:

> there is a scientific justification if, on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement, a Member determines that the relevant international standards, guidelines or recommendations are not sufficient to achieve its appropriate level of sanitary or phytosanitary protection.[303]

The following international organizations involved in setting standards relating to sanitary and phytosanitary protection are specifically mentioned in the SPS Agreement: Codex Alimentarius Commission (Codex) (an intergovernmental body that operates under the FAO and the WHO and sets the relevant international standards, guidelines and recommendations for food safety); the International Office of Epizootics; and the international and regional organizations operating with the International Plant Protection Convention (which sets standards, guidelines and recommendations for plant health).[304] Member nations are expected to be involved in these organizations to the extent feasible.[305] The United States continues to involve itself in the development of international standards, particularly with respect to issues of non-tariff trade barriers, such as notification procedures, transparency, basis in scientific evidence and resolution of SPS-related trade problems.[306]

Codex has a Committee on Food Labeling, which is currently considering the issue of labeling GMOs and products derived from GMOs.[307] The Committee on Food Labeling's Executive Committee proposed recommendations for the labeling of foods derived from GMOs.[308] According to its proposal, mandatory labeling would apply to those foods not substantially equivalent to existing conventionally-produced foods in composition, nutritional value, or intended use.[309] However, most dele-

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302 *See id*. art. 3.3; *Understanding the SPS Agreement*, *supra* note 270.

303 SPS Agreement art. 3.

304 *See id*. art. 3.4; Barton, *supra* note 15, at 101.

305 *See* SPS Agreement art. 3.4.

306 *See* Amy Zuckerman, *At Washington Standards Summit, US Wonders Where Industry Goes From Here*, J. COM., Sept. 23, 1998, at 14C; Use of International Standards, *supra* note 294; Preliminary Outline, *supra* note 294.

307 *See* Redick et al., *supra* note 8, at 22.

308 *See* Beach, *supra* note 80, at 188.

309 *See* Beach, *supra* note 80, at 188.

gations strongly opposed the proposal.[310] Comments by the United States reveal its opposition to any mandatory labeling of foods based on their production methods. According to the United States, mandatory labeling would be impractical, inequitable and would not result in greater safety.[311]

e. *Product Safety and the SPS Agreement: The United States-EU Beef-Hormone Dispute*[312]

The SPS Agreement was first applied in 1996, when the United States formally challenged the EU Directive banning the import of beef treated with certain natural and synthetic hormones as lacking scientific basis. Consultations with the EU had failed to resolve the dispute, so the United States called upon the WTO Dispute Settlement Body (DSB) to establish a dispute settlement panel, which it did.[313] After the establishment of the panel, the United States revoked the duties that had been imposed on certain products imported from EU member states.[314] Canada also requested a panel, established on October 16, 1996 and consisting of the same panelists the United States had received.[315]

The panel report issued on August 18, 1997 found that the ban on imports of livestock and meat treated with these hormones was inconsistent with the SPS Agreement.[316] The EU's food safety measures were not based on relevant international standards, on risk assessments conducted, or on science. The European Union appealed the panel report,[317] which the appellate

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310 *See* John Fagan & Richard Wolfson, *A Report on the Codex Committee on Food Labeling* (visited Jan. 27, 2000) <http://www.netlink.de/gen/codex97.htm>.

311 *See* Beach, *supra* note 80, at 187.

312 WTO Dispute Panel, European Communities—Measures Concerning Meat and Meat Products (Hormones), Aug. 18, 1997, WT/DS26/R/USA [hereinafter Hormones Panel Report].

313 *See* Silverglade et al., *supra* note 82, at 6; Shailagh Murray et al., *A Special Background Report on European Business and Politics*, WALL ST. J. EUR., May 23, 1996, at 1.

314 *See* Office of the United States Trade Representative, *Report to Congress on Section 301 Developments Required By Section 309(a)(3) of the Trade Act of 1974* (visited Aug. 27, 2000) <http://www.ustr.gov/reports/301report/sec301.pdf> [hereinafter Section 301 Report].

315 *See* Office of the United States Trade Representative*, WTO Arbitrator Decides EU Must Comply With WTO Obligations and Remove Beef Hormone Ban by May 1999*, (visited Dec. 29, 1998) <http://www.ustr.gov/releases/1998/05/98-54.pdf> [hereinafter WTO Arbitrator].

316 *See* Hormones Panel Report, *supra* note 312.

