Genetically Modified Organisms in Food: a Model of Labeling and Monitoring with Positive Implications for International Trade

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I. Introduction

First patented in 1980, genetic engineering is the process of manipulating a gene using recombinant DNA (rDNA) methods.[1] Genetically modified organisms (GMOs) can be defined as organisms in which the genetic material (DNA) has been altered in a way that does not occur naturally by mating or natural recombination. The use of recombinant DNA technology or genetic engineering allows selected individual genes to be transferred from one organism into another, sometimes between non-related species.[2] Such methods, also called modern biotechnology or gene technology, are used to create GM plants that are then used to grow GM food crops.[3]

Virtually unheard of in the field before the 1990s, the first GM crop-tomato was sold in the market in 1994.[4] Since then, GMOs have grown exponentially; between 1996 and 2001, the total area of biotech crops had increased thirty times. By 2001, the estimated global area of transgenic or GM crops was 52.6 million hectacres in thirteen countries. As of 2001, 99 percent of GM crops had been produced in four countries: 68 percent in the United

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1. "Recombinant DNA methods enable the insertion of a gene or gene sequence in an exact place in the DNA of the new host, thus producing a targeted result." NATIONAL RESEARCH COUNCIL, SAFETY OF GENETICALLY ENGINEERED FOODS: APPROACHES TO ASSESSING UNINTENDED HEALTH EFFECTS (July 2004), *available at* http://www.nap.edu/html/ge_foods/ge-foods-reportbrief.pdf [hereinafter NRC SAFETY].

2. Binas Online, Facts on GMOs in the EU, http://binas.unido.org/binas/regs.php (last visited Feb. 3, 2006) [hereinafter Facts on GMOs].

3. World Health Organization, Food Safety, Biotechnology, 20 Questions on Genetically Modified (GM) Foods, http://www.who.int/foodsafety/publications/biotech/20questions/en/index.html (last visited Feb. 3, 2006) [hereinafter Questions on GM Foods].

4. Tzu-Ming Pan, *Current Status and Detection of Genetically Modified Organism*, 10 J. FOOD & DRUG ANALYSIS 229, 230 (2002) (citing ISAA ANNUAL REPORT 2002).

States, 11.8 percent in Argentina, 6 percent in Canada, and 3 percent in China.[5] Of these crops, GM soybean made up 63 percent of the global GM planting area; GM corn, 19 percent; GM cotton, 13 percent; and GM canola, 5 percent.[6] The two major GMO traits in 2001 were herbicide tolerant crops that accounted for 77 percent of all GM crops, and insect resistant crops such as *Bacillus thuringiensis* (Bt) maize that accounted for 11 percent.[7] In 2004, the area of GM crops cultivated worldwide increased by no less than 20 percent, up from 15 percent in 2003.[8] GM crops are estimated to cover almost 4 percent of arable land.[9]

When compared to the total crop population, the statistics of GM crops in the United States are even more striking. As global plantings of biotech crops grew to about 200 million acres last year, about two-thirds of it took place in the United States.[10] In the United States, more than 40 percent of the corn, more than 50 percent of the cotton, and more than 80 percent of soybean acres planted have been genetically modified. At least 70 percent of food products in U.S. supermarkets—boxed cereals, other grain products, frozen dinners, cooking oils and more—contain GMOs.[11] The Grocery Manufacturers of America (GMA) estimates that 75 percent of all processed foods in the United States contain a GM ingredient, because nearly every product with a corn or soy ingredient, as well as some containing canola or cottonseed oil, has a GM component.[12]

Biotechnology is one of the fastest-growing sectors of the economy in recent years. [13]The interests of global business are substantial as well—71 percent of all agrobiotechology patents are owned by the top five companies in the area: Pharmacia (now owned by Pfizer Inc.) (21 percent, 287 patents), DuPont (20 percent, 279 patents), Synenta (13 percent, 173 patents), Dow (11 percent, 157 patents), and Aventis (6 percent, 77 patents).[14] It is not surprising then, that the regulation of GM foods manifests itself as an economic and trade issue as well as a scientific and health issue.

Differences in the attitudes towards GM foods in the United States and the international community—and, in particular, differing perceptions and views of risk—have resulted in vastly different levels of regulation of these foods in whether GMOs are monitored or even

5. *Id.*; *see also* Press Release, International Service for the Acquisition of Agri-biotech Applications, INT-GM Crop Area Continues Growth Globally (Jan. 13, 2003), *available at* http://www.afaa.com.au/news/news-1357.asp (announcing that double-digit growth continues for biotech crops worldwide; and providing statistics on biotech crop area by country).

6. Pan, *supra* note 4, at 230.

7. *Id.* Bt maize is corn modified with a gene from the bacterium *Bacillus thuringiensis* in order to create an internal pesticide against predatory insects.

8. CropGen, While we were away (Mar. 30, 2005), http://www.cropgen.org/article_2.html.

9. World Health Organization, Modern Food Biotechnology, Human Health and Development: An Evidence-Based Study (June 23, 2005), *available at* http://www.who.int/foodsafety/publications/biotech/biotech_en.pdf [hereinafter WHO Study].

10. Associated Press, *Americans Clueless About Gene-Altered Foods* (Mar. 24, 2005), *available at* http://pewagbiotech.org/newsroom/ summaries/display.php3?NewsID=857 [hereinafter *Americans Clueless*] (statement of Stephanie Childs of the Grocery Manufacturers of America).

11. *Id.*; *see also* Roger N. Beachy, *Facing Fear of Biotechnology*, 285 Sci. 335 (1999), *available at* www.biotech-info.net/facing_fear.html.

12. *Americans Clueless*, *supra* note 10.

13. Pan, *supra* note 4, at 230 (citing ETC Group, Globalization Inc. Communique #71 (2001)).

14. *Id.*

allowed.[15] In seeking an explanation for the greater resistance to food biotechnology in Europe, a study found that different histories of media coverage and regulation combined with different patterns of public perceptions reflect deeper cultural sensitivity not only toward food and novel food technologies but also toward agriculture and the environment.[16] Consumers in the United States seem to be relatively unaware and untroubled by a technology that in Europe has generated widespread resistance and a protracted public debate, due in part to a history of food and environmental concerns, lack of transparency, and mistrust of government bureaucracies.[17] In the international community, these debates have centered on the environmental and public health safety issues of introduced genes, specifically, potential gene flow to other organisms, the destruction of agricultural diversity, allerginicity, antibiotic resistance, and gastrointestinal problems.[18]

As the number of GMOs increases exponentially and becomes an integral part of the U.S. food supply, it is critical to examine the safety concerns that have prompted the international community to take a rigorous regulatory scheme in control of the genetic engineering in comparison to the relatively unrestrictive approach in the United States. Section II of this paper analyzes the U.S. law and applicable regulations, while section III sets forth the contrasting European approach and international law in this area. Section IV discusses the scientific considerations along with particular case examples. Section V proposes a model of labeling and monitoring, in which food products that have been genetically modified should be tracked and assessed post-market, with long-term scientific studies and a reevaluation of their approval, if warranted. Section VI concludes that, in light of scientific uncertainty and risks of unintended adverse effects, the more cautious approach should be adopted in the United States. In view of the differing attitudes of risk and the degree to which scientific uncertainty is factored into risk assessments, it becomes even more important—to the biotechnology and food industries as well as the consumers—to implement more stringent monitoring and labeling of GMOs in the food supply. Only by adopting standards of accountability and regulations akin to those demanded by the international community will U.S. agricultural products once again be accepted into international markets.

II. An Analysis of U.S. Law

Biotechnology products approved for human and animal consumption have been commercially available in the United States since 1995.[19] Genes derived from a bacterium in the soil—*Bacillus thuringiensis* (Bt)—were introduced into certain crops to develop Bt corn,

15. *Id.* at 232; *see also* Farid E. Ahmed, *Detection of Genetically Modified Organisms in Food*, 20 TRENDS IN BIOTECHNOLOGY 215 (2002).

16. George Gaskell et al., *Worlds Apart? The Reception of Genetically Modified Foods in Europe and the U.S.*, 285 SCI. 384 (1999) (an attitudinal study analyzing public perceptions of biotechnology, together with press coverage and policy formation).

17. *Id.*; Ahmed, *supra* note 15, at 215; *see also* Alexander G. Haslberger, *Monitoring and Labeling for Genetically Modified Products*, 287 Sci. 431 (2000).

18. Ahmed, *supra* note 15, at 215.

19. In 1990, the FDA approved the first biotechnology food product for the U.S. market—chymosin, a food-processing enzyme produced by genetically modified bacteria. Chymosin is the active enzyme in rennet, a milk-clotting agent used to make cheese. Traditionally rennet was obtained from calf stomach linings. U.S. FOOD AND DRUG ADMINSTRATION, SAFETY ASSURANCE OF FOODS DERIVED BY MODERN BIOTECHNOLOGY IN THE UNITED STATES (July 1996), *available at* http://www.cfsan.fda.gov/~lrd/biojap96.html.

Bt cotton, Bt potato, Bt rice, and Bt tomato, giving these crops resistance to certain insects. Glyphosate-tolerant soybeans (for example, Roundup Ready by Monsanto) contain a gene that protects them from the herbicide glyphosate, so that the soybeans can be sprayed along with weeds without being affected by the herbicide. There are also herbicide-resistant varieties of canola, cotton, corn, radicchio, rice, and sugar beet on the market. Virus-resistant varieties of papaya, potato, and squash have been approved, as have tomato and cantaloupe, containing a gene that slows the ripening process to allow fruit to ripen longer on the vine.[20]

In the United States, regulation of biotechnology food products does not differ fundamentally from regulation of conventional food products. Three agencies primarily share the regulatory oversight responsibility for these products: the U.S. Department of Agriculture (USDA) and its agencies,[21] which regulate and monitor the use of biotechnology for agriculture; the Environmental Protection Agency (EPA), which approves new pesticidal and herbicidal substances; and the Food and Drug Administration (FDA), which has legal authority with respect to food safety and labeling. Depending on its characteristics, a product may be subject to review by one or more of these agencies. The agencies apply existing food safety and environmental protection laws and regulations to GM products and approve their entry into the market based on the characteristics of the products rather than whether the products are derived from genetic engineering.[22] Each agency applies its own perspective and area of concern. For example, the USDA focuses on questions of possible plant pest consequences, possible consequences to other organisms, and possible weed consequences; the EPA considers the effects on non-target organisms (e.g., whether the introduced pesticidal substance is toxic to wildlife); and the FDA asks the developer to examine whether the introduction of the genetic material into the plant caused any unexpected effects by analyzing the composition of the food, paying particular attention to levels of known toxicants and significant nutrients.[23]

U.S. regulations do not mandate labeling of GM foods, but instead recommend a voluntary labeling of bioengineered foods and request that companies notify the FDA of their intent to market GM foods at least 120 days before launch.[24] The inquiry focuses on whether the GM foods are substantially equivalent to their parent crops.[25] If so, only the

20. U.S. Food and Drug Administration, List of Completed Consultations on Bioengineered Foods, http://www.cfsan.fda.gov//~lrd/biocon.html (last visited Feb. 3, 2006); *see also* Monsanto, Products and Solutions, Setting the Standard in the Field, http://www.monsanto.com/monsanto/layout/products/default.asp (last visited Feb. 3, 2006) (bringing to market second generation of biotech traits, e.g., soybeans that can reduce the amount of trans fat in processed foods).

