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Genetically Modified Foods in the International Arena: Trade Conflicts, Labeling Controversy, and the Importance of Informed Consumer Choice

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GENETICALLY MODIFIED FOODS IN THE INTERNATIONAL ARENA: TRADE CONFLICTS, LABELING CONTROVERSY, AND THE IMPORTANCE OF INFORMED CONSUMER CHOICE

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I. INTRODUCTION

Do we really know what is in the food we eat? Most of us do not know that the majority of foods found in grocery stores in the United States contain Genetically Modified (GM) ingredients.[1] Recent studies show that "[a]bout two-thirds of consumers do not know supermarkets already offer GE[2] food, and according to surveys in 2001 and 2003 by the Pew Initiative on Food and Biotechnology—an independent biotechnology group—only one in five people thinks he or she has eaten a genetically modified product."[3] Many U.S. consumers who are aware of GM foods are concerned with the possible impacts on human health and the environment.[4]

The concerns are not unique to U.S. consumers—the public worldwide shares them.[5] A recent British survey shows that the public's concern about GM foods is rapidly increasing.[6] Most

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* J.D., St. Thomas University (2006); Editor-in-Chief, *St. Thomas Law Review*; B.A. Political Science, University of Alaska-Anchorage (2002).

[1] Elizabeth Suh, *GE Foods Still Lacking Consumer Awareness*, WASH. TIMES, Sept. 2, 2004, http://washingtontimes.com/upi-breaking/20040819-023903-2211r.htm.

[2] The terms GE (Genetically Engineered) and GM (Genetically Modified) will be used interchangeably throughout the article.

[3] Suh, *supra* note 1.

[4] *Id*.

[5] *See* Kathleen Hart, *An Introduction to Genetically Modified Foods*, 10 RICH. J.L. & TECH. 6 (2004) (In April of 2004, about one-fifth of the Austrian adults urged the government to ban GM foods. "Fifteen grocery store chains in the United Kingdom, France, Denmark, Sweden, Germany, and Switzerland…[pled] with growers…and shippers to separate genetically modified corn from regular corn and genetically modified soybeans from regular soybeans.").

[6] *Health Fears Put Future of GM Foods in Doubt*, THE EXPRESS, Sept. 2, 2004, at 24 (discussing a recent survey for consumer magazine *Which?*, finding that "[f]ifty-eight per cent [of consumers] are so concerned they try to avoid GM ingredients

consumer uneasiness probably arises from the average consumer's lack of scientific knowledge about the sophisticated process of genetic engineering. In addition, people know little of the long-term health and environmental effects of GM foods due to the fact that they entered the market little over a decade ago. As a result, the controversy surrounding GM foods has been a hot topic in the international arena for the past several years.

Genetically modified foods first entered the market in 1992. Since then, the agricultural industry has experienced a scientific breakthrough, resulting in advancements in both the quality and quantity of food supplies worldwide.[7] GM foods are "resistant to pests and diseases…could grow in various environmental conditions,…[and are] capable of maintaining improved flavor, texture, shelf life, and protein content."[8] As a result of the benefits derived from genetic modification, GM products are more marketable and result in increased profits for the companies involved in their production and distribution. The increased marketability of GM foods has caused many multinational corporations to vigorously sponsor GE research and lobby the government for wider acceptance of GM foods.[9] As with any profit-driven research, many ethical, environmental, legal, and health concerns are often overlooked.

There have been zealous campaigns around the world both in support and in opposition of GM foods.[10] The issues of regulation and labeling have caused friction between the United States and the European Union (E.U.), which are engaged in a wide-ranging trade

altogether," and that "[s]hoppers also have no confidence in food labelling [sic], with sixty-one per cent convinced they are eating GM food without knowing it").

[7] *See* Chineme OK Anyadiegwu, *Health Risks of Genetically Modified Food: A Need for Unbiased Research into the Potential Health Risks of Genetically Engineered Crop Products*, 13 SAN JOAQUIN AGRIC. L. REV. 203, 203–04 (2003); *see also* Julian Wong, *Are Biotech Crops and Conventional Crops Like Products? An Analysis Under GATT*, 2003 DUKE L. & TECH. REV. 27, ¶ 3 (2003) ("A study by the U.S. Department of Agriculture showed that the total pesticide use was reduced by 6.2 percent in 1997 as a result of the use of biotechnology." Biotechnology also results in higher crop yields, which means that land can be used for agricultural purposes for longer periods of time, thus minimizing harm to the environment.).

[8] Anyadiegwu, *supra* note 7, at 204.

[9] *See* Kim JoDene Donat, *Engineering Akerlof Lemons: Information Asymmetry, Externalities, and Market Intervention in the Genetically Modified Food Market*, 12 MINN. J. GLOBAL TRADE 417, 423 (2003).

[10] *See* Michele M. Compton, *Applying World Trade Organization Rules to the Labeling of Genetically Modified Foods*, 15 PACE INT'L L. REV. 359, 360 (2003).

relationship with each other.[11] This paper will compare the E.U. and U.S. approach to regulating GM products while arguing that the United States should adopt a labeling standard similar to that of the E.U. and require more consumer education and input so that consumers can make better informed decisions about the foods they purchase. Part II of this article will discuss the existing controversies between the United States and the European Union with respect to the regulation and labeling of GM foods. Next, it will make a comparison between the "permissive strategy"[12] adopted by the United States and the new "precautionary approach"[13] followed by the E.U. Furthermore, Part II will highlight the U.S. and E.U. laws concerning GM foods and policy changes in view of the World Trade Organization's (WTO) rules.

Part III will discuss the social and political settings that affect the laws dealing with GM foods in different countries. Since, admittedly, different political and economic priorities result in different approaches to GM food regulation, this article will include an examination of the reasons for such differing attitudes towards biotechnology in the United States and the E.U. Furthermore, this article will examine the role of corporate lobbyists and consumer advocacy groups in pressuring U.S. and E.U. authorities to regulate or de-regulate the GE industry.

Part IV will address the need for more public discussion arising from the fact that consumers are largely left in the dark and excluded from the decision-making process. Part IV will also assert that the lack of public involvement has resulted in decreased consumer confidence and that the public needs to receive more information and more choices in order to rebuild consumer trust.[14] In conclusion, this comment will call for the mandatory labeling of GM foods sold in the United States, despite scientific findings indicating an absence of health risks.

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[11] *See* Terence P. Stewart & David S. Johanson, *Policy in Flux: The European Union's Laws on Agricultural Biotechnology and Their Effects on International Trade*, 4 DRAKE J. AGRIC. L. 243, 246 (1999); *see also* Jeffrey Sparshott, *U.S., EU Sue Each Other over Subsidies; Boeing, Airbus at Center of Market Friction*, WASH. TIMES, Oct. 7, 2004, at C08 (stating that the United States and the European Union have the biggest trade partnership in the world, dealing goods and services worth over US$400 billion per year).

[12] Donat, *supra* note 9, at 427.

[13] *Id*.

[14] *See* Suh, *supra* note 1.

Safety is not the only consideration for consumers—ethics, morals, religion, personal beliefs, and individual preferences often play an important role for people in deciding what goes into their body. Safe or not, consumers should be able to make an informed decision, and adopting labeling rules will serve that purpose.

II. REGULATIONS OF GENETICALLY MODIFIED ORGANISMS IN THE UNITED STATES AND THE EUROPEAN UNION: RECENT HISTORY AND THE ROLE OF THE WORLD TRADE ORGANIZATION

While the regulation of genetically modified organisms (GMO) in the United States is tightening in response to U.S. consumer concerns, E.U. policies are slowly relaxing, thus giving rise to European consumer resistance. Historically, the U.S. government has been very unhappy with the E.U.'s cautious approach and has argued that the six-year moratorium on the importation of GM foods (which was lifted in April 2004) cost U.S. farmers nearly $300 million each year.[15] In contrast, European lobbyists strongly favor a ban on the importation and production of GM foods and fear that the mixing of modified and conventional crops would limit the ability of consumers to avoid GM foods.[16]

A. Regulatory Process in the United States

The regulatory scheme in the United States for approving GMOs is well established and the process of introducing GM foods into the market is fairly routine, although U.S. consumers have challenged the entry of GM foods into U.S. markets.[17] In the United States there is no single government agency designated to deal with matters of biotechnology. Instead, three different agencies regulate GMOs: the United States Department of Agriculture (USDA), the

[15] Paul Meller, *Europe Rejects Looser Labels for Genetically Altered Food*, N.Y. TIMES, Sept. 9, 2004, at W7, *available at* http://www.agobservatory.org/headlines.cfm?RefID=37075.

[16] *See EU Approves GMO Seed for Planting Across Bloc*, IRISH TIMES, Sept. 9, 2004, at 12, *available at* http://www.planetark.com/dailynewsstory.cfm/newsid/27022/story.htm [hereinafter *EU Approves GMO Seed*].

[17] *See* Stewart & Johanson, *supra* note 11, at 246.

Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA).[18]

The primary role of the USDA with regard to biotechnology is the approval of testing, through the Animal and Plant Health Inspection Service (APHIS), in order to ensure the safety of new GMO varieties.[19] APHIS issues an environmental impact statement and then conducts field trials to determine whether the GM products have any adverse effects.[20] If no adverse effects are found, GM products gain a "nonregulated status," meaning that they can be freely placed on the market and treated in the same way as non-GMO foods.[21]

The EPA conducts reviews of bio-engineered pesticides in order to protect public health and the environment.[22] The same laws apply to GM food regulation as to existing similar non-GMO products.[23] The regulation is done under the Toxic Substances Control Act (TSCA)[24] and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).[25] The purpose of TSCA and FIFRA is to create a comprehensive national system to protect human health and the environment from chemical substances including GMOs that contain pesticide chemicals.[26]

The FDA ensures the safety of GM foods for consumption.[27] The FDA does not require safety reviews of GM foods before they enter the market because it considers them to be "substantially equivalent to conventional food."[28] Thus, as long as the end product

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[18] Heather N. Ellison, *Genetically Modified Organisms: Does the Current Regulatory System Compromise Consumer Health?*, 10 PENN ST. ENVTL. L. REV. 345, 349 (2002).

[19] Donat, *supra* note 9, at 428. The USDA's authority to regulate GM foods stemmed from the Plant Pest Act and the Plant Quarantine Act. Both acts were repealed in 2000. However, the USDA continues to have authority to limit or prohibit the movement of GM products under the newly enacted Plant Protection Act, which is part of the Agricultural Risk Protection Act of 2000. Margaret Rosso Grossman, *Biotechnology, Property Rights and the Environment*, 50 AM. J. COMP. L. 215, 224 (2002).

[20] Grossman, *supra* note 19, at 224.

[21] *Id*.

[22] Donat, *supra* note 9, at 428.

[23] Stewart & Johanson, *supra* note 11, at 247.

[24] 15 U.S.C. § 2601 (2004).

[25] 7 U.S.C. § 136 (2004).

[26] Grossman, *supra* note 19, at 224–25.

[27] Donat, *supra* note 9, at 428.

[28] Suh, *supra* note 1; Grossman, *supra* note 19, at 225 (explaining that since GM foods are not "inherently dangerous," no approval is required before placing them on

is "substantially equivalent to the traditional product," the means used to achieve that result is immaterial in safety determinations.[29] It is also optional for companies to consult the FDA before placing GM products on the market.[30] The only products that require labeling are foods that contain common allergens.[31] Nevertheless, it is in the manufacturers' best interests to voluntarily undergo an FDA review of all products they intend to market because the FDA has the authority to remove unsafe products from the market and criminally prosecute the manufacturers of those products.[32] In addition to not requiring pre-market approval, the United States has

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the market); Starla L. Borg, *Waiting for the River: The United States and European Union, Heads Up and High Strikes in the WTO–Genetically Modified Organisms in International Trade*, 43 WASHBURN L.J. 681, 715 (2004); *see also* Matthew Rich, *The Debate over Genetically Modified Crops in the United States: Reassessment of Notions of Harm, Difference, and Choice*, 54 CASE W. RES. L. REV. 889, 902 (2004) ("[T]he FDA has stated that there is no material difference in nutrition, composition, or safety between genetically modified food and non-modified food.").

[29] Donat, *supra* note 9, at 428. Bioengineers add fish genes to tomatoes to prolong their freshness. Since a genetically modified tomato did not become "fish-like" and still "looks and tastes like a tomato," the FDA states that "the only information that will be provided to the consumer is that which is traditionally provided with tomatoes." *See also* Katharine Van Tassel, *The Introduction of Biotech Foods to the Tort System: Creating a New Duty to Identify*, 72 U. CIN. L. REV. 1645, 1655 (2004).

[30] Stewart & Johanson, *supra* note 11, at 248; Grossman, *supra* note 19, at 225 (stating that the FDA implemented a "voluntary consultation process," giving companies an opportunity to determine whether the GM food possesses unusual attributes or substances that would warrant the need for approval of such foods before they are placed on the market).

[31] Kim Brooks, *History, Change and Policy: Factors Leading to Current Opposition to Food Biotechnology*, 5 GEO. PUB. POL'Y REV. 153, 153 (2000). However, GMOs may contaminate conventional crops that do not pose a risk of allergies and thus create allergic reactions in people who consume foods produced from such contaminated crops. *See* Wong, *supra* note 7, ¶ 4 (providing as an example a year 2000 incident, when U.S. grocery stores had to recall taco shells "found to contain genetically modified corn that was unapproved for human consumption due to the possible allergic reactions"). In 2001, the Wall Street Journal reported that out of twenty products labeled as "non-GMO," sixteen contained traces of genetic modification. The reason for this is that "some genetically modified crops—which have been designed to resist disease, pests and chemicals—can cross-pollinate freely with regular crops, passing along their altered traits to the next generation." Neil E. Harl, *Biotechnology Policy: Global Economic and Legal Issues*, 12 WILLAMETTE J. INT'L L. & DISP. RES. 1, 14 (2004) (quoting Patricia Callahan & Scott Kilman, *Seeds of Doubt: Some: Ingredients Are Genetically Modified, Despite Labels' Claims*, THE WALL ST. J., Apr. 5, 2001, at 17).

[32] Stewart & Johanson, *supra* note 11, at 248–49.

declined to require labeling.[33] This regulatory scheme has become known as the permissive strategy.[34]

Unfortunately, the U.S. government enthusiastically welcomed GM foods without first considering the potential problems they may cause.[35] In accordance with the permissive strategy, manufacturers often place foods derived from biotechnology on the market before any thorough testing takes place, and government agencies remove these foods from the market only after they find them unsafe.[36] For example, the long-term effects of many transgenic crops, such as soybeans and corn, underwent research and safety testing only *after* the widespread commercialization of such crops.[37] The lack of research and the potential harmful effects

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[33] *See* Suh, *supra* note 1 (stating that since the FDA considers GM foods to be "substantially equivalent to conventional food," there is no requirement for manufacturers to label GM foods as such).

[34] *See* Donat, *supra* note 9, at 428.

[35] Some of the potential problems that arise from genetic modification of foods include:

(1) *Inadvertent creation of new allergens*. "[K]nown allergens could be transferred from traditional foods into GM foods."

(2) *Development of resistance to antibiotics*. Bioengineers sometimes insert marker genes into GM foods to help bioengineers determine "whether a new gene has been successfully introduced to the host DNA." If humans consume marker genes coded for resistance to particular antibiotics, "the effectiveness of antibiotics could be reduced and human infectious disease risk increased."

(3) *Cross-breeding*. Cross-breeding between GM crops and surrounding vegetation "could result in weeds that are resistant to herbicides and would thus require a greater use of herbicides, which could lead to soil and water contamination."

(4) *Pesticide resistant insects*. "[T]he genetic modification of some crops to permanently produce the natural biopesticide *Bacillus thuringiensis* (Bt) toxin could encourage the evolution of Bt-resistant insects, rendering the spray ineffective."

(5) *Biodiversity*. "[G]rowing GM crops on a large scale may also have implications for biodiversity, the balance of wildlife and the environment."

(6) *Cross-contamination*. "[P]lants bioengineered to produce pharmaceuticals (medicines, e.g.) may contaminate food crops."

GM foods also present numerous ethical, religious, and philosophical concerns. Better Health Channel, *Genetically Modified Foods*, http://www.betterhealth.vic.gov.au/bhcv2/bhcarticles.nsf/pages/Genetically_modified_foods (last visited Mar. 25, 2006).

[36] Brian Halweil, *Portrait of an Industry in Trouble*, WORLDWATCH INST., Feb. 17, 2000, http://www.worldwatch.org/press/news/2000/02/17/.

[37] *Id*. (stating that only after more than half of the U.S. soybeans and corn were already genetically engineered, the U.S. Secretary of Agriculture, Dan Glickman, stated the need for long term effects of these crops on human health and the environment).

of GM foods before they enter the market show an alarmingly deficient regulatory method.

B. Regulations in the European Union

In contrast to the permissive approach of the United States, the E.U. has adopted a precautionary approach that "defines genetic modification based on the process rather than product."[38] Therefore, under this precautionary approach, if a crop is genetically modified to have a longer shelf life, it is defined as genetically modified even though it is substantially equivalent to the genetically unmodified product. The precautionary approach has emerged from opposition to the strong support of GM foods from the United States.[39] Another fundamental difference between the permissive strategy and the precautionary approach is that "[i]nstead of requiring critics to prove that a technology poses potential dangers, the producers of the technology shoulder the burden of presenting evidence that the technology is safe."[40]

As part of the precautionary strategy, the E.U. mandates labeling of all GM products, a controversial subject that U.S. officials view as an illegal barrier to trade.[41] In fact, the United States brought a complaint against the E.U. before the WTO settlement committee addressing this matter.[42] Brian Halweil, speaking about the precautionary approach and the U.S. position toward it, states:

> Industry has long labeled the precautionary approach as reactionary, arguing that it stifles research and prevents economic progress. On the contrary, advocates realize that all stakeholders[–]including consumers, government, and industry[–] benefit from an open and democratic attempt to anticipate any undesirable social and financial surprises. The goal is to apply wisdom and

[38] Donat, *supra* note 9, at 429.

[39] Michelle K. McDonald, *International Trade Law and the U.S.-EU GMO Debate: Can Africa Weather This Storm?*, 32 GA. J. INT'L & COMP. L. 501, 504 (2004).

[40] Halweil, *supra* note 36.

[41] Elizabeth Suh, *Opposing Views on GE Food Review, Labeling*, WASH. TIMES, Sept. 2, 2004, *available at* http://washingtontimes.com/upi-breaking/20040823-033223-4180r.htm.

