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# FOOD AND DRUG LAW JOURNAL

*Analyzing the Laws, Regulations, and Policies  
Affecting FDA-Regulated Products*

## The International Regulation of Genetically Modified Organisms: Importing Caution Into the U.S. Food Supply

*Debra M. Strauss*

# The International Regulation of Genetically Modified Organisms: Importing Caution Into the U.S. Food Supply

DEBRA M. STRAUSS\*

## I. INTRODUCTION

Biotechnology is big business.<sup>1</sup> As such, the use of biotechnology to engineer plants, and the regulation of the resulting food crops, involves economic and trade issues, as well as science and health issues.<sup>2</sup>

Through modern biotechnology, selected individual genes are transferred from one organism into another, sometimes between nonrelated species, using recombinant DNA (rDNA) methods.<sup>3</sup> The genetically modified organisms (GMOs) that are created as GM plants then produce GM foods.<sup>4</sup> The first GM crop—the GM tomato—was sold in the market in 1994,<sup>5</sup> and genetically modified products have been commercially available in the United States since 1995.<sup>6</sup> Genes derived from a bacterium in the soil, *Bacillus thuringiensis* (Bt), have been inserted into crops to promote resistance to certain insects, producing Bt-corn, Bt-cotton, Bt-potato, Bt-rice, and Bt-tomato. Glyphosate-tolerant soybeans (e.g., Roundup Ready® by Monsanto) contain a gene that protects them from the herbicide glyphosate so that the fields can be sprayed with the herbicide, thus killing the weeds while leaving the soybeans standing. Herbicide-resistant varieties of canola, cotton, corn, radicchio, rice, and sugar beet also are on the market. The United States has approved virus-resistant varieties of papaya, potato, and squash, along with tomato

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<sup>1</sup> Biotechnology is one of the fastest-growing sectors of the U.S. economy. The interests of global business are substantial as well—71% of all agrobiotechnology patents are owned by the top five companies in the area: Pharmacia (now owned by Pfizer Inc.) (21%, 287 patents), DuPont (20%, 279 patents), Syngenta (13%, 173 patents), Dow (11%, 157 patents), and Aventis (6%, 77 patents). Tzu-Ming Pan, *Current Status and Detection of Genetically Modified Organism*, 10 J. FOOD & DRUG ANALYSIS 229, 230 (2002) (citing ETC Group, Globalization Inc. Communique #71 (2001)).

<sup>2</sup> For background on this issue, including additional statistics, see Debra M. Strauss, *Genetically Modified Organisms in Food: A Model of Labeling and Monitoring With Positive Implications for International Trade*, 40 INT'L LAW. 95 (2006). Some of the points that will be discussed here expand upon points that were raised in this article.

<sup>3</sup> BINAS Online, Facts on GMOs in the EU, <http://binas.unido.org/binas/regs.php> (last visited Mar. 16, 2006) [hereinafter Facts on GMOs in the EU]; NATIONAL RESEARCH COUNCIL, SAFETY OF GENETICALLY ENGINEERED FOODS: APPROACHES TO ASSESSING UNINTENDED HEALTH EFFECTS (July 2004) [hereinafter NRC SAFETY], available at [http://www.nap.edu/html/ge\\_foods/ge-foods-reportbrief.pdf](http://www.nap.edu/html/ge_foods/ge-foods-reportbrief.pdf) (“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.”).

<sup>4</sup> World Health Organization (WHO), Food Safety, 20 Questions on Genetically Modified (GM) Foods, <http://www.who.int/foodsafety/publications/biotech/20questions/en/index.html> (last visited May 11, 2006) [hereinafter WHO, Questions on GM Foods].

<sup>5</sup> Pan, *supra* note 1, at 230 (citing ISAA ANNUAL REPORT 2002).

<sup>6</sup> In 1990, FDA approved the first biotechnology food product for the U.S. market—chymosin, a food-processing enzyme produced by GM 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 ADMINISTRATION (FDA), SAFETY ASSURANCE OF FOODS DERIVED BY MODERN BIOTECHNOLOGY IN THE UNITED STATES (July 1996), available at <http://www.cfsan.fda.gov/~lrd/biojap96.html>.

and cantaloupe, which contain a gene that slows the ripening process to allow fruit to ripen longer on the vine.<sup>7</sup>