21. For example, the USDA's Biotechology Regulatory Services, which is a branch of the Animal and Plant Health Inspection Services, "regulates the field testing, movement, and importation of genetically engineered (GE) organisms that are known to be, or could be plant pests." Biotechnology Regulatory Services, Introduction to Biotechnology Regulatory Services of the Animal & Plant Health Inspection Service, http://www.aphis.usda.gov/brs/ (last visited Feb. 3, 2006); *see, e.g.*, 7 C.F.R. § 340 (1997).

22. James Stamps, *Trade in Biotechnology Food Products*, INT'L ECON. REV. 5-6 (2002).

23. U.S. Department of State, *Food Safety: Regulating Plant Agricultural Biology in the United States* (Oct. 2000), *available at* http://usinfo.state.gov/products/pubs/archive/biotech/ (outlines regulatory procedures from the time a scientist has an idea for a potentially marketable bioengineered plant product to when the product appears in the local food market).

24. Ahmed, *supra* note 15, at 215.

25. There is no definition provided in the regulations for substantial equivalence and no clear and universal guidelines stipulating what to test and how similar the items in question should be. It has been said that the amount of comparative data required to establish substantial equivalence involved a somewhat subjective judg-

general labeling requirements for all foods would apply. Section 403(i) of the Federal Food, Drug, and Cosmetic Act requires that "each food bear a common or usual name or, in the absence of such a name, an appropriately descriptive term." In addition, under section 201 (n), the label of the food must reveal all material facts about the food.[26]

> Thus, consumers must be informed, by appropriate labeling, if a food derived from a new plant variety differs from its traditional counterpart such that the common or usual name no longer applies to the new food, or if a safety or usage issue exists to which consumers must be alerted.[27]

In its policy statement, the FDA uses as an example a tomato that has had a peanut protein introduced into it. If "there is insufficient information to demonstrate that the introduced protein could not cause an allergic reaction in a susceptible population," a warning on the label "would be required to alert consumers who are allergic to peanuts."[28]

From the FDA's perspective, these products are seen as substantially equivalent to conventional food products because there is no scientific basis to presuppose that biotechnology foods are more risky or substantially different from other food products. The FDA states in its regulations that it

> believes that the new techniques are extensions at the molecular level of traditional . . . plant breeding. The agency is not aware of any information showing that foods derived by these new methods differ from other foods in any meaningful or uniform way, or that, as a class, foods developed by the new techniques present any different or greater safety concern than foods developed by traditional plant breeding. For this reason, the agency does not believe that the method of development of a new plant variety (including the use of new techniques including [rDNA] techniques) is normally material information . . . and would not usually be required to be disclosed in the labeling for the food.[29]

Accordingly, if GM soy contains the same nutritional and dietary content as its predecessor, the FDA does not require that it be labeled as a biotechnologically altered food.

In November 2004, the FDA proposed a Draft Guidance for Industry for New Plant Varieties Intended for Food Use.[30] This guidance provides a scientific framework in which

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ment. THE ROYAL SOCIETY, GENETICALLY MODIFIED PLANTS FOR FOOD USE AND HUMAN HEALTH—AN UPDATE (Feb. 2002), *available at* http://www.royalsoc.co.uk/displaypagedoc.asp?id=11319. As a result, this controversial concept has been disfavored in Europe where the capability to classify a novel food as being substantially equivalent no longer justifies a lack of safety assessments.

26. 21 U.S.C. § 343(i); 21 U.S.C. § 343(a); 21 U.S.C. § 321(n) (2005); *see also* Letter from Catalina Ferre-Hockensmith, Department of Health and Human Services, Division of Standards and Labeling Regulations, to Vircher B. Floyd (Sept. 17, 2002), *available at* http://www.fda.gov/ohrms/DOCKETS/dailys/02/Sep02/092502/8002a5c7.pdf.

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

28. *Id.* For critiques of this regime, *see, e.g.*, Lara Beth Winn, *Special Labeling Requirements for Genetically Engineered Food: How Sound are the Analytical Frameworks used by the FDA and Food Producers?*, 54 FOOD & DRUG L.J. 667 (1999); Carl R. Galant, Comment, *Labeling Limbo: Why Genetically Modified Foods Continue to Duck Mandatory Disclosure*, 42 HOUS. L. REV. 125 (2005).

29. Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. at 22,991.

30. U.S. Food and Drug Adminstration, FDA Talk Paper, *FDA Proposes Draft Guidance for Industry for New Plant Varieties Intended for Food Use* (Nov. 19, 2004), *available at* http://www.fda.gov/bbs/topics/ANSWERS/2004/ANS01327.html [hereinafter FDA TALK PAPER]; Draft Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use, 69 Fed. Reg. 68,381 (Nov. 24, 2004); *see also* U.S. Department of Health and Human Services, *FDA to Strengthen Pre-Market Review of Bioengineered Foods* (May 3, 2000), *available at* http://www.cfsan.fda.gov/~lrd/hhbioen2.html (announcing the FDA's "plans to draft labeling guidance to assist manufacturers who wish to voluntarily label their foods being made with or without the use of bioengineered ingredients").

to evaluate the food safety of new proteins, and provides recommendations to foster early communication by encouraging developers to submit to the FDA their evaluation of the food safety of their new protein. The FDA recognized the possibility that

> [s]cientific advances are expected to accelerate over the next decade, leading to the development and commercialization of a greater number and diversity of bioengineered crops. As the number and diversity of field tests for bioengineered plants increase, the likelihood that cross-pollination due to pollen drift from field tests to commercial fields and commingling of seeds produced during field tests with commercial seeds or grain may also increase.[31]

The FDA recommends that sponsors and developers of new plant varieties intended for food use "consult with [the] FDA about their evaluation of the food safety of any new proteins produced in these plants prior to the stage of development where the new proteins might inadvertently enter the food supply."[32] The Agency "believes that any food safety concern related to such material entering the food supply would be limited to the potential that a new protein in food from the plant variety could cause an allergic reaction in susceptible individuals or could be a toxin" in people or animals.[33] The FDA emphasized that this guidance does not establish legally enforceable responsibilities, but "describe[s] the agency's current thinking on a topic and should be viewed only as recommendations. . . ."[34]

Efforts to strengthen the U.S. government's control of GM foods through legislation have been unsuccessful thus far. In May 2002, Representative Dennis J. Kucinich (D-OH) introduced H.R. 4814, the Genetically Engineered Food Right to Know Act, a bill that would require biotechnology food products to be so labeled.[35] The purpose of the bill was "[t]o amend the Federal Food, Drug, and Cosmetic Act, the Federal Meat Inspection Act, and the Poultry Products Inspection Act to require that food that contains a genetically engineered material, or that is produced with a genetically engineered material, be labeled accordingly."[36] Although H.R. 4814 gained thirty-eight cosponsors, the bill died in a subcommittee.[37]

H.R. 4814 was one of five bills introduced by Rep. Kucinich that sought to tighten regulations pertaining to agricultural biotechnology and called for labeling of biotech foods. H.R. 4812, the Genetically Engineered Crop and Animal Farmer Protection Act, would

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31. FDA TALK PAPER, *supra* note 30.

32. U.S. Food and Drug Administration, *Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use* (2004), *available at* http://www.cfsan.fda.gov/~dms/bioprgui.html [hereinafter *Guidance for Industry*].

33. Draft Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use, 69 Fed. Reg. at 68,382.

> Based on [the] EPA's finding that the genetically engineered proteins in Bt 10 are safe, the extremely low levels of Bt 10 corn in the food and feed supply, and the fact that corn does not contain any significant natural toxins or allergens, [the] FDA has concluded that the presence of Bt 10 corn in the food and feed supply poses no safety concerns.

U.S. Food and Drug Administration, *Statement on Bt 10* (Apr. 27, 2005), *available at* http://www.cfsan.fda.gov/~lrd/biobt10.html.

34. *Guidance for Industry*, *supra* note 32.

35. Genetically Engineered Food Right to Know Act, H.R. 4814, 107th Cong. (2002).

36. *Id.*

37. H.R. 4814 was referred to the House subcommittee on Farm Commodities and Risk Management on June 4, 2002. *Id.*; *see also* Pew Initiative on Food and Biotechnology, Factsheet, Unisted States HR 4814 (May 2005), http://pewagbiotech.org/resources/factsheets/legislation/bill.php?LegislationID = 167.

"provide additional protections for farmers and ranchers that may be harmed economically by [biotech] seeds, plants, or animals," establishing a Farmer's Bill of Rights.[38] H.R. 4813, the Genetically Engineered Food Safety Act, would "amend the Federal Food, Drug, and Cosmetic Act with respect to the safety" of biotech foods.[39] H.R. 4813 would require that all GMOs are safe for human consumption, and would give the FDA a right to impose independent testing and to seek input from the National Academy's Institute of Medicine.[40] H.R. 4815, the Real Solutions to World Hunger Act, would restrict genetically engineered exports to GMOs approved in the United States and by the importing nation.[41] The purpose of this bill was "[t]o ensure that efforts to address world hunger through the use of [biotech] animals and crops actually help developing countries and people, while protecting human health and the environment . . . ."[42] Finally, H.R. 4816, the Genetically Engineered Organism Liability Act, would assign liability for injury caused by biotech events to the biotechnology companies that created the GMOs.[43] All of these bills were referred to subcommittees with no further action.