[42] *Id.*

> judgment about the potential effects of a new technology before flooding the marketplace with the products of that technology.[43]

The E.U. achieves its regulation of GM foods through the legal framework that incorporates provisions of the U.N. Codex Alimentarius (Codex), the Cartagena Protocol to the Convention on Biological Diversity (Cartagena Protocol), the Organization for Economic Cooperation and Development Working Parties on Safety of Novel Foods (OECD), and the WTO.[44] The Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) jointly created the Codex to develop standards for food safety and ensure fair trade practices.[45]

The Cartagena Protocol, enacted in 2003, is an international agreement that establishes rules and regulations for GMO trade to protect human health and the environment.[46] The agreement insists that countries research genetically altered organisms and assess possible risks prior to releasing such products into the market.[47] One hundred and thirty U.N. member nations have ratified the Cartagena Protocol,[48] which entered into force as a result of the

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[43] Halweil, *supra* note 36.

[44] Compton, *supra* note 10, at 366. International policymakers "have attempted to fit square pegs into round holes, applying existing trade law to the novel features of biotechnology." Wong, *supra* note 7, ¶ 2.

[45] Codex Alimentarius, http://www.codexalimentarius.net/web/index_en.jsp (last visited Mar. 7, 2006) [hereinafter Codex].

[46] *See* Sara J. MacLaughlin, *Food for the Twenty-First Century: An Analysis of Regulations for Genetically Engineered Food in the United States, Canada, and the European Union*, 14 IND. INT'L & COMP. L. REV. 375, 402-03 (2003). The Cartagena Protocol has the following objective:

> [T]o contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.

Cartagena Protocol on Biosafety to the Convention on Biological Diversity, art. 1, Jan. 29, 2000, http://www.biodiv.org/biosafety/protocol.asp (last visited Mar. 7, 2006) [hereinafter Cartagena Protocol]. The term living modified organism (LMO) is interchangeable with genetically modified organism (GMO).

[47] MacLaughlin, *supra* note 46, at 403.

[48] The Cartagena Protocol has been ratified by thirty-seven African countries, thirty-three countries of Asia and the Pacific, nineteen countries in Central and Eastern

U.N. Convention on Biological Diversity; the United States participated in the creation of the Convention on Biological Diversity and signed it but has not ratified it.[49] Nearly all nations are parties to the Convention on Biological Diversity, which negotiated the Cartagena Protocol.[50] This protocol reiterates the precautionary principle,[51] embraced by European countries, that permits countries to enact trade restrictions to avoid the adverse effects of GMOs, even in the absence of scientific certainty with respect to such potential adverse effects.[52]

The E.U. regulations governing GM products of direct interest to the United States include Council Directive 90/220 (replaced by 2001/18/EC), which concerns "GMO products that may be described as raw materials," and Council Regulation 258/97, which

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Europe, twenty-three countries in Latin America and the Caribbean, and twenty countries in Western Europe and other regions. Convention on Biological Diversity, May 15, 2000, *Cartagena Protocol on Biosafety (Montreal, 29 January 2000): Status of Ratification and Entry into Force*, http://www.biodiv.org/biosafety/signinglist.aspx?sts=rtf&ord=dt (last visited Mar. 22, 2006).

[49] *Id.* Ratification occurs when a State "establishes on the international plane its consent to be bound by a treaty." Vienna Convention on the Law of Treaties, 22 May 1969, 1155 U.N.T.S. 331, 8 I.L.M. 679, 681. The concept of ratification provides the states with the "necessary time-frame to seek the required approval for the treaty on the domestic level and to enact the necessary legislation to give domestic effect to that treaty." United Nations Treaty Collection: Treaty Reference Guide, ¶18, http://untreaty.un.org/English/guide.asp (last visited Mar. 22, 2006).

[50] Olivette Rivera-Torres, *The Biosafety Protocol and the WTO*, 26 B.C. INT'L & COMP. L. REV. 263, 263, 269 (2003) (stating that 186 countries are parties to the Convention on Biological Diversity).

[51] The Cartagena Protocol integrates precautionary principle through the following language:

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

Cartagena Protocol, *supra* note 46, art. 10.

[52] The Cartagena Protocol permits countries to limit or even prohibit the importation of GMOs. The provision authorizing countries to restrict the importation of GMOs has raised a controversy because the importing nations regard it as a barrier to trade. Patrick J. Vallely, *Tension Between the Cartagena Protocol and the WTO: The Significance of Recent WTO Developments in an Ongoing Debate*, 5 CHI. J. INT'L L. 369, 372 (2004).

concerns "'novel foods,' including foods containing GMOs."[53] The purpose of Council Directive 2001/18/EC is to protect human health and the environment in accordance with the precautionary principle.[54] It aims to accomplish that objective by "controlling risks from the deliberate release into the environment of genetically modified organisms…."[55] The Directive requires notification before the deliberate release of a GMO.[56] It also contains a safeguard procedure under which member states may deny consent to GM products.[57] If a member state objects to the release of GMOs, it should submit a proposed measure to a scientific committee to evaluate adverse effects on human health and the environment.[58] The committee, "composed of individuals from all member states[,] advises the Commission, and voting is [done] by qualified majority."[59] The Council and the Parliament resolve any disagreements that may arise.[60] It is very important to consider that, unlike the completely nontransparent U.S. regulations, the E.U. Directive requires the states to consult the public about the intended releases and give consumers an opportunity to voice their opinions.[61] Regular consumer opposition, which strives for tougher regulation, often clashes with the anxieties of the member states' governments that struggle to stay competitive in the field of biotechnology. As a result, the laws frequently change and there is no conclusive strategy.[62]

Council Regulation 258/97 ensures that GM foods are safe, not misleading, and not "nutritionally disadvantageous" to consumers.[63] The regulation achieves this objective through pre-market safety

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[53] Stewart & Johanson, *supra* note 11, at 256; Johannes S.A. Claus III, *The European Union's Efforts to Sidestep the WTO Through Its Ban on GMOs: A Response to Sarah Lively's Paper, "The ABCs and NTBs of GMOs*," 24 NW. J. INT'L L. & BUS. 173, 178 (2003) (describing European Union's Directives and Regulations that emerged in recent years in response to adverse public opinion with respect to biotechnology).

[54] Council Directive 2001/18/EC, art. 1, 2001 O.J. (L 106) 1 [hereinafter Council Directive 2001/18].

[55] *Id.* at (5) Preamble.

[56] Council Directive 2001/18, *supra* note 54, art. 6.

[57] Borg, *supra* note 28, at 717.

[58] Council Directive 2001/18, *supra* note 54, art. 28.

[59] Borg, *supra* note 28, at 718.

[60] *Id.*

[61] Council Directive 2001/18, *supra* note 54, art. 9.

[62] *See* Stewart & Johanson, *supra* note 11, at 246–47.

[63] Council Regulation 258/97/EC, art. 3, 1997 O.J. (L 043) 1.

assessments of novel foods before placing them on the market.[64] Furthermore, the regulation sets out the specific labeling requirements that apply to GM foods.[65] The regulation puts U.S. exporters in distress because meeting the traceability and labeling requirements is too burdensome under the permissive regulatory system that exists in the United States.[66]

C. Recent Developments in the United States

In recent years, the United States has experienced a number of developments in the area of GMO regulation, including the formation of a Biotechnology Advisory Committee to review testing and approval procedures.[67] The EPA is doing a similar review.[68] There were also several lawsuits filed addressing the developments in biotechnology. For example, a suit filed by Greenpeace against the EPA was dismissed, and another suit opposing the FDA's approval of genetically altered organisms resulted in a summary judgment for the government.[69] Legislators have also become increasingly involved in the decision-making process regarding the regulation of GM foods.[70]

In 2000, President Clinton formed the U.S.-E.U. Biotechnology Consultative Forum, consisting of "representatives of consumer groups, academia, and industry from the United States and the European Union," to make recommendations regarding the regulation of GM foods.[71] The panel issued a report, recommending "safety reviews and mandatory labeling for GMOs," which resulted in amplified demands to increase the regulation of the GM industry and biotechnology as a whole.[72]

During the 2004 Presidential Campaign, President George W. Bush and his challenger, Senator John F. Kerry, highlighted their

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[64] *Id.* at (2) Preamble.

[65] *Id.* at art. 8.

[66] Marsha Echols, *Bioethics Symposium: National and Global Implications of Genetically-Modified Organisms: Law, Ethics & Science: The WTO Biotechnology Dispute*, 34 CUMB. L. REV. 445, 445–46 (2003–04) ("While the dispute primarily pits the United States against the European Communities, the debate in reality involves the world and will not be resolved by these cases.").

[67] Ellison, *supra* note 18, at 353.

[68] *Id.*

[69] *Id.*

[70] *Id.* at 360.

[71] *Id.* at 361.