317 *See* WTO Arbitrator, *supra* note 315.

body affirmed in part on January 16, 1998.[318] In February of 1998, the WTO DSB adopted the appellate body and panel reports.[319]

One of the EU's complaints concerned the United States' refusal to disclose the scientific data leading to its conclusion that the beef hormone was safe.[320] However, the appellate body held that the complaining party bears the burden of demonstrating prima facie inconsistency with the SPS Agreement.[321] When a prima facie case is made, the burden then shifts to the defending party to counter the inconsistency.[322] The standard of review in proceedings under the SPS is defined by the appellate body as neither de novo nor deferential, but rather "objective assessment of the facts" by reference to Article 11 of the WTO DSU: "a panel should make an objective assessment of the matter before it, including an objective assessment of the facts of the case and the applicability of and conformity with the relevant covered agreements."[323]

The EU pressed for the acceptance of the precautionary principle as a general rule of customary international law.[324] The appellate body declined to take a definitive stance on the issue, but did state that the principle is relevant to the SPS Agreement as incorporated into Article 5.7, although it does not override the explicit wording of Articles 5.1 and 5.2, namely the need for sufficient scientific evidence.[325] Reversing the panel, the appellate body also held that "based on" relevant international standards does not mean "conforms to" as the panel held. "Based on" can signify that some, not all, of the elements of an international standards are met by the measure.[326]

Although it held that the EU was in violation of Article 5.1, by requiring that SPS measures are based on risk assessment, the appellate body provided helpful guidance as to what suffices as

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318 *See* Hormones Appellate Body Report, *supra* note 296.

319 *See* Section 301 Report, *supra* note 314.

320 *See EU's Fischler Meets U.S. Delegation Over Trade Rows*, REUTERS, Dec. 1, 1998.

321 *See* Hormones Appellate Body Report, paras. 108-109, *supra* note 296, at 39-40.

322 *See* Hormones Panel Report, paras. 102, 109, *supra* note 312.

323 DSU art. 11. *See also* Hormones Appellate Body Report, para. 117, *supra* note 296, at 43.

324 *See* Hormones Appellate Body Report, para. 121, *supra* note 296, at 45.

325 *See* Hormones Appellate Body Report, para. 124, *supra* note 296, at 46.

326 *See* Hormones Appellate Body Report, para. 163, *supra* note 296, at 63.

risk assessment. It held that Articles 2.2 and 5.1 should be read together; in other words that risk assessments are part of showing a measure is based on scientific principles and maintained with sufficient scientific evidence.[327] Relevant to concerns that lab and field tests are not sufficient to determine risk, the appellate body stated:

> It is essential to bear in mind that the risk that is to be evaluated in a risk assessment under Article 5.1 is not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die.[328]

A SPS measure may be based on risk assessment conclusions of a "divergent opinion coming from qualified and respected sources."[329] The reasonableness of the relationship between the risk assessment and resulting SPS measure must be determined on a case-by-case basis.[330]

Providing a potential analogy between the Beef-Hormone case and the GMO dispute, the appellate body recognized as valid the distinction between levels of protection applied to added hormones in treated meat and to naturally-occurring hormones in food.[331] The differences are not arbitrary and unjustifiable. The appellate body described the difference between added hormones and naturally-occurring hormones in meat and other foods as "fundamental."[332]

Another contested issue was the EC use of hormones for therapeutic and zootechnical purposes while banning the same hormones for growth purposes. The appellate body held that the difference in levels of protection depending on use is not in itself arbitrary or unjustifiable.[333]

The EU argued that it applied its hormone-treated beef regulations to domestic and imported beef alike.[334] It emphasized that the motivation was not to protect local industry, but to pro-

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[327] *See* Hormones Appellate Body Report, para. 180, *supra* note 296, at 69.
[328] Hormones Appellate Body Report, para. 187, *supra* note 296, at 72-73.
[329] Hormones Appellate Body Report, para. 194, *supra* note 296, at 75.
[330] *See* Hormones Appellate Body Report, para. 194, *supra* note 296, at 75.
[331] *See* Hormones Appellate Body Report, para. 221, *supra* note 296, at 87.
[332] *See* Hormones Appellate Body Report, para. 221, *supra* note 296, at 87.
[333] *See* Hormones Appellate Body Report, para. 225, *supra* note 296, at 88.
[334] *See* Hormones Appellate Body Report, paras. 244-45, *supra* note 296, at 94-96.

tect the health and safety of its population, address consumer concerns, and harmonize internal regulations of EU member states.[335] The appellate body reversed the panel's finding with respect to Article 5.5 of the SPS Agreement, holding that the EU regulations did not result in discrimination or a disguised restriction of international trade.[336]