In the U.S. Senate in October 2002, Senator Richard Durbin (D-IL) introduced S. 3095, the Genetically Engineered Foods Act (GEFA), 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."[44] This legislation would require the FDA to review and approve all genetically engineered foods prior to introduction into interstate commerce. It would authorize approval exemptions for a food category deemed not to be a food safety risk and would provide for trade secret protection. Specifically, the GEFA would direct the Secretary of Health and Human Services to establish (1) a program to test for the presence of genetically engineered ingredients in food from all stages of agricultural production to retail distribution and (2) a genetically engineered food registry that contains the regulatory status of all such approved foods. It also applied provisions respecting adulterated drugs and devices to genetically engineered animals; set forth application criteria, including provisions for protection of trade secrets and environmental assessments; and incorporated prohibitions against unlawful use of trade secret information and adulterated food. There was apparently no action on this bill; on the day it was introduced in the Senate, it was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry.[45]

The U.S. government does not appear to be launching, or acting upon, initiatives to change the way it handles bioengineered food. In the 108th Congress (2003–2004), thirteen bills and two resolutions specifically addressing agricultural biotechnology were introduced. Of those, only two non-binding resolutions—supporting the Administration's efforts to bring a complaint against the European Union (EU) for its restrictions on GM crops—passed (H.R. Res. 252 and S. Res. 154).[46] The stated purpose of these resolutions was to

38. Genetically Engineered Crop and Animal Farmer Protection Act of 2002, H.R. 4812, 107th Cong. (2002).

39. Genetically Engineered Food Safety Act of 2002, H.R. 4813, 107th Cong. (2002).

40. *Id.*

41. Real Solutions to World Hunger Act of 2002, H.R. 4815, 107th Cong. (2002).

42. *Id.*

43. Genetically Engineered Organism Liability Act of 2002, H.R. 4816, 107th Cong. (2002).

44. Genetically Engineered Foods Act, S. 3095, 107th Cong. (2002).

45. *Id.*

46. H.R. Res. 252, 108th Cong. (2003) (introduced by Representative Roy Blunt, R-MO); S. Res. 154, 108th

express the support of the House of Representatives and the Senate of the United States "in its efforts within the World Trade Organization (WTO) to end the [EU's] protectionist and discriminatory trade practices of the past five years regarding agriculture biotechnology."[47] Each resolution "supports and applauds the efforts of the Administration on behalf of the Nation's farmers" and sound science by "challenging the long-standing, unwarranted moratorium imposed by the [EU] on [agriculture and food biotech products] and encourages the President to continue to press this issue."[48]

With the U.S. Congress continuing to see relatively little activity on biotechnology-focused legislation, state legislatures have come forward as the main venue for issues pertaining to agricultural biotechnology.[49] In the 2003–2004 legislative session, thirty-five states introduced 170 pieces of legislation (156 bills and fourteen resolutions), which represented a 7 percent increase over the amount of legislation introduced in thirty-nine different state legislatures in 2001–2002.[50] Of these, thirty-seven bills and resolutions on agricultural biotechnology passed (22 percent of the total introduced in 2003–2004). This was down slightly from the 2001–2002 legislative session, which saw forty-five pieces of legislation (28 percent) pass.[51] In 2004, two states passed legislation that would "assert state preeminence over agricultural biotechnology and prevent local initiatives from countering state authorities."[52]

Activities to date suggest that agricultural biotechnology issues will continue to be of interest, particularly with respect to concerns about marketing, economics, and liability—issues that have historically fallen outside the scope of federal regulations.[53] "But some state legislation has also addressed labeling and the safety of new products such as transgenic fish—areas much more commonly handled by federal agencies."[54] In the absence of a comprehensive system of federal legislation, these state and local restrictions could result in "a patchwork of inconsistent regulatory requirements . . . ."[55]

III. A Contrasting Approach: EU and International Law

In the area of determining the food safety of GMOs, the Europeans and the international community take a directly contrasting approach. The cultural difference in attitudes is

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Cong. (2003) (introduced by Senator Jim Talent, R-MO); *see also* Pew Initiatives on Food and Biotechnology, Factsheet, State Legislative and Local Activities related to Agricultural Biotechnology Continue to Grow in 2003-2004 (May 2005), http://pewagbiotech.org/resources/factsheets/legislation/factsheet.php [hereinafter Legislative Activities].

47. H.R. Res. 252.

48. *Id.*

49. Legislative Activities, *supra* note 46.

50. *Id.*

51. *Id.*

52. *Id.*

South Dakota enacted HB1237 which authorizes the patent holder of any GM organism authorized for release by the federal government to use it in that state. Pennsylvania enacted HB2387, which establishes that no ordinance or local rule can prohibit or regulate the sale of seeds in a manner that contradicts state regulations.

53. *Id.*

54. Legislative Activities, *supra* note 46. This development potentially raises issues of a constitutional dimension, such as pre-emption and the Commerce Clause.

55. *Id.*

reflected in the law and in the approach and level to which scientific uncertainty is factored into risk assessment. The international community gives greater weight to this uncertainty than the U.S. government.[56] Moreover, "[b]ecause U.S. regulators [do] not see biotechnology as posing special risks, regulation [has been] contained within existing laws addressing known physical risks of new products."[57] In contrast, "European regulators have dealt with biotechnology as a novel process requiring novel regulatory provisions, and a complex series of national and European initiatives have embraced a wider range of both known and unknown risks (including risks to the environment)."[58]

The Codex Alimentarius Commission is an international standard setting body for food safety jointly administered by two United Nations agencies: the Food Agriculture Organization (FAO) and the World Health Organization (WHO). To provide international consistency in the assessment of GM foods, the Codex Commission adopted principles that set a uniform standard for assessing food safety for foods derived from modern biotechnology.[59] The Codex principles prescribe a premarket assessment, performed on a case-by-case basis, including an evaluation of both direct effects (from the inserted gene) and unintended effects (that may arise as a consequence of insertion of the new gene). The safety assessment principles for GM foods require an investigation of the direct health effects (toxicity), the tendency to provoke allergic reactions (allergenicity), the specific components thought to have nutritional or toxic properties, the stability of the inserted gene, the nutritional effects associated with the specific gene modification, and any unintended effects that could result from the gene insertion.[60] Although the Codex principles do not have a binding effect on national legislation, they are incorporated into treaties such as the Agreement on the Application of Sanitary and Phytosantiary Measures of the World Trade Organization and are often used as a reference in cases of trade disputes, including those involving the United States.[61]

A recent study by the World Health Organization concluded that the risk assessment guidelines specified by the Codex Commission are adequate for the safety assessment of GM foods currently on the international market.[62] The potential risks associated with GMOs and GM foods should be assessed on a case-by-case basis taking into account the characteristics of the GMO or the GM food and possible differences in the receiving environments. For potential risks from outcrossing or contamination from GM crops, relevant consequences need to be investigated for specific crops and strategies for risk management need to be explored. In addition, a better understanding of the impact and interaction of food with the immune system is required to determine how and whether conventional and GM foods cause specific health and safety problems. The Codex Commission assumes that improvements in risk assessment techniques will be incorporated in the premarket approval

56. Haslberger, *supra* note 17.

57. Gaskell et al., *supra* note 16.

58. *Id.*

59. Codex Alimentarius Commission, Principles for the Risk Analysis of Food Derived from Modern Biotechnology, CAC/GL 44-2003 (2003), *available at* http://www.codexalimentarius.net/download/standards/10007/CXG_044e.pdf.

60. WHO Study, *supra* note 9, at 12.

61. The United States has participated in Codex since it was formed in 1962. *Id.*; Stamps, *supra* note 22, at 5, 7; *see also* Questions on GM Foods, *supra* note 3.

62. WHO Study, *supra* note 9, at 23.

process established by many countries under this international guidance.[63] The WHO study expressed support for this process, emphasizing the need for case-by-case risk assessments to consider both the intended and unintended effects before the release of GM foods.[64]

In the international community, the Cartagena Protocol on Biosafety of the Convention on Biological Diversity[65] is the only international regulatory instrument that deals specifically with the potential adverse effects of GMOs (known as living modified organisms or LMOs under the Protocol) on the environment, taking also into account the risks to human health.[66] The Cartagena Protocol, an environmental treaty legally binding for its Parties, regulates the trade and transfer of LMOs across borders (e.g., labeling on shipments of GM commodities) and allows governments to prohibit the import of GM foods where there is concern over its safety.[67] Established with the intention of protecting biological diversity from the risks associated with living modified organisms related to biotechnology, it delineates risk assessment techniques and scientific detection methods. An Advance Informed Agreement (AIA) must inform potential participatory countries of all of the information associated with organisms before they allow their import to permeate their borders.[68] The Cartagena Protocol embraces a precautionary approach in accordance with the language of the Rio Declaration on Environment and Development.[69] Lastly, the Cartagena Protocol establishes a Biosafety Clearing-House that aids in the exchange of scientific, technical, environmental, and legal information on living modified organisms and assists countries in the implementation of the Protocol.[70]

The WHO study observed that while the Cartagena Protocol is the key basis for international regulation of LMOs, its scope does not consider GM foods that do not meet the definition of an LMO.[71] GM foods are within the scope of the Cartagena Protocol only if

63. *Id.*

64. *Id.*

65. Cartegena Protocol on Biosafety to the Convention on Biological Diversity (2000), *available at* http://www.biodiv.org/biosafety/. The Cartagena Protocol (sometimes referred to as the Biosafety Protocol) was put forth in January 2000 and went into effect on September 11, 2003, the ninetieth day after receiving the fifty instruments of ratification by States or regional economic integration organizations that are Parties to the UN Convention on Biological Diversity (CBD), which was adopted in Rio de Janeiro in 1992. *See* IISD Linkages, A Brief Introduction to the Convention on Biological Diversity, http://www.iisd.ca/biodiv/cbdintro.html (last updated Feb. 18, 2000). As of July 27, 2005, there were 125 Parties who had ratified the Protocol. The United States, which had signed the CBD, but had not ratified it, is not among them. For a list of the status of the ratifying Parties, *see* The Convention on Biological Diversity, Parties to the Convention on Biological Diversity/Cartegena Protocol on Biosafety, http://www.biodiv.org/world/parties.asp (last visited Feb. 3, 2006).