[72] *Id.* at 361–62.

differences on the issue of genetically modified crops.[73] In discussing the regulation of GMOs, Bush stressed the importance of the "regulatory framework [that] keeps pace with science," while Kerry shared his plan to "give government agencies the power to effectively regulate genetically modified food products."[74] Mindful of the fact that the United States produces the vast majority of the world's genetically modified foods, President Bush argued to protect U.S. farmers and opposed the labeling of products derived by means of biotechnology.[75] U.S. farmers largely use GM crops; thus, the non-restrictive regulation of GM foods means higher revenues for the farmers exporting GM crops. Conversely, restrictions on the use of GM foods make it hard for U.S. farmers to sell GM foods in Europe, which ends up costing U.S. farmers millions of dollars annually.[76] The approach that President Bush argued for mirrored his father's (former President Bush) strategy of not requiring companies to conduct safety testing on GM foods.[77] Kerry, on the other hand, promised to greatly increase government efforts to ensure that genetically modified products are safe for consumers as well as the environment.[78] Since President Bush has been re-elected for his second term, his policies regarding GM foods are currently in place.

D. Recent Developments in the European Union

In 2004, European scientists concluded that GM foods are safe for human consumption.[79] Pursuant to that conclusion, in April

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[73] *Campaign 2004 II: Bush, Kerry Face Off in Science Questionnaire,* GREENWIRE, Sept. 16, 2004, at Politics Vol.10 No.9.

[74] *Id.*

[75] Kevin Diaz, *Minnesota's Top Issues Agriculture: Farming, Biotechnology and Trade; The Records, Opinions and Plans of the Two Leading Presidential Candidates*, STAR TRIB., Oct. 20, 2004, at 17A (stating that while GM foods yield large revenues to American farmers, there are safety concerns associated with production and consumption of such foods in parts of South America, Africa and Europe).

[76] Brandon Mitchener, Scott Kilman & Scott Miller, *EU Court Upholds Italy's Ban on Genetically Modified Food*, WALL ST. J., Sept. 9, 2003, *available at* http://www.mindfully.org/GE/2003/EU-Italy-Ban-GMO9sep03.htm.

[77] Hart, *supra* note 5, ¶ 8.

[78] Diaz, *supra* note 75 (Kerry promised to push for acceptance of American exports of GM foods and mindful of safety concerns, "Kerry has also criticized the Europeans and others who he says should not use safety as a 'pretext' to close their markets to U.S. exports.").

[79] Meller, *supra* note 15.

2004, the European Commission lifted a moratorium on the importation of GM foods that had been in effect for the past six years.[80] However, the E.U. remains firm on the labeling issue, and prior to lifting the moratorium, the European Commission passed strict laws mandating labeling of GM foods.[81] The new regulations include Regulation (EC) No. 1829/2003, dealing with GM food and feed, and Regulation (EC) No. 1830/2003, dealing with traceability and labeling of GM foods.[82] The objective of both regulations is to "protect the environment, human and animal welfare and…consumer choice."[83]

In September 2004, the E.U., for the first time, approved the planting and selling of certain seeds derived by biotechnological means in Europe.[84] The E.U. made the decision in spite of widespread opposition by European consumers.[85] Nevertheless, support for GM foods in the E.U. continues to grow. The Danish nominee for the post of the European Agriculture Commissioner, Mariann Fischer Boel, expressed her support for both GM and conventional (including organic) foods by stating that "no form of agriculture (GMO or non-GMO) should be excluded in the EU in the future."[86]

E. The Role of the World Trade Organization

Existing regulations cannot keep up with rapidly developing technology. Because neither the supporters nor the opponents of GM foods are willing to give in, there is a great need for a common-ground, international regulatory scheme that would take both the objectives of international trade and the need to protect human health and the environment into consideration. Traditionally, these two interests have clashed, and therefore "the question which must be addressed by future policy makers is not

[80] *Id.*

[81] *Id.*

[82] Brian Schwartz, Student Note, *WTO and GMOs: Analyzing the European Community's Recent Regulations Covering the Labeling of Genetically Modified Organisms*, 25 MICH. J. INT'L L. 771, 781 (2004). Both regulations went into effect on April 18, 2004. Regulation (EC) No. 1829/2003 preempts the provisions of the Council Regulation 258/97 (Novel Foods Regulations) that deal with GM foods. *Id.*

[83] *Id.* at 783.

[84] *EU Approves GMO Seed*, *supra* note 16.

[85] *Id.*

[86] Sara Lewis, *Incoming EU Farm Commissioner Calls for Biotech Coexistence,* 46 FOOD CHEMICAL NEWS, Sept. 27, 2004, at 10.

which aspect should prevail, but rather how to create harmony between the two."[87] Achieving such balance will not be easy, but because the industry is so new, there is "a unique opportunity to tailor regulatory requirements closely to the needs of the time and to find a sensible balance between the concerns of the industry, government, science, and the public."[88] The organization that should play a central role in achieving a higher level of understanding between the advocates and the critics is the WTO.

The WTO has established procedures by which countries can notify it if certain measures taken by member states may potentially affect international trade.[89] If such measures are in violation of WTO trade rules, the WTO may impose trade sanctions.[90] Two mutually exclusive WTO agreements deal with GM foods: the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), and the Agreement on Technical Barriers to Trade (TBT Agreement).[91] The goal of the TBT and SPS Agreements is to advance trade and expound the General Agreement on Tariffs and Trade (GATT).[92]

The SPS Agreement was implemented in 1995 to prevent certain scientifically unfounded safety measures from impeding the trade of food products.[93] While the SPS Agreement "permits countries to maintain SPS measures necessary to protect human, animal, and plant life and health," it also facilitates trade by requiring that such protective measures are not used "as disguised barriers to trade."[94] The SPS Agreement promotes conformity of national measures with international standards and encourages

[87] Jennifer A. Bernazani, *The Eagle, the Turtle, the Shrimp and the WTO: Implications for the Future of Environmental Trade Measures*, 15 CONN. J. INT'L L. 207, 208 (2000).

[88] Frederick H. Degnan, *The Food Label and the Right-to-Know*, 52 FOOD & DRUG L.J. 49, 49 (1997).

[89] Compton, *supra* note 10, at 372.

[90] *Id*. at 372–73

[91] *Id.* at 373–74.

[92] Norbert L.W. Wilson, *Clarifying the Alphabet Soup of the TBT and the SPS in the WTO*, 8 DRAKE J. AGRIC. L. 703, 705 (2003).

[93] Terence P. Stewart & David S. Johanson, *A Nexus of Trade and the Environment: The Relationship Between the Cartagena Protocol on Biosafety and the SPS Agreement of the World Trade Organization*, 14 COLO. J. INT'L ENVTL. L. & POL'Y 1, 25 (2003).

[94] *Id.*

countries to enact measures based on an international standard.[95] The SPS Agreement also provides for another way of establishing SPS measures by basing them on risk assessment.[96] Risk assessment bases itself on the following factors: "available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment."[97] Lastly, countries can also enact provisional SPS measures "on the basis of available pertinent information."[98]

The TBT Agreement "encourages the development of international regulatory standards" and prevents deceptive practices.[99] It requires that measures "are not applied in a manner

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[95] *Id.* at 26. Scientific justifications may warrant higher standards that are stricter than the international norm. Borg, *supra* note 28, at 689. Under the SPS Agreement, scientific justifications also permit countries to implement measures that are "neither based on, nor exceed international standards." Rivera-Torres, *supra* note 50, at 296.

[96] Article Five of the SPS Agreement provides: "[m]embers shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations." The WTO Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, art. 5(1), http://www.wto.org/English/tratop_e/sps_e/spsagr_e.htm (last visited Mar. 22, 2006) [hereinafter SPS Agreement].

[97] *Id.* at art. 5(2).

[98] Article Five of the SPS Agreement provides:

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

Id. at art. 5(7).

[99] Borg, *supra* note 28, at 693. The TBT Agreement sets the following standards:

> Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil [sic] a legitimate objective, taking account of the risks non-fulfilment [sic] would create. Such legitimate objectives are, *inter alia*: national security requirements; the

[that] would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade."[100] Risk assessment under the TBT Agreement shall base itself on the following factors: "available scientific and technical information, related processing technology or intended end-uses of products."[101] Article 1.5 of the TBT Agreement limits its scope by stating that the agreement does not apply to sanitary and phytosanitary[102] measures, thus making the TBT and the SPS Agreements mutually exclusive.[103]

The GATT, first signed in 1947, regulates tariffs on goods and provides a forum for settling trade disputes, thus encouraging free trade between member states.[104] The framework for free trade under GATT is built upon the following three principles: "prohibiting discrimination between the products imported by member states," "prohibiting discrimination between imported and domestic goods," and "prohibiting quantitative restrictions on trade."[105] GATT Article XX sets forth general exceptions to unrestricted trade, which include measures "necessary to protect human, animal or plant life or health."[106] However, even if the exception is made in accordance with Article XX provisions, it still "shall not depart from the provisions of this Agreement relating to non-discrimination."[107]

Clearly, all WTO agreements aim at facilitating trade and requiring countries to restrain from imposing measures that will

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> prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment.

Agreement on Technical Barriers to Trade, Apr. 15, 1994, http://www.worldtradelaw.net/uragreements/tbtagreement.pdf (last visited Mar. 25, 2006) [hereinafter TBT Agreement].

[100] *Id.* at Preamble.

[101] *Id.* at art. 2.2.

[102] Phytosanitary is defined by Merriam-Webster as "of, relating to, or being measures for the control of plant diseases especially in agricultural crops."

[103] Article 1.5 of the TBT Agreement reads: "[t]he provisions of this Agreement do not apply to sanitary and phytosanitary measures as defined in Annex 4 of the Agreement on Application of Sanitary and Phytosanitary Measures." TBT Agreement, art. 1.5.

[104] *See* Rivera-Torres, *supra* note 50, at 289.