In spite of the many reversals of panel conclusions, the appellate body agreed with the conclusion that the EU regulation constituted a violation of Article 5.1 of the SPS Agreement.[337] As the United States, Canada and the EU could not agree on a reasonable time for compliance, the EU requested binding arbitration. The WTO arbitrator rejected the EU argument that further studies needed to be conducted prior to compliance and maintained that fifteen months was a reasonable amount of time to comply with the ruling that the embargo was illegal.[338] This could significantly impact the EU, which has banned U.S. hormone-treated beef since 1989.[339]

3. *Labeling Requirements: The Tuna-Dolphin Case*[340]

The 1991 GATT Panel decision concerning the United States ban on tuna imports from Mexico and intermediary nations pursuant to the 1972 Marine Mammal Protection Act[341] addressed the validity of labeling requirements pursuant to the 1990 Dolphin Protection Consumer Information Act (DPCIA).[342] Unlike the EU's GMO labeling requirements, the DPCIA only regulated *optional* labeling voluntarily used to indicate that methods harmful to dolphins were not used to catch the tuna.[343] If placed on tuna products, the labels must reflect that

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335 *See* Hormones Appellate Body Report, paras. 244-45, *supra* note 296, at 94-96.

336 *See* Hormones Appellate Body Report, para. 246, *supra* note 296, at 96.

337 *See* Hormones Appellate Body Report, para. 253(a), *supra* note 296, at 98.

338 *See WTO Arbitrator*, *supra* note 315.

339 *See* Charles Owen Verrill, Jr. et al., *International Trade*, 32 INT'L LAW. 319, 329 (1998).

340 United States Restrictions on Imports of Tuna, Sept. 3, 1991, GATT B.I.S.D. (39th Supp.) at 155 (1993) [hereinafter Tuna] (although circulated on Sept. 3, 1991, the report was never adopted and thus does not hold the force of law).

341 16 U.S.C. §§ 1361-1384 (2000).

342 16 U.S.C. § 1385 (2000).

343 *See* 16 U.S.C. § 1385(d)(1).

driftnets were not used on the high seas.[344] In the case of the Eastern Tropical Pacific Ocean, the labels must state that purse-seine nets were not used unless evidence was provided that such nets were not intended to encircle dolphins.[345]

The Panel found the labeling provisions were GATT-compatible.[346] The use of a "Dolphin Safe" label is voluntary. As noted by the Panel, the sale of tuna products was not restricted by the DPCIA labeling provisions; tuna products not bearing the labels could be freely sold. Also critical to the decision was the fact that the provisions conditioned the receipt of government-conferred advantages on meeting these tuna harvesting requirements: "Any advantage which might possibly result from access to this label depends on the free choice by consumers to give preference to tuna carrying the 'Dolphin Safe' label."[347] The Panel also noted that a contracting party may regulate imported products and like domestic products as long as it does not discriminate against imported products or protect domestic producers.[348] The DPCIA labeling provisions were consistent with Article I.1 because they applied to all countries whose vessels fished in this geographical area and did not distinguish products originating in Mexico from those originating in other countries.[349]

VI
The United Nations Convention on Biological Diversity and the Biosafety Protocol Negotiations

To avoid duplication and promote harmonization, communication between the Conference of Parties, the WTO Committee on Sanitary and Phytosanitary Measures, and other organizations named in the SPS Agreement is essential.[350] The SPS Agreement may overlap and conflict with the U.N. Convention on Bio-

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344 *See* Tuna, para. 5.6, *supra* note 340, at 192; Philippe Sands, 1 Principles of International Environmental Law: Frameworks, Standards and Implementation 695 (1995).

345 *See* Tuna, para. 5.43, *supra* note 340, at 203; Sands, *supra* note 344, at 695.

346 *See* Tuna, para. 5.42, *supra* note 340, at 203.

347 Tuna, para. 5.42, *supra* note 340, at 203.

348 *See* Tuna, para. 6.2, *supra* note 340, at 204.

349 *See* Tuna, para. 5.42, *supra* note 340, at 203; Sands, *supra* note 344, at 698.

350 *See* Barton, *supra* note 15, at 114.

logical Diversity (CBD) and its Biosafety Protocol negotiations. Under the CBD, each contracting Party must establish and maintain a means to control the risks associated with the use and release of living modified organisms (LMOs) derived from biotechnology and likely to adversely impact the environment.[351] The CBD focuses specifically on conservation and sustainable use of biological diversity, also taking risks to human health into account.[352] There is no express authority under the CBD to regulate genetically-engineered food products which are sterile and have no ability to reproduce, spread or directly affect biodiversity. However, there are CBD issues as to the management of whole foods derived from genetic engineering, such as Bt-corn.