66. WHO STUDY, *supra* note 9, at 19.

67. Aarti Gupta, *Governing Trade in Genetically Modified Organisms: The Cartagena Protocol on Biosafety*, 42 ENV'T 22, 22-23 (2000); *see also* Lisa A. Tracy, *Does a Genetically Modified Rose Still Smell as Sweet?—Labeling of Genetically Modified Organisms under the Biosafety Protocol*, 6 BUFF. ENVTL. L.J. 129 (1999).

68. Cartagena Protocol, *supra* note 65; *see* Aarti Gupta, *Advance Informed Agreement: A Shared Basis for Governing Trade in Genetically Modified Organisms?*, 9 IND. J. GLOBAL LEGAL STUD. 265 (2001).

69. The precautionary approach states that "[w]here there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." Comisión Nacional de Recursos Fitogenéticos, Frequently Asked Questions about the Cartagena Protocol on Biosafety, http://www.conarefi.ucr.ac.cr/Bioseguridadl.htm (last visited Feb. 3, 2006).

70. *Id.* For a general discussion of the Cartagena Protocol, *see* David J. Schnier, *Genetically Modified Organisms & the Cartagena Protocol*, 12 FORDHAM ENVTL. L.J. 377 (2001).

71. Under the Cartagena Protocol, a living modified organism (LMO) is defined as "any living organism that possesses a novel combination of genetic material obtained through the use of modem biotechnology" and living organism means "any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids." Cartagena Protocol, *supra* note 65, at art. 3(g)-(h).

they contain LMOs that are capable of transferring or replicating genetic material. Its primary focus on biodiversity limits its consideration of human health issues; accordingly, "the Protocol alone . . . is not sufficient for the international regulation of GM foods."[72] In addition, the study reported that the possibility of implementing post-market surveillance in the future is being explored, but tools to identify or trace GMOs or products derived from GMOs in the environment or food chain are a prerequisite for any kind of monitoring. Detection techniques are in place in a number of countries to facilitate monitoring of GMOs and attempts to standardize analytical methods for tracing GMOs have been initiated.[73] The study itself grew out of the hope that "this report could form the basis for a future initiative towards more systematic, coordinated, multi-organizational and international evaluation of certain GM foods."[74]

Some of this goal is being reached through the efforts of the Organization for Economic Cooperation and Development (OECD) that established the Internal Coordination Group on Biotechnology in 1993 to facilitate international coordination in the areas of agriculture, technology, and trade. The OECD Bio Track provides a clearinghouse of information on biotechnology products and field trials, as well as Consensus Documents for the Work on Harmonisation of Regulatory Oversight in Biotechnology.[75] This OECD effort seeks to promote international harmonization in the safety assessment and regulation of biotechnology food products, including food-labeling practices that have a potential to impede international trade in food products as nontariff trade barriers.[76]

The EU has taken a proactive role in enacting strict legislation to control the spread of GMOs. Recently the EU introduced a new Directive, 2001/18/EC,[77] that places tighter restrictions on the distribution of items containing GM ingredients. By its terms, the Directive states that "[t]he protection of human health and the environment requires that due attention be given to controlling risks from the deliberate release into the environment of [GMOs]."[78] It recognizes that "[l]iving organisms, whether released into the environment in large or small amounts for experimental purposes or as commercial products, may reproduce in the environment and cross national frontiers thereby affecting other Member States. The effects of such releases on the environment may be irreversible."[79] Directive 2001/18/EC also provides a notification procedure before a GMO or GM product is placed on the market, a period of public comment, an assessment report, criteria for the monitoring and handling of new information, and principles for environmental risk assessment. It also sets forth specific provisions for labeling and packaging, including a requirement that the words "this product contains [GMOs]" shall appear either on a label or in an accompanying

72. WHO STUDY, *supra* note 9, at 19.

73. *Id.* at 23 (citing European Network of GMO Laboratories (2002), *available at* http://engl.jrc.it/).

74. Questions on GM Foods, *supra* note 3, at Q20.

75. Organisation for Economic Co-operation and Development, Consensus Documents for the Work on Harmonisation of Regulatory Oversight in Biotechnology, http://www.oecd.org/document/51/0,2340,en_2649_37437_1889395_1_1_1_37437,00.html (last visited Feb. 3, 2006).

76. Stamps, *supra* note 22, at 8 (citing OECD, Biosafety—BioTrack, About, http://www.oecd.org/about/0,2337,en_2649_34385_1_1_1_1_37437,00.html (last visited Feb. 3, 2006)).

77. Council Directive 2001/18/EC, 2001 O.J. (L106), *available at* http://binas.unido.org/binas/regs.php; *see also* Facts on GMOs, *supra* note 2.

78. Council Directive 2001/18/EC, *supra* note 77, at cl. 5.

79. *Id.* at cl. 4.

document.[80] The Directive further calls for a legislative proposal for implementing the Cartagena Protocol on Biosafety, including appropriate measures to require community exporters to ensure that all requirements of the AIA procedure of the Cartagena Protocol are fulfilled. It went beyond the previous Directive 90/220/EC[81] in allowing a temporary ban of GM products if evidence could be provided exposing risks to human health or the environment.[82]

The moratorium has been a source of friction between the United States and the EU, costing the United States an estimated $200 million in corn exports.[83] As discussed previously, the United States filed a complaint with the WTO challenging the ban, contending that it was an impediment to trade.[84] In addition, the EU approved enhanced labeling requirements for biotechnology food and feed in November 2002.[85] The U.S. Government had previously delivered a demarche to the EU in September 2002 outlining U.S. concerns about the pending traceability and labeling regulations and their likely adverse impact on U.S. bulk shipments.[86]

To further monitor food safety, the EU created the European Food Safety Authority (EFSA) in May 2003 that assumed a number of tasks previously entrusted to the European

80. *Id.* at art. 13, § 2, ¶ f.

81. Council Directive 90/220/EEC, 1990 O.J. (L 117), *available at* http://binas.unido.org/binas/regs.php. Directive 90/220/EEC regulated deliberate releases for research and development and the placing on the market of GMOs and products containing a GMO such as GM tomatoes, but did not extend to products derived from GMOs, such as paste or ketchup from a GM tomato. It was strengthened through the mandatory labeling requirements of Council Regulation (EC) No. 1139/98, 1998 O.J. (L159), *available at* http://www.biosafety.be/GB/Dir.Eur.GB/FF/1139_98/1139_98.html. Council Directive 90/220/EEC was repealed by the new Directive 2001/18/EC.

82. *See generally* Brian Schwartz, 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 (2004).

83. The Non-GMO Report, *EU tightens GM food labeling requirements* (Nov. 2002), http://www.non-gmo source.com/GM_food_labeling_requirements.php; *see generally* David Winickoff et al., *Adjudicating the GM Food Wars: Science, Risk, and Democracy in World Trade Law*, 30 YALE J. INT'L L. 81 (2005); THOMAS BERNAUER, GENTS, TRADE, AND REGULATION: THE SEEDS OF CONFLICT IN FOOD BIOTECHNOLOGY (Princeton University Press 2003); *see* Charles R. McManis, *Wither the Conflict over Agricultural Biotechnology?*, 6 MINN. J.L. SCI. & TECH. 737 (2005) (reviewing THOMAS BERNAUER, GENES, TRADE, AND REGULATION: SEEDS OF CONFLICT IN FOOD BIOTECHNOLOGY (2003)).

84. In May 2003, the United States, Argentina, and Canada filed a formal complaint with the World Trade Organization against the EU over its illegal five-year moratorium on approving crops improved through biotechnology. Biotechnology Industry Organization, European Union Moratorium, http://www.bio.org/foodag/background/eumoratorium.asp (last visited Feb. 3, 2006). *But see* Press Release, European Union, European Commission Regrets U.S. Decision to File WTO Case on GMOs as Misguided and Unnecessary (May 23, 2003), *available at* http://www.eurunion.org/news/press/2003/2003036.htm; *see also* John Stephen Fredland, *Unlabel Their Frankenstein Foods!: Evaluating a U.S. Challenge to the European Commission's Labeling Requirements for Food Products Containing Genetically Modified Organisms*, 33 VAND. J. TRANSNAT'L L. 183, 187 (2000).

85. Stamps, *supra* note 22, at 10.

86. *Id.* (citing *U.S. Demarche Highlights Priority Changes to EU Biotech Rules*, INSIDE U.S. TRADE (Oct. 11, 2002)). For further analysis on the U.S.-EU debate, *see* Mystery Bridgers, Comments and Notes, *Genetically Modified Organisms and the Precautionary Principle: How the GMO Dispute Before the World Trade Organization could Decide the Fate of International GMO Regulation*, 22 TEMP. ENVTL. L. & TECH. J. 171 (2004); Starla L. Borg, Note, *Waiting for the River: The United States and European Union, Heads Up and High Stakes in the WTO—Genetically Modified Organisms in International Trade*, 43 WASHBURN L.J. 681 (2004); Sarah Lively, Comment, *The ABCs and NTBs of GMOs: The Great European Union-United States Trade Debate—Do European Restrictions on the Trade of Genetically Modified Organisms Violate International Trade Law?*, 23 NW. J. INT'L L. & BUS. 239 (2002).

Commission.[87] The role of the EFSA differs from its American counterpart in that the EFSA deals only with risk assessment, unlike the FDA that also handles risk management. The European Parliament wanted an organization that gave objective, independent and public advice, leaving the policy judgments to the Commission. The Executive Director of the EFSA, Geoffrey Podger, favors the labeling approach. He stated that

> [i]n [his] view, it is quite clear that the only practical way of ever getting out of the problem of European public opinion in relation to GMOs is through labeling, even though American exporters do not like the idea. The great advantage of labeling is that it provides a choice. And while the people who insist on choice may be quite a small part of the population, they are very vociferous and they are often in positions of power and prominence.[88]

Dr. Podger believes that it is "only going to be possible to open [the market for GMOs] if products come onto the market that have obvious advantages for consumers," even if "some people say there may be a risk."[89] Public perceptions, he notes, are open to change with new information.