[105] *See id.*

[106] General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat.A-11, 55 U.N.T.S. 194 at art. XX., *available at* http://www.ciesin.org/TG/PI/TRADE/gatt.html (last visited Mar. 22, 2006) [hereinafter GATT].

[107] *Id.* at XX(i).

restrict the transboundary movement of goods.[108] Conversely, the Cartagena Protocol, concerned with the environment, requires states to take affirmative steps to regulate GMOs appropriately in ways that ensure the preservation of biodiversity.[109] As a result, there is a risk that measures enacted under the Cartagena Protocol would deviate from the WTO rules. To prevent measures enacted under the Cartagena Protocol from being invalidated as unreasonable barriers to trade, such measures must comply with the international standards provided for by the WTO.[110] Moreover, when disputes are resolved through the WTO Dispute Settlement Procedures, "environmental treaties may be invalidated as trade barriers, as they are not considered when all GATT parties have not approved of their recognition."[111]

In 2001, the Commission of the European Community proposed regulations "concerning traceability and labelling [sic] of genetically modified organisms."[112] The objectives of the proposed regulations are to facilitate quality control, to provide a "safety net" in all stages of production and marketing, and to create mechanisms for removing unsafe foods from the market.[113] The proposal also creates a framework for controlling labeling and verifying claims made on food labels.[114] The proposed regulations "provide legal

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[108] *See* Rivera-Torres, *supra* note 50, at 302.

[109] *Id.*

[110] Borg, *supra* note 28, at 696 (stating that unless environmental measures are enacted in accordance with the international standard recognized by the WTO, "the environmental mission may be seen as irrelevant and, in some instances, as an obstruction to free trade").

[111] *Id.*

[112] *Commission Proposal for a Regulation of the European Parliament and of the Council Concerning Traceability and Labelling [sic] of Genetically Modified Organisms and Traceability of Food and Feed Products Produced from Genetically Modified Organisms and Amending Directive 2001/18/EC*, at 9, COM (2001) 182 final (July 25, 2001), *available at* http://europa.eu.int/comm/food/fs/biotech/biotech09_en.pdf [hereinafter *Proposal for Traceability and Labeling of GMOs*]. In the explanatory section of the proposal, it is recognized that disparities between laws of different exporting and importing countries with regard to GM food regulation "may hinder the free movement of products, creating conditions of unequal and unfair competition." The proposal remedies this problem by creating a coherent and consistent framework for tracing and labeling GM foods. *Id.*

[113] The traceability requirements allow for continued tracking of products containing GMOs and ensure that such information is retained through every stage of placing the product of the market and never discontinued. *Id.* at 8.

[114] All GM products placed on the market have to carry a label saying "[t]his product contains genetically modified organisms." In the case of impossibility of

certainty for traders" and ensure "that ethical, legal, social and wider cultural aspects are taken into account in policy-making and research funding."[115]

The United States did not favor the proposal, and in a secret document sent to the WTO, the United States subjected it to vast criticism calling into question the majority of its objectives.[116] The United States expressed concerns that the proposed regulation was "not workable or enforceable, would be very expensive to implement, and would not achieve the stated objectives."[117] The United States opposed labeling on the grounds that it would do "nothing to ensure food safety," would "encourage[] fraudulent labelling [sic] claims," and "would undermine consumer confidence."[118] Moreover, the proposed regulation "would be disastrous for U.S. farmers" and would "disrupt market access from Europe's major trading partner and from developing countries, again stifling development of the technology."[119]

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placing a label directly on a product, appropriate documentation should accompany the product. *Id.* at 7.

[115] *Biotechnology: National Rules to Resolve Problem of Co-Existence of Crops*, EUROPEAN REPORT, Mar. 8, 2003, at 3.

[116] *See U.S. Comments: Proposal for a Regulation of the European Parliament and of the Council Concerning Traceability and Labeling of Genetically Modified Organisms and Traceability of Food and Feed Products from Genetically Modified Organisms and Amending Directive 2001/18/EC* (Dec. 6, 2001), *available at* http://www.foeeurope.org/press/USG_comments_G_TBT_N_EEC_7.pdf [hereinafter U.S. WTO TBT Response].

[117] *Id.* Consider the following example:

> A medium sized food company can have more than 6,000 products that contain 8,000 ingredients from 1,000 suppliers that move through 30 processing plants on their way to being exported to as many as 100 countries. Implementing a system to track all of these ingredients from their source (as far back as to the farm) to the final destination is a daunting task that would cost billions of dollars and even then it may not be infallible.

Mystery Bridges, *Genetically Modified Organisms and the Precautionary Principle: How the GMO Dispute Before the World Trade Organization Could Decide the Fate of International GMO Regulations*, 22 TEMP. ENVTL. L. & TECH. J. 171, 178 (2004).

[118] Press Release, Friends of the Earth, U.S. Steps up the Pressure on EU GMO Legislation (Jan. 16, 2002), *available at* http://www.genet-info.org/genet/2002/Jan/msg00021.html [hereinafter EU GMO Legislation].

[119] Alan Larson, The Future of Agricultural Biotechnology in World Trade: The Promise and Challenges, Feb. 21, 2002, http://www.state.gov/e/rls/rm/2002/8447.htm.

Instead, the United States favors a less restrictive system that it has followed for years.[120] Under that system, instead of communicating the biotech information to all the recipients of the GM products, such products would simply be recalled from the market if a valid safety concern arose.[121] In other words, the United States considers foods derived from biotechnology to be safe until proven harmful.[122] Labeling, in the view of the United States, is too burdensome, and it is not in any country's interest because it "encourages fraudulent claims."[123] Moreover, the United States argues that this regulation would do nothing to protect consumers and instead would "discourage trade and increase delays and liability costs for exporters, EU importers, and processors."[124]

The U.S. criticism of the proposed regulation caused a huge wave of frustration and resentment in the European countries.[125] Friends of the Earth food campaigner, Adrian Bebb, expressed this intensifying sentiment in response to the U.S. comments:

> The Bush Administration is trying to take away our right to decide on GM food. The public has made it very clear that they want proper labelling [sic] and proper testing for GM foods. The proposed EU laws are at least a step in the right direction. The US wants to weaken these laws to protect the likes of…American agri-business. European countries must refuse to bow to this bullying. European citizens demand the right to choose.[126]

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[120] *See* U.S. WTO TBT Response, *supra* note 116.

[121] *Id*.

[122] Halweil, *supra* note 36 (discussing the fundamental differences between the permissive approach, applied in the United States, and the precautionary principle, followed in Europe and many other countries, with respect to GM food regulation).

[123] U.S. WTO TBT Response, *supra* note 116.

[124] *Id.*

[125] *See* EU GMO Legislation, *supra* note 118.

[126] Press Release, Friends of the Earth, U.S. Steps Up Pressure on GM Food: US Threatens the Public's Right to Choose on GM Food (Jan. 16, 2002), *available at* http://www.foe.co.uk/resource/press_releases/20020116125140.html. European consumers are not the only ones demanding the right to choose. In addition to the E.U. member countries, Japan, South Korea, Australia, Mexico, and other nations enacted laws mandating labeling of foods containing genetically modified ingredients. Halweil, *supra* note 36.

The U.S. view focuses more on the development and marketing of biotechnology rather than on testing for possible risks it may pose, which demonstrates misplaced priorities and poor planning.[127] The position of the E.U. is that it "should not have to suffer for incorporating the precautionary principle into its regulation from the beginning simply because of decisions made by the [United States]."[128]

The disputes involving WTO regulations are settled through the well-established WTO Dispute Settlement Process.[129] Although the WTO usually favors U.S., European, and Japanese businesses, there is a growing concern that it tends to render more support to the United States than to other countries. As a result, European corporations are having a harder time trying to produce safer foods.[130] In fact, some have accused the WTO of being a "cat's paw of the United States government" for frequently siding with U.S. businesses in spite of disapproval of European resistance to GMOs.[131]

Recently, at the request of the United States, Canada, and Argentina, the WTO agreed to investigate the E.U.'s position on GMOs.[132] The WTO organized a three-judge panel in August 2003[133] and should have issued its report on January 5, 2006.[134] However, two days before the panel issued its scheduled report, the panel's chair announced that the interim preliminary report would

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[127] Bridges, *supra* note 117, at 178–79.

[128] *Id.* at 179.

[129] Stewart & Johanson, *supra* note 93, at 26. Among the disputes involving SPS measures, "three…have reached the Dispute Settlement Body, five are pending consultations, and two have been settled." *Id.*

[130] *See* Anup Shah, *A Huge Wave of Public Concern,* http://www.globalissues.org/EnvIssues/GEFood/PublicReaction.asp (last visited Mar. 23, 2006).

[131] John Moore, *John Moore Urges Us to Assert Our Right to Economic and Cultural Diversity and Stand Up to the Unaccountable WTO*, MORNING STAR, Oct. 4, 2004, at 9.

[132] *Europe Reflects Italian Battle over Biotech Coexistence*, ANSA ENGLISH MEDIA SERVICE, Oct. 13, 2004, 2004 WL 86476169 [hereinafter *Europe Reflects Italian Battle*]. In response to the moratorium on the importation of GMOs imposed by the E.U., the United States, joined by Argentina and Canada, initiated a Dispute Settlement Process through the WTO. The negotiation deadlocked, and after 60 days, a panel was appointed to adjudicate on the issue of the E.U.'s *de facto* ban on GM foods. Wong, *supra* note 7, ¶1.