Worldwide, GMOs have grown exponentially; the total area of biotech crops increased thirty times between 1996 and 2001. As global plantings of biotech crops grew to about 200 million acres in 2004, about two-thirds of the plantings took place in the United States.<sup>8</sup> More than 40% of the corn, more than 50% of the cotton, and more than 80% of soybean acres planted in the United States have been genetically modified. As a conservative estimate, at least 70% of food products in U.S. supermarkets—boxed cereals, other grain products, frozen dinners, cooking oils, and more—contain GMOs.<sup>9</sup> The Grocery Manufacturers of America (GMA) estimates that 75% of all processed foods in the United States contain a GM ingredient, including almost every product with a corn or soy ingredient and some containing canola or cottonseed oil.<sup>10</sup>

Yet, obstacles from abroad have closed the international market not only for foods genetically engineered in the United States, but also for a significant portion of all U.S. produce.<sup>11</sup> This ban has occurred in part because, unlike the European community, the United States does not segregate, label, or treat GM foods differently from traditional foods. The divergent approaches to the regulation of GM foods—ranging from pre-market approval requirements, bans, and strict monitoring to voluntary guidelines for the industry—originate from differences in the attitudes towards GM foods between the United States and the international community.<sup>12</sup> In the international community, heated debates have focused on the public health, safety, and environmental issues of introduced genes, particularly, allergenicity, antibiotic resistance, gastrointestinal problems, potential gene flow to other organisms, and destruction of biodiversity.<sup>13</sup> Most significant is the way U.S. and foreign regulators have reacted to these concerns, reflecting conflicting perceptions and views of the potential risks involved with GMOs and how to manage these risks.

As GMOs become an increasingly dominant part of the U.S. food supply, it is important to explore the basis for these concerns and the disparity in the regulatory responses to this technology. Part II of this article analyzes the science of GMOs, particularly the potential risks and level of uncertainty. Part III examines the rigorous regulatory scheme set forth by the international community in response to this scientific uncertainty. Part IV discusses the relatively unrestrictive approach of the United States towards GM foods, which contrasts markedly with the view overseas. Part V establishes the foundation for a new regulatory approach in the United States, while considering the increased costs, based on increased consumer demand and the need for transparency to make choice possible. Accordingly, this article sets forth an expanded model for the United States

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<sup>7</sup> FDA, List of Completed Consultations on Bioengineered Foods (Nov. 2005), <http://www.cfsan.fda.gov/~lrd/biocon.html>; see also Monsanto, Products and Solutions, Setting the Standard in the Field, <http://www.monsanto.com/monsanto/layout/products/default.asp> (last visited May 11, 2006) (bringing to market second generation of biotechnological traits, e.g., soybeans that can reduce the amount of trans fat in processed foods).

<sup>8</sup> Associated Press, *Americans Clueless About Gene-Altered Foods* (Mar. 24, 2005) [hereinafter *Americans Clueless*], available at <http://pewagbiotech.org/newsroom/summaries/display.php3?NewsID=857> (statement of Stephanie Childs, Grocery Manufacturers of America).

<sup>9</sup> *Id.*; see also Roger N. Beachy, *Facing Fear of Biotechnology*, 285 Sci. 335 (1999), available at [www.biotech-info.net/facing\\_fear.html](http://www.biotech-info.net/facing_fear.html).

<sup>10</sup> *Americans Clueless*, *supra* note 8.

<sup>11</sup> For a discussion of the EU moratorium and the efforts of the United States to challenge the ban in the WTO, see *infra* notes 104-06, 161-63 and accompanying text.

<sup>12</sup> Pan, *supra* note 1, at 232; see also Farid E. Ahmed, *Detection of Genetically Modified Organisms in Food*, 20 TRENDS BIOTECHNOLOGY 215 (2002).

<sup>13</sup> Ahmed, *supra* note 12, at 215.

of mandatory labeling and pre- and postmarket monitoring, including the development of more sophisticated testing and tracking of GM food components. Part VI concludes that, in light of scientific uncertainty and risks of unintended adverse effects, a more cautious approach akin to the international scheme should be adopted in the United States. By fulfilling its responsibility to respond appropriately to the concerns of its citizens, the U.S. government actually would be aiding the viability of GM development in the long run—thereby facilitating industry efforts to gain acceptance, building consumer confidence in the food supply, and opening additional markets to their products. More stringent monitoring and labeling of GMOs in the food supply is critical for the biotechnology and food industries, as well as consumers, particularly in the area of international trade. Only by implementing standards of accountability and regulations comparable to the international community can the United States truly achieve its goal of opening the global marketplace to U.S. agricultural products.