> The one thing EFSA can do is to keep a straight course in terms of giving people all the information we have on the science, and to continue to make clear that we believe in the regulatory process that we are using. Equally, of course, we are always open to new scientific evidence and to improving the regulatory process if necessary.[90]

All GM products seeking to enter the EU market as food or feed must undergo an extensive authorization procedure, including a scientific safety assessment by the EFSA. Thus, the EU and the international community continue to pursue an aggressive policy of caution against the importation of bioengineered foods and food products.[91]

IV. Scientific Considerations and Case Examples

Arpad Pusztai, a scientist who has reviewed the research and acts as a consultant to groups starting up research into the health effects of GM food, asks "[h]ow can the public make informed decisions about genetically modified foods when there is so little information about its safety?"[92] GM crops and food are being grown and consumed by the public even though there is little scientific study about their health risks, safety test technology is inadequate to assess potential harm, they can carry unpredictable toxins, and they may increase the risk of allergenic reactions. Pusztai attributes the lack of data to a number of reasons, including the fact that it is "more difficult to evaluate the safety of crop-derived foods than individual chemical, drug, or food additives. Crop foods are more complex and

87. Geoffrey Podger, *European Food Safety Authority Will Focus on Science*, EUROPEAN AFFAIRS (2004), *available at* http://www.europeanaffairs.org/current_issue/2004_winter/2004_winter_77.php4.

88. *Id.*

89. *Id.*

90. *Id.*

91. *See* THE NATIONAL FOREIGN TRADE COUNCIL, INC., LOOKING BEHIND THE CURTAIN: THE GROWTH OF TRADE BARRIERS THAT IGNORE SOUND SCIENCE (May 2003), *available at* http://www.wto.org/english/forums_e/ngo_e/posp47_nftc_looking_behind_e.pdf.

92. Arpad Pusztai, *Genetically Modified Foods: Are They a Risk to Human/Animal Health?* (June 2001), http://www.actionbioscience.org/biotech/pusztai.html.

their composition varies according to differences in growth and agronomic conditions."[93] Additionally, publications on GM food toxicity are scarce, there are few animal studies, and peer-reviewed publications of clinical studies on the human health effects of GM food are needed.[94] The preferred approach of the industry has been to use compositional comparisons between GM and non-GM crops. When they are not significantly different the two are regarded as substantially equivalent, and therefore the GM food crop is regarded as safe as its conventional counterpart. This ensures that GM crops can be patented without animal testing. Substantial equivalence, however, is an unscientific concept that has never been properly defined or provided with a legal standard for implementation.[95]

The WHO recently commissioned a study to establish a knowledge base for evaluating the application of modern technology in food production. The study recognized as benefits for human health "the potential for increased agricultural productivity or improved nutritional values [and] there may also be indirect benefits, such as reduced agricultural chemical usage and enhanced farm income, and improved crop sustainability and food security, particularly in developing countries."[96] Indeed, one of the most often cited benefits of biotechnology in agriculture is the ability to increase food productivity and thus reduce hunger. Proponents also cite the goals of conserving the environment by reducing pesticide and herbicide uses, enhancing nutritional content, and improving food quality.[97] Whether these goals and uses have in fact been met or implemented is another matter.

A. Possible Hazards to Human Health

The WHO study, however, also identified several risks presented by GMOs and GM foods for human health and the environment. The safety assessment of GM foods generally investigates the following risks to human health: direct health effects (toxicity), tendencies to provoke allergic reaction (allergenicity), specific components thought to have nutritional or toxic properties, the stability of the inserted gene, nutritional effects associated with genetic modification, and any unintended effects that could result from the gene insertion.[98] One of the main health issues of concern is gene transfer, in which the genes from GM foods could transfer "to cells of the body or to bacteria in the gastrointestinal tract" and adversely affect human health.[99] This would be particularly troublesome if, for example, the antibiotic-resistant marker genes used in creating GMOs—typically inserted with GM material to allow identification of GM cells or tissue during development—were to be

93. *Id.*

94. *Id.* (citing Jose L. Domingo, *Health risks of genetically modified foods: Many Opinions but few Data*, 288 Sci. 1748 (2000)).

95. Pusztai, *supra* note 92 (citing Erik Millstone, et al., *Beyond Substantial Equivalence*, Nature, Oct. 7, 1999, at 525).

96. Who Study, *supra* note 9, at iii; *see also* Fred Gould & Michael B. Cohen, *Sustainable Use of Genetically Modified Crops in Developing Countries*, *in* Agricultural Biotechnology and the Poor: Conference Papers 139 (Oct. 1999), *available at* http://www.cgiar.org/biotech/rep0100/Gould.pdf (discussing the potential of biotechnology crops for increasing yield in developing countries, but recognizing the need for long-term food security and decreased environmental risks).

97. Pan, *supra* note 4, at 230.

98. *See* WHO Study, *supra* note 9.

99. Questions on GM Foods, *supra* note 3.

transferred, causing a person to be resistant to antibiotic medicines. As a result, an FAO/WHO expert panel recommended the use of technology without antibiotic-resistant genes.[100]

Information is scarce about health hazards, such as toxicity in GM crops. In the few animal studies that have been done, some of the initial results have been troubling.[101] The following serve as examples of these studies' troubling results: some rats died within a few weeks after eating GM tomatoes; the rats' ability to digest was decreased after eating GM corn; allergen content increased when soybeans were genetically modified; the toxin level of GM cotton was found to be unpredictable; rats had meager weight gain when fed GM soybeans; and toxins were found in mice after eating GM potatoes.[102] Additionally, "allergies are a major concern with GM food, especially if ingredients are not labeled in packaged food," yet "there are no reliable ways to test GM foods for allergies."[103] These studies have led some scientists to conclude that "we need more and better testing methods before making GM foods available for human consumption."[104]

One of the first GM products brought to market revealed a story of toxicity. In the late 1980s, Showa Denko, Japan's third largest chemical company, introduced a genetically altered version of the dietary supplement L-tryptophan into the United States. Within a period of months, thousands of people who had taken the supplement began to suffer from eosinophilia myalgia syndrome, which included neurological problems. Eventually, at least 1500 people were permanently disabled and thirty-seven died. The Showa Denko tryptophan contained a toxic contaminant that appears to have been a byproduct of the increased tryptophan production of the genetically engineered bacteria. But it took months before the doctors who treated the syndrome discovered this link. If the supplement had been labeled as genetically engineered, the source of the problem might have been identified earlier.[105]

The hazard of allergens in bioengineered foods has also surfaced. In 1996, a company called Pioneer Hi-Bred spliced Brazil nut genes into soybeans to improve the soybean's

100. *Id.* At least one study found that the antibiotic-resistant marker from a burger containing GM soy found its way into human gut bacteria; "the bacteria had taken up the herbicide-resistant gene from the GM food at a very low level." *Study Shows Disadvantages of GM Foods to Human Health*, THE GUARDIAN, Aug. 2002, *available at* http://www.non-gmosource.com/disadvantages_GM_food_health.php; *see also* THE ROYAL SOCIETY, *supra* note 25.

101. Pusztai, *supra* note 92; *see also* Nathan Batalion, *50 Harmful Effects of Genetically Modified Food* (2000), http://www.cqs.com/50harm.htm. *But see* ROYAL SOCIETY, *supra* note 25 ("studies, on the results of feeding GM sweet peppers and GM tomatoes to rats, and GM soya to mice and rats, have [found] no adverse effects") (citing Michael Gasson & Derek Burke, *Scientific Perspectives on Regulating the Safety of Genetically Modified Foods*, 2 NATURE REVIEWS GENETICS 207, 217 (2001)).

102. Pusztai, *supra* note 92.

103. *Id.*

104. *Id.* For a related examination of the health issues, *see, e.g.*, MARIE-CLAIRE CORDONIER SEGGER & ASHFAQ KHALFAN, SUSTAINABLE DEVELOPMENT LAW: PRINCIPLES, PRACTICES, AND PROSPECTS (Oxford University Press 2004); *see also* Craig Segall, *Book Review*, 24 STAN. ENVTL. L.J. 341 (2005) (reviewing MARIE-CLAIRE CORDONIER SEGGER & ASHFAQ KHALFAN, SUSTAINABLE DEVELOPMENT LAW: PRINCIPLES, PRACTICES, AND PROSPECTS (Oxford University Press 2004)); Heather N. Ellison, *Genetically Modified Organisms: Does the Current Regulatory System Compromise Consumer Health?*, 10 PENN ST. ENVTL. L. REV. 345 (2002); Julie Teel, *Rapporteur's Summary of the Deliberative Forum: Have NGO's Distorted or Illuminated the Benefits and Hazards of Genetically Modified Organisms?*, 13 COLO. J. INTL ENVTL. L. & POL'Y 137 (2002); Ellen Messer, *Food Systems and Dietary Perspective: Are Genetically Modified Organisms the Best Way to Ensure Nutritionally Adequate Food?*, 9 IND. J. GLOBAL LEGAL STUD. 65, 69-70 (2001).

105. Batalion, *supra* note 101 (citing Arthur N. Mayeno & Gerald J. Gleich, *Eosinophilia Myalgia Syndrome and Tryptophan Production: A Cautionary Tale*, 12 TRENDS IN BIOTECHNOLOGY 346 (1994)).

protein content. The altered soybean provoked serious allergic attacks in eight individuals sensitive to Brazil nuts but not soybeans. A study confirmed that the allergen from Brazil nuts was transferred to the soybean and produced an allergic response comparable to that encountered in the Brazil nut alone.[106] Fortunately, the product was removed from the market before any fatalities occurred.[107] Because the public had no label advising them that a soybean could contain genes from a highly allergic nut, even those who were aware of their severe allergies had no warning.[108]

There is strong evidence that certain ingredients in GM foods can be linked to cancer.[109] In 1994, the FDA approved Monsanto's rBGH (recombinant Bovine Growth Hormone), a genetically produced growth hormone, for injection into dairy cows, despite warnings from scientists that the resulting increase of IGF-1, a potent chemical hormone, is linked to 400 to 500 percent higher risks of human breast, prostrate, and colon cancer.[110] Studies show that rBGH increases the levels in milk of insulin-like growth factor (IGF-1)—"a powerful stimulator and regulator of cell-growth and division in humans and cows," and particularly children—with converging evidence of a cancer link.[111] Samuel Epstein, M.D., Professor of Environmental Medicine at the University of Illinois School of Public Health, Chairman of the Cancer Prevention Coalition, and the author of its report, concluded that "'[t]he entire nation is currently being subjected to a large-scale adulteration of an age-old dietary staple by a poorly characterized and unlabeled biotechnology product which is very different than natural milk.'"[112]

B. Potential Risks for the Environment

According to the WHO study, the "[p]otential risks for the environment include unintended effects on non-target organisms, ecosystems and biodiversity."[113] For insect-resistant GM crops developed from the Bt bacterium, the concerns are "[d]etrimental effects on beneficial insects" or heightened development of resistant insects.[114] "Outcrossing of transgenes has been reported from fields of commercially grown GM plants, including oilseed rape and sugar beet, and has been demonstrated in experimental releases for a number of

106. Julie A. Nordlee et al., *Identification of a Brazil Nut Allergen in Transgenic Soybeans*, 334 New Eng. J. Med. 688 (1996).