[133] *Europe Reflects Italian Battle, supra* note 132.

[134] *GMO Update: WTO Biotech Case, ISAAA, EU, APEC*, 6 BRIDGES TRADE BIORES 1, Jan. 20, 2006, *available at* http://www.ictsd.org/biores/06-01-20/story3.htm.

not be issued until February 2006.[135] One commentator compared the WTO with the game of poker, where "every player must be aware of the rules and work within their confines in order to succeed."[136] He added that "[w]hile each player is familiar with the house rules, whether the WTO is equipped to handle genetic engineering concerns remains to be seen."[137]

While the decision is pending, certain predictions can be made based on precedents. In 1997, the WTO supported the U.S. position in the dispute that arose between the United States and the E.U. over the European ban on the importation of beef containing synthetic growth hormone that farmers had administered to cows to enhance their growth.[138] The WTO ruled that the European ban was not based "on scientific evidence, risk assessment, or relevant international standards…."[139] Still, the issue of the E.U.'s ban on GMOs is not a clear-cut case for the United States because the WTO will have to decide whether the E.U.'s GMO restrictions fit into a GATT Article XX exception for the protection of "human, animal, or plant life or health."[140] Even though the precautionary principle adopted by the E.U. had little support in WTO precedents, it can potentially be considered as customary international law, and

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[135] *Id.*

[136] Borg, *supra* note 28, at 696–97.

[137] *Id.* at 697.

[138] Wilson Huhn, *Three Legal Frameworks for Regulating Genetic Technology*, 19 J. CONTEMP. HEALTH L. & POL'Y 1, 34–35 (2002). Certain socio-political factors may account for the differences between the U.S. and E.U. positions:

> The United States, an individualistic society with a capitalistic economy, is likely to continue to approach [the] issues [of biotechnology] from a rights or a scientific regulation perspective, while more communitarian societies that have a stronger commitment to traditional values will opt for a stricter regulatory regime or for legislative preemption. National preferences for different models of regulation will hamper the development of a rational and comprehensive scheme of international regulation of biotechnology.

Id. at 35.

[139] *Id.* at 34. The WTO ordered the E.U. to pay the United States over US$100 million in damages that incurred as a result of the ban on the importation of hormone-treated beef. *Id.* at 35.

[140] Bridges, *supra* note 117, at 183 (quoting TBT Agreement, *supra* note 99, at preamble).

as such, the WTO cannot ignore it.[141] Accordingly, there is a sound possibility that the WTO will uphold E.U. restrictions on the importation of GMOs.

III. POLITICAL AND SOCIAL CONTEXT OF GMO REGULATIONS AND CONFLICTING PRIORITIES BETWEEN THE UNITED STATES AND THE EUROPEAN UNION

Biotechnology is young and developing at a rapid pace, making it hard for consumers and governments worldwide to adjust.[142] Consumer groups are putting pressure on the FDA "to require mandatory, transparent reviews and appropriate labeling…."[143] The movement seems to echo the European trend of opposing biotechnology.[144]

At the root of this disagreement are a number of clashing legal principles and cultural values between the United States and the E.U. member-states. The United States has been at the forefront of biotechnological developments and one of the first countries to apply them to agricultural industry, harvesting GM crops on millions of acres of land.[145] Accordingly, liberal regulations of GM foods in the United States derive from the profound interest of the government and businesses in international exports of these advanced crops.[146] Furthermore, lobbyists for the GE industry greatly influence agricultural departments who receive financial incentives to promote the GE industry.[147]

The members of the E.U., however, do not share this attitude. They follow a more cautious approach and implement significant restrictions on imports of GM foods as well as rigid labeling standards.[148] Due to safety concerns, the E.U. member states and

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[141] *Id.* at 184 (arguing that because the precautionary principle is used worldwide in cases of scientific uncertainty, "the WTO should accept the EU's restrictions as necessary and reasonable" because the E.U. used the precautionary principle to design their GMO regulations).

[142] Compton, *supra* note 10, at 364–65.

[143] Suh, *supra* note 1.

[144] *Id*. Labeling has been or is likely to be adopted by about forty-eight countries. *See* Harl, *supra* note 31, at 4.

[145] Compton, *supra* note 10, at 365.

[146] *Id*.

[147] Shah, *supra* note 130.

[148] Compton, *supra* note 10, at 365.

many other WTO members enacted trade restrictions on the importation of GM foods.[149]

There is a difficult controversy over the need to provide safeguards due to the lack of knowledge regarding the long-term effects of biotechnology.[150] Scientific studies have exposed certain risks to humans, such as allergic reactions, and more potential harms may exist.[151] Risks to the environment also remain uncertain. Although many speculations take place in the scientific community, some predict unintended, permanent damage to our ecosystem.[152] Supporters, however, say that the known benefits of biotechnology outweigh the potential risks.[153] They also stress the need to use biotechnology to help developing countries fight hunger and malnutrition.[154]

A range of cultural values also need to be taken into consideration. Even if GM foods were safe in every aspect and safety was not an issue, disagreements regarding the use of biotechnology would probably not cease.[155] Many attitudes toward biotechnology are based on cultural values and ethical concerns, and certain countries may have "a real, but unquantifiable, unverifiable, non-science-based aversion to a certain product."[156]

When the United States embraced biotechnology, many foreign consumers vehemently voiced their opposition based not only on safety, but also on their uneasiness with the idea that U.S. corporations would "dare to 'play God' by altering the genetic make-up of plants."[157] Many people are uncomfortable with change.

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[149] McDonald, *supra* note 39, at 503–04.

[150] *Id.* at 504.

[151] *Id*.

[152] *Id.*

[153] *See id*. at 520.

[154] *Id*. at 521.

[155] Frank Loy, *Genetically Modified Organisms: Colloquium Article Statement on Biotechnology: A Discussion of Four Important Issues in the Biotechnology Debate*, 8 N.Y.U. ENVTL. L.J. 605, 605 (2000).

[156] *Id*.

[157] Brooks, *supra* note 31, at 154. Europeans express ethical concerns regarding biotechnology because they feel that "genetic modification or engineering of crops is not a natural extension of traditional plant breeding techniques as it violates a 'natural order' which should be respected and not violated." Wong, *supra* note 7, ¶ 6. Proponents of biotechnology, however, say that genetic modification is just a modern form of selective breeding, in which people have engaged for centuries and which has proven to be safe. Rich, *supra* note 28, at 890. *See* Thomas O. McGarity, *Seeds of Distrust: Federal Regulation of Genetically Modified Foods*, 35 U. MICH. J.L. REFORM. 403, 427 (2002) (arguing that unlike traditional breeding that "take[s]

Because scientific evolution has been so rapid, people's mentalities have not had enough time to adjust. The United States greatly relies on technology, which may help explain why people in the United States are more comfortable with biotechnology than people in other countries who do not have the same trust for or reliance on technology.[158]

A number of other theories exist that help explain the reasons for public opposition to biotechnology in Europe. In recent years, for example, Europe has suffered a number of health scares, such as the "mad cow disease" and dioxin-tainted products.[159] Epidemics of this kind naturally make consumers anxious about the foods placed on the market, especially when those foods are novel and controversial. Alternately, European apprehension over GM foods may stem from the "more enduring ties between urban populations and agriculture and food products."[160] Europeans conceptualize food in a way that attaches symbolic value to it. "In many European countries there is a strong link between culture and food…David Byrne, the EU Health and Consumer Safety Commissioner, has said, referring to food quality, that '[f]or some member states it's nearly synonymous with sovereignty.'"[161] As a result, "the degree of risk of GM food products may not be as important…as the fact that this risk touches something of great symbolic importance," rather than just "a means of survival."[162] Still some hold that the

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advantage of nature's vast storehouse of information", biotechnology accomplishes changes "that could never occur in nature"). Consequently, "[b]ecause modern genetic engineering is a hit-or-miss process that 'disrupts the existing genome in a random way,' it is more likely to create unexpected, unintended side effects than the conventional approaches." *Id*. at 427–28. Furthermore, "[t]he new technology allows for a far greater number of organisms to be produced at a far greater speed compared to traditional methods, and the collective impact of these organisms presents problems for risk assessment." Rich, *supra* note 28, at 891. *Contra* J. Howard Beales III, *Modification and Consumer Information: Modern Biotechnology and the Regulation of Information*, 55 FOOD & DRUG L.J. 105, 105–06 (2000) (arguing that genetic engineering is "not fundamentally different from old methods of selective breeding").

[158] Brooks, *supra* note 31, at 162.

[159] Emily Marden, *Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture*, 44 B.C. L. REV. 733, 744 (2003).

[160] *Id*.

[161] Brian P. Rafferty, *The Door Opens Slightly: Recent European Union Regulations on Genetically Modified Products and the Ongoing United States-European Union GM Product Dispute*, 16 GEO. INT'L ENVTL. L. REV. 281, 295 (2004) (quoting Lizette Alvarez, *Consumers in Europe Resist Gene-Altered Foods*, N.Y. TIMES, Feb. 11, 2003, at A3) (discussing the roots of the European views on GM food).

[162] *Id*. at 295.