The CBD directs the Parties to develop a Biosafety Protocol (Protocol) setting out appropriate procedures for the safe transfer, handling and use of any LMO derived from biotechnology and likely to have a negative impact on biodiversity. These procedures must include an "advance informed agreement."[353] A contracting Party must inform a receiving party about the regulations required by that contracting Party for such LMOs, as well as provide available information on the potential adverse impact of the specific LMOs to the receiving Party.[354] In effect, this could mean prior government approval is required before any transfer of LMOs, including commonly traded goods such as soybeans and corn, occurs. The United States advocates a more limited definition of LMO that would only regulate those LMOs/GMOs that will be field-tested or planted.[355] Otherwise, the Protocol could have a heavy effect on trade, as thousands of products shipped from the United States contain GMOs.[356]

In February 1999, negotiators met in Cartagena, Colombia for ten days of Protocol negotiations. The talks focused on issues including the definition of "modified organisms," the subject matter scope of the Protocol, labeling and the scope of liability under the Protocol.[357] The talks were suspended and resumed in

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351 *See* Convention on Biological Diversity, June 5, 1992, 31 I.L.M. 818, art. 8(g) [hereinafter CBD].

352 *See id.* art. 8(g).

353 *See id.* art. 19.3.

354 *See id.* art. 19.4.

355 *See* Hart, *supra* note 243.

356 *See* Hart, *supra* note 243.

357 *See* Paul E. Hagen et al., *The Road From Rio: International Environmental Issues for U.S. Business in 1997*, SB79 ALI-ABA 65, 84.

May 2000.[358] Although President Clinton signed the CBD in 1993, Congress has never ratified it.[359] This failure to act resulted in observer status for the United States at the Protocol talks. Nevertheless, the United States was very involved in the negotiations.[360] Under the Cartagena Protocol, non-member nations like the United States and their industries would have to comply with the Biosafety Protocol in the export of goods to CBD Parties, which includes many key export markets for American corporations.[361] Despite its technical lack of voting power, the United States was part of a vocal and powerful minority of the negotiating countries that called for the exclusion of crops from coverage.[362] The other members of what has been called the "Miami Group" were Canada, Australia, Chile, Argentina and Uruguay.[363] U.S. negotiator Rafe Pomerance, Deputy Assistant Secretary of State for Environment and Development, identified two compromises the United States was unwilling to make: "One is to tie up trade in the world's food supply. The second is to allow this regime, without a lot of deliberation, to undermine the WTO trading regime."[364]

Although the Cartagena negotiations stalled, the parties reconvened in Montreal in January 2000, where a compromise was finally reached in which more than 130 countries allowed nations to restrict trade based on legitimate concerns.[365] However, the question remains open as to what actually constitutes a "legitimate concern." The Protocol adopted in Montreal allows countries to take a precautionary principle approach by which "governments take action if they find reasonable cause for concern about consumer or environmental safety."[366] There is still considerable debate over what the precautionary principle actually means, and whether legitimate concerns must be proven

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358 *See* Andrew Pollack*, U.S. Sidetracks Pact to Control Gene Splicing*, N.Y. TIMES, Feb. 25, 1999, at A1.

359 *See* Redick et al., *supra* note 8, at 17.

360 *See* Hart, *supra* note 243.

361 *See* Hagen et al., *supra* note 357, at 83.

362 *See* Helene Cooper & Scott Kilman, *Trade Rules on Biocrops Benign to U.S.,* WALL ST. J., Jan. 31, 2000, at A3.

363 *See* Pollack, *supra* note 358, at A1.

364 Pollack, *supra* note 358, at A1.

365 *See* Brandon Mitchener, *Biosafety Agreement Raises Question,* WALL ST. J. EUR., Jan. 31, 2000, at 4.

366 *Id.*

through scientific findings.[367] Although the United States had opposed the earlier agreement in Cartagena because of potential damage it might cause to domestic agricultural trade,[368] the United States won a victory when the Montreal Protocol established that it would not take precedence over existing agreements, including the WTO Agreements.[369]

CONCLUSION

The EU's GMO labeling regulations do not prohibit imports or marketing of GMOs, but rather impose a lesser, arguably non-discriminatory intrusion that may reasonably be characterized as justifiably differentiating between unlike products and complying with international trade agreements.[370] If, however, the WTO analyzes the EU's 1998 Regulation under the TBT Agreement, SPS Agreement, or both, and concludes it is more stringent than either the TBT Agreement's requirements of "non-discrimination" and "not more trade-restrictive than necessary" or the SPS Agreement's obligation of basis in science will allow, then the EU regulation may violate the SPS Agreement. Not only would such a decision frustrate consumer efforts to secure a right-to-know about the genetically-modified nature of the products they are buying and consuming, but it would also join the growing list of WTO decisions striking down national legislation attempting to implement more stringent environmental and health standards.