107. Marion Nestle, *Allergies to Transgenic Foods: Questions of Policy*, 334 New Eng. J. Med. 726 (1996).

108. "About 25% of Americans have adverse reactions to foods. 8% of children and 2% of adults have food allergies as tested by blood immunoglobins." Some "individuals . . . are so allergic to [the Brazil] nut, they go into apoplectic shock (similar to a severe bee sting reaction), which can cause death." Batalion, *supra* note 101.

109. Several GM food products approved for use in the United States "involve herbicides that are commonly known carcinogens—bromoxynil used on transgenic cotton and Monsanto's Roundup or glufonsinate used on GM soybeans, corn, and canola." In addition, "unexpected gene fragments have shown up in GM soy crops"—and research has shown that "foreign DNA fragments that are not fully digested in the human stomach and intestines" enhance a number of autoimmune diseases. *Id.*

110. *Id.*

111. Press Relase, Cancer Prevention Coalition, New Study Warns of Breast and Colon Cancer Risks from rBGH Milk (Jan. 23, 1996), *available at* http://www.preventcancer.com/press/conference/jan23_96.htm; *see, also*, Samuel Epstein, *Potential Public Health Hazards of Biosynthetic Milk Hormones*, 20 Int'l J. Health Services 73 (1990); National Institutes of Health, Technology Assessment Conference Statement on bovine Somatotropin, 265 JAMA 1423 (1991).

112. Cancer Prevention Coalition, *supra* note 112.

113. WHO Study, *supra* note 9.

114. *Id.*

crops, including rice and maize."[115] Outcrossing can have an impact directly on human health and food safety as well as occur "when traces of a maize type that was only approved for feed use appeared in maize products for human consumption in the United States . . . ."[116]

> StarLink, a variety of corn genetically altered to include a [Cry9C] protein that can protect crops against several insects, was only deemed suitable for animal feed . . . due to concerns that it could cause allergic reactions [in humans]. But StarLink inadvertently entered the world's food supply last year, triggering a massive recall of about 300 corn products.[117]
>
> As a result of the StarLink imports, Japanese imports of U.S. corn declined by 1.3 million metric tons (8 percent in volume terms) in 2001 . . . The Japanese government now requires that unapproved biotechnology food and feed ingredients be segregated from the export channel, [but allows] a 1 percent tolerance for the unintended presence of such unapproved products.[118]

Ultimately, there is a very real danger that the GMO species may crossbreed with non-GMO species, become the dominant species, and thus transform the ecosystem.

Another use of biotechnology in crops that has recently raised concerns about the U.S. food supply involves drug production. A small biotechnology company, Ventria Biosciences, plans to cultivate transgenic rice with human genes that cause the plant "to make two proteins normally found in breast milk, tears, and saliva."[119] These substances would be turned "into therapeutic food products to treat stomach disorders." Using plants with human genes to produce drugs in mass quantities of field plantings is a cheaper method than those employed by a traditional biotech factory.[120] Several other biotech companies are experimenting with drugs grown in plants. A consulting firm predicts the first plant-manufactured drugs will hit the market next year and develop into a $2.2 billion-per-year industry by 2011.[121]

Consumer and environmental advocates fear that pollen from genetically engineered plants could drift into fields containing food crops and produce contaminated hybrids.[122] In addition, there is nothing to prevent a bird from eating the bioengineered seeds and then depositing them intact in a field hundreds of miles away.[123] Margaret Mellon, director of the food and environment program for the Union of Concerned Scientists in Washington, cautions that it is "virtually certain this stuff will make it into food-grade rice."[124] In

115. *Id.*

116. Questions on GM Foods, *supra* note 3, at Q5.

117. Martin A. Lee, *Food Fight: International Protests Mount against Genetically Engineered Crops*, SAN FRANCISCO BAY GUARDIAN, June 25, 2001, *available at* http://www.gefoodalert.org/News/news.cfm?News_ID=2780. "While acknowledging that nearly a half billion bushels of corn in storage nationwide contain StarLink, Aventis denies that it poses a health risk to humans."

118. Stamps, *supra* note 22, at 13-14; *see also* StarLink Information Center, StarLink History, StarLink—What Happened? http://www.starlinkcorn.com/History/What%20Happened.htm (last visited Feb. 3, 2006).

119. Arlene Weintraub, *What's So Scary About Rice? Biotech Crops Can Make Drugs—But They Must Be Kept Out of the Food Chain*, BUSINESSWEEK, Aug. 1, 2005, at 58.

120. "A traditional biotech factory might cost Ventria . . . $125 million," but rice yields "the same output for $4 million." CEO Scott Deeter says "he intends to pass the savings to consumers." *Id.*

121. *Id.*

122. *Id.*

123. *Id.*

124. *Id.*, In an interview Margaret Mellon of the Union of Concerned Scientists further explained, "when you're genetically engineering bioactive molecules—drugs—into crops and they're growing outdoors, you must be able to assure those [engineered traits] don't move to food crops. Otherwise you're imposing health and environmental risks." *Online Extra: The Side Effects of Drugged Crops*, BUSINESSWEEK, July 26, 2005, http://www.businessweek.com/magazine/content/05_31/b3945092mz018.htm.

2002, a drug-producing corn made by ProdiGene Inc. somehow began sprouting in soybean fields near its Nebraska and Iowa sites.[125] The USDA seized 500,000 bushels of soybeans and charged ProdiGene nearly $3 million in fines and disposal costs. Even Anheuser-Busch has opposed the use of biotech crops for drug production, fearing that the Missouri rice plants that are a key ingredient in its beer will be contaminated.[126] In addition to posing risks to the consumer and the environment, the stakes are high for international trade. At risk is some $1.3 billion in annual U.S. rice sales to foreign countries, many of which are wary of biotech crops; if they found drugs in commodity crops, they could buy their agricultural products elsewhere.[127] Unless companies like Ventria and the agencies that regulate them work harder to allay the world's food-safety fears, this biotech method of drug production will not have a healthy future.[128]

The question of the possible impact of GMOs on ecosystems was dramatically illustrated by a study at Cornell University of biotech corn and monarch butterflies.[129] Bt corn contains a gene from the bacterium *Bacillus thuringiensis* that enables it to internally produce a pesticide intended to kill a specific pest. When Cornell University scientists applied pollen from Bt corn to milkweed, a crop that the butterflies eat and that grows near cornfields, 44 percent of the monarch larvae died.[130] None of the monarch larvae in the study that were fed corn pollen from non-engineered plants died. A report from the non-governmental Institute for Energy and Environmental Research (IEER) concluded from this study that "[w]hile the ecological significance of this experiment is not yet clear, it is evident that genetically engineered corn has been introduced on a vast scale without sufficient consideration of its effects on ecosystems."[131] Scientists cautious about biotechnology welcome the IEER assessment. Richard Strohman, a molecular and cell biologist at the University of California at Berkeley, concludes that "[b]iogenetic engineering where unanticipated results could cause damage to individuals or to millions of acres of cropland should cease except under tightly controlled laboratory conditions . . . ."[132]

Some of the major regulatory and scientific agencies in the world believe that GM crops pose a greater threat than those generated by traditional crop breeding approaches.[133] Sci-

125. Weintraub, *supra* note 119, at 58.

126. *Id.* In April 2004, when Anheuser-Busch threatened to boycott all Missouri rice, Ventria shifted its plans; in June 2005, the USDA approved Ventria's application for plants in North Carolina instead.

127. *Id.*; *Online Extra*, *supra* note 124.

128. Weintraub, *supra* note 119, at 58-59; *see also* Carie-Megan Flood, Note, *Pollen Drift and Potential Causes of Action*, 28 J. CORP. L. 473, 477-82 (2003) (for legal liability issues associated with these environmental risks).

129. Arjun Makhijani, *Ecology & Genetics: An Essay on the Nature of Life and the Problem of Genetic Engineering*, ch. 5 (The Apex Press 2001).

130. *Id.*

131. *Id.*; *see also* Danielle Knight, *Environment: New Report Fuels Debate on GMO's*, ENVTL. BULL., June 4, 2001, at 1, 2; Press Release, Institute for Energy and Environmental Research, Ecological Impacts of Genetically Engineered Plants May Be Severe Harm Possibly Greater than From Toxic Chemicals (June 4, 2001), *available at* http://www.ieer.org/comments/genetics/e&g-prl.html [IEER Press Release].

132. IEER Press Release, *supra* note 131.

133. NATIONAL RESEARCH COUNCIL, GENETICALLY MODIFIED PEST-PROTECTED PLANTS: SCIENCE AND REGULATION (National Academy Press 2000); Declan Butler & Tony Reichhardt, *Long-Term Effect of GM Crops Serves Up Food For Thought*, NATURE, Apr. 22, 1999, at 651-56; *see also* John E. Beringer, *Releasing Genetically Modified Organisms: Will any Harm Outweigh any Advantage?*, 37 J. APPLIED ECOLOGY 207 (2000) (arguing that most concerns about environmental harm are more relevant to existing crops, that virtually all changes in agricultural practice have an adverse impact on wildlife, and that identifying the problem as how to manage agriculture to ensure that we maintain or enhance species diversity of wild plants and animals within this context).

entists have identified the following as key issues in the environmental assessment of GM crops: putative in vasiveness; vertical or horizontal gene flow; other ecological impacts; effects on biodiversity; and the impact of the presence of GM material in other products.[134] In making this ecological risk assessment, the baseline reference point has been the impact of plants developed by traditional breeding that in comparison is recognized as "an integral and accepted part of agriculture."[135] Yet others have complained that,

> [i]n particular short-term or laboratory studies identifying possible hazards or impacts often receive widespread media attention but the thorough ecological field-based studies which either evaluate exposure to a hazard or assess fitness over several generations are rarely carried out, or, in the classic case of the impact of Bt maize on the Monarch butterfly, pass almost unnoticed.[136]

In view of the problems of variability, complexity, and uncertainty, it is increasingly important that trained ecologists and other scientists with expertise in developing the necessary predictive tools for risk assessment become involved in the public debate.[137]

A National Academies of Sciences' National Research Council report explains that "[t]he process of genetic engineering has not been shown to be inherently dangerous, but rather, evidence to date shows that any technique, including genetic engineering, carries the potential to result in unintended changes in the composition of the food."[138] The report differentiates between genetic engineering methods[139] and non-genetic engineering methods[140] of modifying plants and animals and presents some possible mechanisms of unintended change for organisms genetically engineered using rDNA techniques. For instance, the sequence of interrupted DNA may be a functional gene, resulting in a loss or gain of whatever function the gene provided. Chromosomal changes may occur depending on where the genes were inserted, and spontaneous mutation may occur. After evaluating the likelihood for an unintended health effect to occur as a result of various methods of genetic modifications, the committee found genetic engineering to present the greatest likelihood of unintended effects on its scale in comparison to non-genetic engineering methods, but noted that other criterion should be used as well to evaluate the risks. The committee reported that targeted, quantitative analysis, which is the traditional approach of determin-

134. Anthony J. Conner et al., *The Release of Genetically Modified Crops into the Environment*, 33 THE PLANT J. 19 (2003); *see also* Stephen Tromans, *Promise, Peril, Precaution: The Environmental Regulation of Genetically Modified Organisms*, 9 IND. J. GLOBAL LEGAL STUD. 187 (2001).