European objection to biotechnology is "simply an indirect route for rejecting American corporate arrogance."[163] In all likelihood, however, no single factor is responsible for the European reaction to genetic engineering and many different variables contribute to that attitude.[164]

In August 2003, the OECD held a biotechnology conference in Europe.[165] The conference report listed the issues of general agreement as well as the more controversial issues that did not reach agreement.[166] The parties did, however, reach a consensus regarding the need for more public discussion as well as research.[167] The areas of disagreement included moral issues, environmental concerns, and mandatory labeling of GM foods.[168] Authors of a paper written for the biotechnology conference stressed the need for a long-term strategy and proposed a "holistic approach" that would benefit the industry, the science, and the consumers.[169] They remained optimistic that the European public would warm up to biotechnology, as long as effort was put into rebuilding consumer confidence, which is what the industry is trying to do by introducing new products that will benefit the public.[170]

IV. THE NEED FOR MORE PUBLIC DISCUSSION IN THE DECISION-MAKING PROCESS AND THE IMPORTANCE OF INFORMED CONSUMER CHOICE

Studies on consumer perception show that support for GM foods has declined due to the weakening of consumer trust in governmental regulation.[171] No matter how much money gets pumped into the GE industry, "developers and producers' money and efforts are wasted if consumers lack confidence in the

[163] Marden, *supra* note 159, at 744–45.
[164] *Id*. at 745.
[165] Compton, *supra* note 10, at 370.
[166] *Id.* at 370–71.
[167] *Id*. at 370.
[168] *Id.* at 370–71.
[169] John Mason, *European Consumers Put Up Tough Fight: Genetically Modified Food: The Debate About GM Food Is More Heated in the UK and the Rest of Europe Than It Is Elsewhere*, FIN. TIMES (London), Sept. 8, 2004, at 4.
[170] *Id*.
[171] *See* Compton, *supra* note 10, at 365 (2003) (interpreting the studies by Thomas Hoban, professor of sociology and food science at North Carolina State University in Raleigh).

product."[172] Accordingly, the "consumer right-to-know" is at the core of the GM controversy.[173]

A. Informed Consumer Choice Issues in the United States

The Federal Food, Drug and Cosmetic Act of 1938 ("FDCA") prohibits misbranding and misleading representations about food and requires that certain essential information be included on a label.[174] Specifically, five pieces of information are required: (1) "the name and place of business of the manufacturer, packer, or distributor;" (2) "an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count;" (3) "the common or usual name of the food;" (4) "the common or usual name of each…ingredient" (if two or more ingredients are used); and (5) a label containing complete nutritional information.[175] The purpose of the label is to provide consumers with essential information about the food, but due to the limited space on a label, the FDA only requires the inclusion of crucial information.[176] The FDA does not consider information on genetic modification crucial, thereby influencing its view that the FDCA does not require the labeling of foods derived from biotechnology.[177] Moreover, in spite of consumer demands for more information regarding genetic engineering, the FDA argues that including such information would only clutter food labels with unnecessarily confusing messages and thus decrease the effectiveness and utility of labeling.[178] For this reason, the agency is even wary of voluntary labeling of GM foods because it can potentially mislead consumers who, due to lack of information, may assume that genetic engineering results in unsafe foods, thereby deterring people from purchasing foods that may, in fact, have higher nutritional value than conventional foods.[179] Accordingly, the FDCA condemns statements they consider

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[172] Christine Cochran, *Premarket Notice Concerning Bioengineered Foods: A Proposed Regulation Satisfying Some of the Players, Some of the Time*, 12 WASH. U. J.L. & POL'Y 173, 200 (2003) (suggesting that the government, producers, and developers of GMOs should put efforts into educating the public about biotechnology before fear of the unknown causes the public to completely reject it).

[173] Degnan, *supra* note 88, at 50.

[174] 21 U.S.C. § 343 (2004).

[175] 21 U.S.C. § 343(e),(i),(q) (2004).

[176] Degnan, *supra* note 88, at 55.

[177] *Id*.

[178] *Id.* at 55–56.

[179] *See id*. at 49.

misleading, even when ambiguity results from "the use of statements not technically false or which may be literally true."[180] Perhaps, a seemingly better solution would be to educate the public rather than to carefully craft the food labels in a way that shields consumers from the information that would allow them to make wise, educated decisions and shop with confidence.

The industry's resistance to labeling is not the only hurdle consumers have to overcome before succeeding in convincing Congress to give the FDA authority to mandate labeling; there are also important constitutional issues at hand. Even if the FDA had authority to mandate labeling, the Supreme Court may hold such requirement unconstitutional with regard to commercial speech.[181] Commercial speech is protected by the First Amendment, and such speech may only be compelled if a substantial governmental interest is present.[182] Mere consumer desire for more information to satisfy curiosity does not rise to the level of a compelling governmental interest under constitutional scrutiny.[183] However, it is not mere curiosity, but health concerns and potential environmental risks that guide many consumers to pursue mandatory labeling.[184] Even these concerns, however, are not likely to be enough to meet the required threshold of scrutiny because of the present consensus between the FDA and the National Academy of Sciences, which concludes that foods derived by means of biotechnology do not differ substantially from traditional products.[185]

A case that illustrates this constitutional issue is *International Dairy Foods Ass'n[BB 10.2.1(c)] v. Amestoy*, 92 F.3d 67 (1996), where dairy manufacturers challenged the constitutionality of a Vermont statute requiring identification of milk products that came from cows that were given bovine growth hormone ("rBST") to increase milk production.[186] The Second Circuit Court of Appeals

[180] United States v. Ninety-Five Barrels (More or Less) Alleged Apple Cider Vinegar, 265 U.S. 438, 443 (1924). In this case, a manufacturer was charged with misbranding of vinegar produced from dried apples as "apple cider vinegar." *Id.* at 439. The U.S. Supreme Court found that the label was misleading and therefore the vinegar was misbranded. *Id.*

[181] Jonathan Adler, *Regulating Genetically Modified Foods: Is Mandatory Labeling the Right Answer?*, 10 RICH. J.L. & TECH. 14, ¶ 1 (2004).

[182] *Id.* ¶ 6.

[183] *Id.* ¶ 8.

[184] *Id.*

[185] *Id.*

[186] Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 69–70 (2d Cir. 1996).

held that since rBST-derived milk was undistinguishable from regular milk, and since Vermont could not prove the existence of harm, the State of Vermont could not compel the dairy manufacturers to "speak against their will."[187] The court further stated that "consumer curiosity alone is not a strong enough state interest to sustain the compulsion of even an accurate, factual statement."[188] "[T]he government must have…a substantial governmental interest to infringe upon commercial speech," such as "unidentifiable health risks, an economic impact, or a physical impact on the consumer."[189] This is a difficult burden to overcome to justify labeling when all the regulatory agencies are in consensus about the safety of GM foods.[190] However, if proponents narrowly tailored labeling requirements, such as applying it to potentially allergenic products, the requirements may pass the threshold of constitutionality.[191]

There may be other considerations about mandatory labeling that would give grounds to a constitutional barrier:

> [T]he GM debate…is mostly about values and about ethical concerns. This fact raises an additional red flag under the First Amendment because the Court has always been very sensitive to the idea that compelling an individual to give voice to a controversial message, or to make a statement with which they disagree, is something that the government should rarely be allowed to do….
>
> A GMO labeling requirement would be likely to face additional scrutiny because there would be real suspicion that the basis for the labeling is not health concerns, but political control over the sorts of messages and values that we communicate in the food distribution process and in the food market process. In that context, courts have made it clear that those are the sorts of debates that the

[187] *Id*. at 74.
[188] *Id.*
[189] Adler, *supra* note 181, ¶ 7.
[190] *Id.* ¶ 8.
[191] *See id.* ¶ 11.

> government should stay out of and should be left to the market place of ideas.[192]

Admittedly, even though biotechnology carries potential risks, the constitutional protection on commercial free speech makes it very difficult to impose mandatory labeling in the United States, absent any explicit evidence of real harm. Despite the possible constitutional barrier, if the public applies enough pressure, there are "other non-governmental labeling schemes which can rise up and provide consumers with the sort of information that they may, for very good reasons, feel that they want or need when they are deciding what products to buy."[193]

Eventually, changes will likely take place because of growing consumer demands for information, irrespective of the safety issue. Seventy-five percent of the respondents of the Pew poll in 2001 pointed to the importance of being aware of the presence of GM ingredients in their food.[194] In 2003, eighty-nine percent of poll respondents expressed the need for mandatory FDA review before the marketing of GM products.[195] In 2002, a bill was introduced in

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[192] *Id.* ¶¶ 13–14.

[193] *Id.* ¶ 16.

[194] Suh, *supra* note 41. *See* Cynthia D. Fisher, *The Genie Is Out of the Bottle: Consumers Demand Mandatory Labeling on Genetically Engineered Foods,* 4 J. LEGAL ADVOC. & PRAC. 88 (2002). Other polls report similar findings:

> In June 2001, an ABC News telephone poll revealed that ninety-three percent of American people support labeling genetically engineered ("GE") foods, and fifty-two percent believe GE foods are unsafe. Time Magazine similarly reported that eighty-one percent of Americans polled support mandatory labeling of GE foods. The Center for Food Safety, a Washington D.C. scientific thinktank and grassroots forum for litigation support and dissemination of issues surrounding food safety, provides a comprehensive report of polls taken throughout the United States. This investigation revealed an overwhelming demand for mandatory labels on GE foods. Such studies show that while consumers are generally not opposed to GE foods, they are adamantly against allowing such foods to be sold without adequate labeling.