While the United States maintains its position that GMOs are safe and that the EU is in violation of WTO agreements, the Clinton Administration has committed to conducting long-term studies on the safety of GMOs in relation to both consumers and the environment.[371] This announcement came in the wake of increased global consumer resistance to GMOs, but before the November WTO talks in Seattle.

The controversy is about more than labeling, which is just one element of the concern for the future course of global agriculture and the environment. While biotechnology has been

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367 *See id.*

368 *See* Cooper & Kilman, *supra* note 362, at A3.

369 *See* Mitchener, *supra* note 365, at 4.

370 *See* Warren H. Maruyama, *A New Pillar of the WTO: Sound Science*, 32 INT'L LAW. 651, 676 (1998).

371 *See* Marian Burros, *Long-term Studies to be Done on Altered Foods*, HOUS. CHRON., July 14, 1999, at A9.

hailed as the "new silver bullet," it is unclear whether it has created a new paradigm or merely provided a vehicle for perpetuating the old paradigm.[372] Part of this old paradigm is an increasing dependence on large chemical companies, a trend that has recently culminated in the new Terminator seed technology,[373] which produces sterile plants forcing farmers to buy new seed each year from the world's biotech companies. How this product squares with the same companies' purported "feed the world" philosophy toward GM technology is unclear.

Biotechnology will undoubtedly play an important role in the future of agriculture. However, it should be just one of many tools used to address environmental and food security issues. Gordon Conway, British agricultural ecologist and president of the Rockefeller Foundation, proposes that the world's food needs can be met with "high-tech contributions from genetic engineering and low-tech contributions from ecologists and farmers."[374] Effort could be re-focused on developing crop varieties that can withstand harsh growing environments such as drought or degraded soil conditions, enhancing the protein in staple foods of developing countries and encouraging developing countries to protect their resources.[375]

As demonstrated by the breakdown in talks during the process of negotiating the Protocol and the protests launched outside the recent WTO meetings in Seattle, the debate concerning the regulation of agricultural biotechnology will continue well into the future. Issues identified by the Organization for Economic Cooperation and Development (OECD) as particularly worthy of further analysis in order to inform discussions and negotiations about food safety are: (1) the interpretation of the precautionary principle, particularly in the SPS Agreement; (2) national GMO regulatory mechanisms and approaches to social concerns and consumer preferences; (3) industry compliance

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372 *See* Pollan, *supra* note 25, at 82.

373 *See id.* at 92.

374 Karen Pennar, *Gordon Conway, Green Revolutionary*, BUS. WK, Nov. 16, 1998, at 191. *See also* World Resources Institute, *New Report Says That Cultivating Agricultural Biodiversity is Necessary for Global Food Security* (visited Aug. 31, 2000) <http://www.wri.org/press/agrobiod.html>.

375 *See* Sabra Chartrand, *When Mom Says, 'Eat Your Vegetables,' She May Soon Mean, 'Make Sure You Get Your Protein,'* N.Y. TIMES, Nov. 30, 1998, at C2.

costs and the associated effects on food prices; and (4) the emergence of private sector food safety and quality standards.[376]

The underlying issue is what course of action to take in this time of conflicting perceptions, divergent concerns, and heated controversy about the future of trade, the environment and the WTO. Some view the risks of using GMOs as too speculative to ignore the benefits and are convinced that measures restricting trade in GMOs are protective of domestic producers, discriminatory towards like products, and not based in science. Others remember the claims and repercussions of miracle pesticides like DDT, which unlike genetic material could be recalled, and are equally convinced that mandatory labeling should withstand challenges under international agreements. In light of the uncertainty associated with the impact of GMOs, a labeling scheme that provides the consumer with a choice of alternatives and raises awareness of the health and environmental risks associated with GMOs, while still permitting the products to be marketed, should be upheld.

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376 *See OECD Highlights Issues in Pacts That Could Lead to Conflicts Before WTO*, Daily Env't Rep. (BNA) No. 223, at A-4 (Nov. 19, 1999) (discussing the February 2000 OECD and U.K. co-sponsored international GMO Food Safety conference in Scotland). OECD's primary concern is that a country's imposition of more stringent environmental regulations, such as restricting imports of GMOs, could conflict with trade liberalization commitments.