135. Connor et al., *supra* note 134.

136. Alan J. Gray, *Ecology and Government Policies: The GM Crop Debate*, 41 J. APPLIED ECOLOGY 1 (2004).

137. *Id. See generally* Margaret Rosso Grossman, *Biotechnology, Property Rights and the Environment*, 50 AM. J. COMP. L. 215, 217-23 (Supp. 2002) (outlining the risks and benefits associated with GM foods).

138. NRC SAFETY, *supra* note 1, at 1.

139. Two GE methods (targeted) were described: microbial vectors, a method which takes advantage of a microbe's ability to transfer and stably integrate segments of DNA into a plant so that the plant expresses those traits, and electroporation. In the latter process, plant cells growing in culture are stripped of their protective walls and electric shock is used to destabilize the cell membrane and allow the introduced DNA to enter the cell. *Id.*

140. Non-GE methods (non-targeted) include: simple selection, in which plants with desired traits are selected for continuous propagation; crossing, brushing pollen from one plant onto a sexually compatible plant to produce a hybrid with genes from both parents; embryo rescue, placing a plant that has naturally cross-pollinated into a tissue culture environment to enable its full development; and mutagen breeding, exposing plants or seeds to mutagenic agents (e.g., ionizing radiation) or chemicals to induce random change in the DNA sequence and assess the new plants for valuable traits. *Id.*

ing the presence or amount of compounds produced, has become much more sophisticated in detecting small molecules, but that more improvements are still needed.[141]

The National Research Council report proposed a new framework that could be used to examine, identify, and evaluate systematically the unintended compositional changes and health affects of all altered foods, including genetically engineered foods.[142] Noting that the current safety assessments only apply to genetically engineered goods before they are put on the market with a focus on identifying any significant differences in physical characteristics of the plant, the report proposed post-market surveillance to identify and monitor unanticipated compositional changes and health effects of all altered foods. The report recommended implementing a safety assessment prior to and after commercialization, involving federal agencies in the determination, using standardized sampling methodologies, and improving tracing and tracking methods when warranted. Most significantly, the report called for additional research such as developing new tools for detecting health changes in the population that could result from genetic alteration and for assessing potential unintended adverse effects.[143]

V. A Model of Caution: Labeling and Monitoring

Despite the benefits of biotechnology identified at the outset, the safety issues from unintended and unknown risks and scientific uncertainty necessitate a more effective approach to risk assessment in the United States. Without transparent information as to the presence of GM products in food, informed choice cannot be attained. The lack of information also impedes the development of biotechnology in the long run. A report by the Atlantic Council of the United States found that "[c]onsumer confidence is the most important determinant of any future market [in] . . . biotechnology."[144] The Council concluded that a credible scientific risk assessment process is essential, and that some form of labeling and traceability may be useful in providing consumers with a choice.[145]

When it comes to GMOs, the most frequent attitude is the demand for choice and for information. According to recent polls, 94.6 percent of Europeans want the right to choose whether or not they eat food that has been genetically modified.[146] Other studies in Japan and Europe indicated a decline of confidence in the biotechnology product.[147] Bioengineered food will face increasing resistance from consumers worldwide until transparent and reliable information, as well as evidence of the potential risks, can be provided.[148]

A similar survey in the United States showed that almost two-thirds of the respondents were very concerned or somewhat concerned about the food safety problem of GM prod-

141. *Id.* at 2.

142. *Id.*

143. *Id.* at 3.

144. DAVID AARON et al., *Risk and Reward: U.S.-EU Regulatory Cooperation on Food Safety and the Environment* (Nov. 2002).

145. *Id.*

146. EUROPEAN COMMISSION RESEARCH DIRECTORATE-GENERAL, EUROPEANS, SCIENCE AND TECHNOLOGY (Dec. 2001), *available at* http://europa.eu.int/comm/public_opinion/archives/eb/ebs_154_en.pdf.

147. Pan, *supra* note 4, at 232 (citing D. Dickson, *Public Attitudes to Biotechnology: Where are They Heading?*, Paper presented at the New Biotechnology Foods and Crops: Science Safety and Society Bangkok Conference, July 10-12, 2001).

148. *Id.*

ucts.[149] Among the U.S. consumers recently surveyed, there appears to be little awareness concerning the genetic modification of agricultural and food products.[150] Even so, over 75 percent of Americans stated that the potential danger from genetic modification is so great that strict regulations are necessary; yet 63 percent believed that the government did not have the tools to regulate GMOs properly,[151] Nine out of ten Americans said that GM foods should be labeled as such, although only about half said they would actually take time to look for foods labeled as not being genetically modified.[152] In another poll, 93 percent of Americans agreed that the federal government should require labels indicating whether the food has been genetically modified, or bioengineered. "'Such near unanimity in public opinion is rare.'"[153] Even among American farmers, "90 [percent] . . . support labels on biotech products if they are scientifically different from conventional foods and 61 [percent] support labels on biotech products even if not scientifically different."[154] This increased attention from the public is forcing legislators to examine current policies.

Industry has begun to respond as well to the perceived risk of biotechnology in food. Large food producers, fearful of losing buyers, have underscored their acceptance of consumer demands for labeling and have asked suppliers to segregate fields, grain bins, and storage elevators, with some even paying a premium for non-GM crops.[155] For instance, in response to consumer worries, Frito-Lay made headlines when it told its suppliers not to use genetically altered corn.[156] Also, Farmers have expressed concern that markets for unmodified grain could be threatened because crops such as maize and canola risk contamination by cross-fertilization with wind-borne pollen.[157]

Countries that have introduced mandatory-labeling legislation for GM foods have done so to give their consumers a choice in selecting the foods according to their comfort level.[158] Realizing the potential of agricultural biotechnology will require activist policy reform rather than a laissez-faire approach. It has been suggested that countries tailor their regulations so as to minimize harm to trade while also responding to consumer concerns.[159] "[L]abeling is a 'market based' alternative [that] requires no new regulatory

149. *Id.*

150. William K. Hallman et al., *Public Perceptions of Genetically Modified Foods: Americans Know Not What They Eat* (Mar. 15, 2002), *available at* http://www.foodpolicyinstitute.org/docs/reports/Public%20Perceptions%20of%20Geneti cally%20Modified%20Foods.pdf.

151. *Id.*

152. *Id.*

153. The GE Food Alert Campaign Center, American Public Opinion Polls on GE Foods, http://www.gefoodalert.org/News/news.cfm?News_ID=3151 (last updated Feb. 1, 2002) (citing an ABCNews.com poll, June 2001).

154. *Id.* (citing Farm Foundation/Kansas State University, Survey of Farms Throughout the United States, Sept. 2001).

155. Haslberger, *supra* note 17.

156. Associated Press, *No Genetically Altered corn, Frito-Lay Tells Suppliers*, THE SACRAMENTO BEE, Feb. 1, 2000, *available at* http://www.biotech-info.net/frito_layl.html (Frito-Lay accounts for two-thirds of PepsiCo sales).

157. Sally Lehrman, *GM Backlash Leaves US Farmers Wondering How to Sell Their Crops*, 401 NATURE, Sept. 9, 1999, at 107 (1999).

158. INTERNATIONAL LIFE SCIENCES INSTITUTE, DETECTION METHODS FOR NOVEL FOODS DERIVED FROM GENETICALLY MODIFIED ORGANISMS (Kevin Yates, ed. 1999) (a summary of a workshop held in June 1998).

159. *See* David G. Victor & C. Ford Runge, *Farming the Genetic Frontier*, 81 FOREIGN AFF. 107 (2002).

authority, or trade restrictions, apart from a mechanism to insure that the labels are accurate."[160]

The cost of this labeling may be less than previously thought. According to William Jaeger, an agricultural economist at Oregon State University, the evidence suggests that mandatory GM labeling need not be highly costly to consumers and government.[161] An analysis of other countries that label GM foods revealed that total annual costs range from twenty-three cents per person to about ten dollars per person, depending on the level and complexity of the labeling.[162] Moreover, the actual cost may be lower to the extent that product segregation, identity preservation, and labeling are already becoming routine for exporters to foreign markets where GM labeling is required.[163] In addition, there may be reduced costs in the form of a significantly diminished risk of liability from lawsuits, at least with respect to potential claims for injuries that may occur due to a failure to warn.[164]

Mandatory labeling of GMOs generally does incur a higher cost than voluntary labeling because the entire market must be segregated and labeled even though only a subset of producers or consumers care about the attribute. A government's choice about whether to require labeling is based in part on what proportion of their citizens want information about the technology.[165] As demonstrated in the surveys above, the U.S. consumer has now reached the point where such information is desired by a vast majority of the citizens and demanded by a vocal portion of these consumers and farmers.[166] The U.S. government should be responsive to its citizenry and restore consumer confidence in the food supply—both domestic and abroad—by requiring the disclosure of this critical feature.