Id.

[195] Suh, *supra* note 41 (discussing a recent Pew poll where respondents were asked to evaluate the statement: "[c]ompanies should be required to submit safety data to the FDA for review, and no genetically modified food product should be allowed on the market until the FDA determines it is safe").

the Senate "that would require FDA approval for all GE food with safety data made public and open to comment."[196] The bill was referred to the Senate committee on October 10, 2002, and then to the Committee on Agriculture, Nutrition, and Forestry.[197] No subsequent major action has been taken with regard to the bill.[198]

The continual disregard for consumer concerns will eventually backfire. Two California counties have recently banned GM crops because of the agricultural industry's failure to address the public's fears.[199] Because of the undisputed benefits of GM foods, banning such crops is not a good strategy. However, it was a natural reaction to the "information vacuum" created by the industry's refusal to educate the public and address consumer fears.[200] The industry refuses to budge on the labeling issue, but "[i]f biotech and agriculture companies want people to make sensible choices, they'll have to trust them with more information."[201]

The U.S. position has been to deny people their right to know how something is produced and to instead align with biotech companies that cumulatively spend approximately fifty million dollars per year propagating biotech foods.[202] The ways in which the U.S. agencies handle GM food regulation send a message that citizen demands should be ignored.[203] Many European countries also feel that the United States puts too much pressure on and interferes with the decision-making process in other countries.[204] The U.S. regulators, on the other hand, are frustrated with the

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[196] *Id*. (discussing the bill introduced by Sen. Richard Durbin, D-Ill.).

[197] A Bill to Amend the Federal Food, Drug, and Cosmetic Act to Require Premarket Consultation and Approval with Respect to Genetically Engineered Foods, and for Other Purposes, http://thomas.loc.gov/cgi-bin/bdquery/z?d107:SN03095:@@@L&summ2=m&#status (last visited Feb. 6, 2006) (providing detailed information about the bill, including its summary and current status).

[198] *Id.*

[199] Paul Holmes, *CA Movement to Ban Modified Crop Stems from Industry's Refusal to Inform the Public*, PRWEEK (U.S.), Aug. 30, 2004, at 9.

[200] *Id.*

[201] *Id*.

[202] Shah, *supra* note 130; Fisher, *supra* note 194, at 89 (discussing how newly developed biotech foods rapidly moved into the marketplace in the United States and abroad due to the efforts of a small number of United States biotech companies, marketing GE foods as a solution to world hunger and environmental problems).

[203] Shah, *supra* note 130. *See* Rich, *supra* note 28, at 906 (arguing that it is irresponsible of the Government to ignore consumers' concerns and that such approach "denotes a paternalistic approach to public policy").

[204] Shah, *supra* note 130.

Europeans' resistance to GM foods and claim that their objections are unreasonable and purely emotional.[205]

B. Informed Consumer Choice Issues on the International Scene

The regulatory philosophy of the E.U. includes much more of the conflicting viewpoints of consumers, scientists, and manufacturers, and reflects a more democratic approach to labeling.[206] Although different legislative institutions have a range of dissimilar theories on what criteria they should use for labeling, there is a consensus among lawmakers that it is necessary to label biotechnology products.[207]

Of particular curiosity is that while the U.S. regulatory agencies oppose labeling of GM foods because it can be misleading and confusing to consumers,[208] the E.U. requires labeling in order to *prevent* consumers from being misled.[209] The Economic and Social Research Council (ESRC) strongly believes that "[t]o assume that the public is ignorant is not only patronizing, but inaccurate and damaging. Global Environmental Change Programme research reveals that people's understandings of the issues are very much better developed than these characterizations imply."[210]

V. CONCLUSION

Many scientists agree that although GM food is basically safe, there could be potential long-term effects. Consequently, there is a need for independent, objective, unbiased research to explore possible undesirable effects of biotechnology. The rapid advances in biotechnology and the increased presence of GM foods in markets and grocery stores worldwide further aggravate the need for such research.

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[205] Kathleen Hart, a journalist writing about health and biotechnology, called the USDA in order to clarify why the Europeans are so apprehensive about biotechnology. An assistant to then Agriculture Secretary Dan Glickman assured Ms. Hart that GM foods do not differ nutritionally from conventional foods and that "[t]he Europeans were basing their objections not on science…but on emotion." Hart, *supra* note 5, ¶ 6.

[206] Degnan, *supra* note 88, at 56.

[207] *Id*. at 57.

[208] *Id.* at 49.

[209] Compton, *supra* note 10, at 383.

[210] ESRC GLOBAL ENVTL. CHANGE PROGRAMME, THE POLITICS OF GM FOOD: RISK, SCIENCE AND PUBLIC TRUST, special briefing No. 5 (1999), http://www.sussex.ac.uk/Units/gec/gecko/gec-gm-f.pdf.

Like any scientific development, biotechnology can be used for various purposes. It can be "democratically managed to the benefit of the most needy or skewed to the advantage of specific groups that hold the vital political, economical and technological power."[211] After analyzing the progress of bioengineering nearly two decades ago, Senator Al Gore warned that "[f]or every use of biotechnology there is potential misuse. For every benefit, there is a potential hazard. Our challenge is to know when we are about to go too far."[212] Therefore, in order to maximize the possibilities and prevent the hazards, governments and people must use this power rationally.[213]

The current U.S. system is fragmented and insufficient to protect consumers because it excludes the public from the decision-making process. One commentator criticized the current system's inability to effectively address the environmental impact of biotechnology:

> At present, the environmental risks posed by genetically engineered organisms are not addressed in a coherent manner. There is no single federal statute that governs the subject matter. The regulatory regime that does exist only confronts a few aspects of the issue, and then only in a piecemeal, haphazard fashion…. Consequently, there are sizable gaps in coverage, with the concomitant risk of significant harms slipping through the cracks and into the environment. Additionally, proponents of new and potentially important genetically engineered "products" are forced to navigate a confusing maze of agencies and statutes, with resulting inefficiency and needlessly steep economic and opportunity costs and delays for industry and the general public.[214]

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[211] MacLaughlin, *supra* note 46, at 405.

[212] Albert Gore Jr., *Federal Biotechnology Policy: The Perils of Progress and the Risks of Uncertainty*, 20 U. MICH. J.L. REFORM 965, 967 (1987).

[213] *See id*.

[214] John Charles Kunich, *Mother Frankenstein, Doctor Nature, and the Environmental Law of Genetic Engineering,* 74 S.C. L. REV. 807, 823 (2001). Due to the ineffectiveness of the current interdependent system, a new agency should be created in place of the existing regulatory framework. The EPA would be the sole agency regulating GMOs under the authority of the Transgenic Release Act ("TRA")

The United States needs a more centralized regulatory system. Since increasing and ensuring cooperation between the USDA, EPA, and FDA will be very difficult, a better approach would be to create a separate federal agency responsible solely for the research and regulation of genetically modified organisms. Instead of relying on the existing regulatory framework, new laws should be created that would correspond with the demands of biotechnology. The creation of a new regime will help improve existing protections for the health of the consumers and the health of the planet.

Furthermore, the United States should adopt labeling standards to allow consumers to make an informed decision as well as to instruct, warn, and educate them about choosing their food wisely. Consumers should have a forum to address their concerns and those concerns should be listened to—"[t]his is the essence of a representative government, a fact not lost to the biotech industry, which has taken full advantage of their lobbying power to ensure technology-friendly regulations."[215]

As for the European policy, as it becomes more liberal in the interest of improving trade relationships, it needs to remain aware of other important considerations. The recent changes towards trade liberalization in Europe are positive for both the E.U. and the United States. Banning biotechnology, which has so much potential, is not a good policy, and Europe should be praised for finally giving genetic engineering a chance to prove its utility. However, the focus should remain on rational management. Eventually, the governments and people will be able to achieve a happy medium because while the United States is tightening its

proposed herein. The statute shall "make sense on a scientific level," taking into consideration both the risks and benefits of biotechnology. Moreover, the statute, "should be an effective mechanism for educating the general public and creating a productive dialogue with people in the communities most directly affected." *Id.* at 863–70.

[215] Rich, *supra* note 28, at 906. *See* Emily Robertson, Note, *Finding a Compromise in the Debate over Genetically Modified Food: An Introduction to a Model State Consumer Right-to-Know Act*, 9 B.U. J. SCI. & TECH. L. 156, 158 (2003) (advocating mandatory disclosure of GMOs in food products because consumers should be able to make informed decisions and "meaningfully participate in [the] marketplace"); s*ee also* Rebecca M. Bratspies, *Consuming (F)ears of Corn: Public Health and Biopharming,* 30 AM. J.L. & MED. 371, 403 (2004) (stating that decisions regarding the regulation of GM foods "should be the product of a public discussion and decision-making process, not the byproduct of private economic ordering"); Rebecca Bratspies, *The Illusion of Care: Regulation, Uncertainty, and Genetically Modified Food Crops*, 10 N.Y.U. ENVTL. L.J. 297, 355 (2002) (stating that because of the corrosive effects of public distrust of the regulatory system, precautionary controls need to be developed that would "enjoy the confidence of the public").

laws regarding biotechnology, European policy is becoming more non-interventional.

The opportunities are great as long as the agenda includes filling the informational void that has been growing since the introduction of biotechnology to consumers, catching them in the crossfire between competing claims and interests.