160. C. Ford Runge & Lee Ann Jackson, *Labeling, Trade and Genetically Modified Organisms (GMOs): A Proposed Solution* (Working Paper WP99-4 Nov. 1999), http://www.gefoodalert.org/library/admin/uploaded files/Labeling_Trade_and_Genetically_Modified_Organi.htm [hereinafter Runge & Lee, *Labeling, Trade, and Genetically Modified Organisms*]; *see also* C. Ford Runge & Lee Ann Jackson, *Negative Labeling of Genetically Modified Organisms (GMOs): The Experience of rBST*, 3 AGBIOFORUM 58, 58-62 (2000).

161. Press Release, Oregon State University, OSU Economist Estimates Cost of GM Food Labels (Oct. 23, 2000), *available at* http://www.biotech-info.net/label_cost.html [hereinafter OSU Estimates]. The entire text of Jaeger's study (an analysis of five alternative options for GM labeling that range in cost and complexity) is *available at* http://eesc.orst.edu/agcomwebfile/edmat/html/em/em8817/em8817.html.

162. "These cost estimates range from 23 cents a year for each consumer for labeling only those products made directly from genetically modified foods, to $3.89 for labeling of products in which genetically modified substances were used during production or processing." The GM labeling options under consideration in the United Kingdom, New Zealand, and Australia, are estimated at $3–$10 a year for each person. OSU Estimates, *supra* note 161.

163. *Id.* As of that date, twenty-two nations, including Great Britain, France, Australia, Japan, South Korea, and Mexico, in addition to the European Union, had passed regulations that require GM food labeling. Since some U.S. food producers and exporters already separate genetically modified foods from the rest to comply with GM labeling requirements in effect in these nations, the incremental cost would be less.

164. For a general discussion of liability issues, *see* Tana N. Vollendorf, Comment, *Genetically Modified Organisms: Someone is in the Kitchen with DNA—Who is Responsible When Someone Gets Burned?*, 21 MISS. C.L. REV. 43 (2001); A. Bryan Endres, *"GMO:" Genetically Modified Organism or Gigantic Monetary Obligation? The Liability Schemes for GMO Damages in the United States and the European Union*, 22 LOY. L.A. INT'L & COMP. L. REV. 453 (2000).

165. Julie A. Caswell, *Should Use of Genetically Modified Organisms Be Labeled?* 1 AGBIOFORUM 22, 24 (1998) (outlining the policy options for governments associated with the types of voluntary and mandatory labeling and their impact on the development of markets for foods produced with GMOs).

166. *See, e.g.*, Luke Brussel, *Engineering a Solution to Market Failure: A Disclosure Regime for Genetically Modified Organisms*, 34 CUMB. L. REV. 427 (2003-04).

Such labeling could either be positive labels stating that "This product may contain GMOs"; or negative labels stating that "This product (or seed) contains no GMOs."[167] In the past, for companies wanting to advertise products as non-GM, the FDA has indicated that it would not allow labels like "GM-free," "GMO-Free" or "biotech-free." The agency stated that "guaranteeing a product to be free of GM material is virtually impossible," but that the labels could say the food was not produced through bioengineering.[168] The determination of the precise form of the labeling should be left to the proper authority of the U.S. government, whether it is the U.S. Congress or an appropriate federal agency, most likely the FDA. In determining the requisite labeling, the U.S. government should study the effectiveness in notification of the consumer, the potential impact on industry, and take into account international standards for uniformity (such as the OECD effort discussed above) in order to facilitate international trade. As they adapt to changes in the regulatory climate, food companies will need to devise marketing strategies that work with labeling policies in promoting the safety and desirability of their products.[169]

In addition to labeling, GM products should be subject to a rigorous system of pre- and post-market monitoring. Testing does involve additional costs for the industry, but such testing, which the FDA requires pre-market in other areas,[170] is necessary to protect the public. Once monitoring is mandated in the United States, science will provide appropriate means to detect and track GM foods and their components. In response to EU regulations, scientists have attempted to develop and analyze reliable and sensitive methods for GMO detection.[171] Several of these methods pose limits, and the efficiency of screening, identification, and confirmation strategies should be examined with respect to false-positive rates and disappearance of marker genes, for example, because heating and other processes in food production can degrade DNA.[172] As scientific research on the long-term human health and environmental effects of bioengineered food progresses, the post-market monitoring of products containing GMOs will be critical in tracing and, if necessary, withdrawing such products from the market and food chain.

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167. Runge & Lee, *Labeling, Trade, and Genetically Modified Organisms*, *supra* note 160 (advocating negative labels for GM foods). No judgment as to the specific type of labels will be made here as the issue of the necessity for labeling must first be resolved.

168. The Non-GMO Report, *FDA's New Regulations Won't Allow Non-GMO, GMO-Free Label*, http://www.non-gmosource.com/FDA_disallows_GMO-free_label.php(last visited Feb. 3, 2006).

169. Caswell, *supra* note 165, at 24.

170. *See, e.g.*, Debra M. Strauss, *Reaffirming the Delaney Anticancer Clause: The Legal and Policy Implications of an Administratively Created De Minimis Exception*, 42 FOOD DRUG COSM. L.J. 393 (1987) (analyzing the Delaney Clause of the Food, Drug, and Cosmetic Act, which prohibits the use of carcinogenic food and color additives in the food supply).

> An additive determined to be "safe" will be approved for the proposed use, provided that "no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal."

Id. at 393 (citing 21 U.S.C. § 348(c)(3)(A) (2005)).

171. *See, e.g.*, Ahmed, *supra* note 15 (discussing methods for GMO detection, including "protein- and DNA-based methods employing western blots, enzyme-linked immunosorbant assay, lateral flow strips, Southern blots, qualitative-, quantitative-, real-time- and limiting dilution-PCR methods;" and new approaches such as near-infrared spectrometry); Pan, *supra* note 4, at 232.

172. Ahmed, *supra* note 15 (proposing a tiered approach combining several methods of detection to counteract these limitations); Pan, *supra* note 4, at 230.

"One key trade concern for U.S. producers is the fact that U.S. farm, grain storage, and transportation systems are not designed to segregate bulk, untagged, biotechnology agricultural products, on a large scale and with precision, from conventional varieties."[173] These changes in the storage and transportation structure would place added costs on the U.S. farm sector. In addition, the U.S. government "'does not have the authority to force farmers to market their crop in one channel or another. Therefore, the U.S. [g]overnment [cannot] certify that certain varieties are completely absent from export channels.'"[174] But if this is true in view of the dangers of unintended cross-contamination—that biotechnology crops will crossbreed with other plants resulting in unintended harmful breeds—the consequences for biodiversity are far more severe than a simple economic inconvenience from labeling. If these variant plants cannot be effectively monitored, a more extreme remedy such as a moratorium or ban may be warranted.

VI. Conclusion

The United States should adopt labeling requirements modeled after international law, choosing the cautious approach to the use of GMOs in food in view of the unknown scientific effects and several negative case examples thus far. When faced with scientific uncertainty, it becomes a matter of risk assessment—determining who should bear the risk, and identifying and quantifying those risks through responsible and appropriate scientific assessments.[175] Public safety and health considerations should be paramount. Moreover, it is important to recognize that, inasmuch as these issues reflect cultural differences in levels of risk aversion with respect to food and food products, they involve international trade policy and economic concerns beyond matters of science.[176]

Adopting a comprehensive system of pre- and post-market monitoring and appropriate labeling would help consumers by increasing the likelihood of informed decision-making, industry by increasing the confidence of consumers, and environmentalists by developing safety provisions without the need for moratoriums. In addition, by establishing standards more consistent with the international scientific community for risk assessment, industry may benefit from more streamlined and timely approval for marketing in the United States with fewer obstacles from abroad.[177] As a matter of international trade, it is important for

173. Stamps, *supra* note 22, at 7.

174. *Id.* (quoting U.S. Department of State, Fact Sheet, Frequently Asked Questions About Biotechnology (Jan. 22, 2001), http://www.state.gov/e/eb/rls/fs/1142pf.htm).

175. *See* VED P. NANDA & GEORGE PRING, INTERNATIONAL ENVIRONMENTAL LAW & POLICY FOR THE 21ST CENTURY (Transnational Publisher 2003) (assessing role of risk analysis); *see also* Lakshman D. Guruswamy, 16 COLO. J. INT'L ENVTL. L. & POL'Y 229 (2005) (reviewing VED P. NANDA & GEORGE PRING, INTERNATIONAL ENVIRONMENTAL LAW & POLICY FOR THE 21ST CENTURY (Transnational Publisher 2003).

176. *See generally* Diane E. Hoffmann & Lawrence Sung, *Future Public Policy and Ethical Issues Facing the Agricultural and Microbial Genomics Sectors of the Biotechnology Industry*, 24 BIOTECH. L. REP. 10 (2005); David Pimentel, *Overview of the Use of Genetically Modified Organisms and Pesticides in Agriculture*, 9 IND. J. GLOBAL LEGAL STUD. 51 (2001); Jeffrey Curtiss, *New Challenges in Regulating Agriculture: Genetically Modified Organisms*, UCLA J.L. & TECH. NOTES 8 (2003); Sophia Kolehmainen, *Genetically Engineered Agriculture: Precaution before Profits: An Overview of Issues in Genetically Engineered Food and Crops*, 20 VA. ENVTL. L.J. 267, 269-72 (2001).

177. *See* Dorothy Nelkin et al., *Foreword, The International Challenge of Genetically Modified Organism Regulation*, 8 N.Y.U. ENVTL. L.J. 523 (2000); Marc Victor, Comment, *Precaution or Protectionism? The Precautionary Principle, Genetically Modified Organisms, and Allowing Unfounded Fear to Undermine Free Trade*, 14 TRANSNAT'L LAW. 295 (2001).

the biotech "industry in the United States to accept the challenge of developing and regulating products that take into account regional diverse needs and concerns of consumers and specificities of the environment."[178]

In fact, only by addressing environmental concerns and consumer demands with U.S. regulations to improve risk management will it be possible for the industry to introduce GMOs into worldwide markets without significant opposition.[179] If neither the U.S. government nor the industry moves forward to address these risks in a meaningful way, increased public awareness and pressure from abroad may spark a backlash that further impedes international trade and may eventually necessitate a ban of GMOs in the U.S. food supply. Thus, the best future for the biotechnology industry, as well as consumers, would be the safest one.

178. Haslberger, *supra* note 17.

179. John S. Applegate, *The Prometheus Principle: Using the Precautionary Principle to Harmonize the Regulation of Genetically Modified Organisms*, 9 IND. J. GLOBAL LEGAL STUD. 207, 207-09 (2001).