## II. THE SCIENCE: RISKS AND UNCERTAINTY

Any fair examination of biotechnology in agriculture should acknowledge the potential benefits of genetically engineered foods. A study commissioned by the World Health Organization (WHO) cited several benefits of this food technology, including the potential for increased agricultural productivity and improved nutritional values, along with “reduced agricultural chemical usage and enhanced farm income, and improved crop sustainability and food security, particularly in developing countries.”<sup>14</sup> Proponents point to the goals of reducing hunger by increasing food productivity; conserving the environment by reducing pesticide and herbicide use; enhancing nutritional content; and improving food quality.<sup>15</sup> Many would argue, however, that the opportunity to direct biotechnology to meet these lofty goals has been squandered (e.g., on the development of herbicide resistant plants engineered to survive the spraying of these pesticides or “terminator” seeds that cannot reproduce, forcing these impoverished developing countries to buy additional seeds from the manufacturer). Moreover, these largely unrealized benefits in fact may be outweighed by the potential of new dangers to human health and the environment.

The WHO study identified several risks presented by GMOs and GM foods for human health as part of its safety assessment, including: direct health effects (toxicity), tendencies to provoke allergic reaction (allergenicity), specific components with toxic properties, the stability of the inserted gene, nutritional impact, and any unintended effects that could result from genetic modification.<sup>16</sup> Of particular concern is gene transfer, whereby genes from bioengineered foods could transfer to bacteria in the gastrointestinal tract or to cells of the body and cause negative health effects.<sup>17</sup> For example, if the antibiotic-resistant marker genes that typically are inserted with GM material to facilitate identification of GM cells were transferred, a person could become resistant

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<sup>14</sup> WORLD HEALTH ORGANIZATION (WHO), MODERN FOOD BIOTECHNOLOGY, HUMAN HEALTH AND DEVELOPMENT: AN EVIDENCE-BASED STUDY, at iii (June 24, 2005) [hereinafter WHO STUDY], available at [http://www.who.int/foodsafety/publications/biotech/biotech\\_en.pdf](http://www.who.int/foodsafety/publications/biotech/biotech_en.pdf); 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).

<sup>15</sup> Pan, *supra* note 1, at 230.

<sup>16</sup> See WHO STUDY, *supra* note 14.

<sup>17</sup> WHO, Questions on GM Foods, *supra* note 4.

to antibiotic medicines. Consequently, WHO cautions against using antibiotic-resistant genes in the GM process.<sup>18</sup>

In addition to human health risks, GM foods pose potential risks for the environment, named in the WHO study as: “unintended effects on non-target organisms, ecosystems, and biodiversity.”<sup>19</sup> The Bt bacterium used to produce insect-resistant GM crops may cause harmful effects on beneficial insects or development of resistant insects.<sup>20</sup> Another concern is the spread of transgenes in the natural environment; the WHO study reports that such outcrossing occurred in “fields of commercially grown GM plants, including oilseed rape and sugar beet, and has been demonstrated in experimental releases for a number of crops, including rice and maize.”<sup>21</sup> Ultimately, there is a fear that through cross-pollination GMOs may become the dominant species and irreversibly alter the ecosystem.<sup>22</sup>

Despite these identified risks, GM crops continue to be developed and GM food continues to be consumed by a public largely unaware of the potential hazards.<sup>23</sup> Few long-term scientific studies have been completed.<sup>24</sup> Arpad Pusztai, a scientist who has reviewed the research and advocates additional studies on the human health effects of GM food, 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 their composition varies according to differences in growth and agronomic conditions.”<sup>25</sup> In the few animal studies that have been done, some of the initial findings have been troubling, including the following results: when fed GM tomatoes, some rats died within a few weeks; after eating GM soybeans, rats had inadequate weight gain; rats that had ingested GM corn had a decreased digestive ability; toxins were present in mice that had eaten GM potatoes; the toxin level of GM cotton was deemed “unpredictable”; and GM soybeans contained increased allergens.<sup>26</sup> These studies have prompted some scientists to recommend “more and better testing methods before making GM foods available for human consumption.”<sup>27</sup>

<sup>18</sup> *Id.* (FAO/WHO expert panel recommendations). 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*, GUARDIAN, Aug. 2002, available at [http://www.non-gmosource.com/disadvantages\\_GM\\_food\\_health.php](http://www.non-gmosource.com/disadvantages_GM_food_health.php); see also THE ROYAL SOCIETY, GENETICALLY MODIFIED PLANTS FOR FOOD USE AND HUMAN HEALTH—AN UPDATE (Feb. 2002), available at <http://www.royalsoc.org.uk/displaypagedoc.asp?id=11319>.

<sup>19</sup> WHO STUDY, *supra* note 14.

<sup>20</sup> *Id.*

<sup>21</sup> *Id.*

<sup>22</sup> See, e.g., Pan, *supra* note 1, at 231; Nathan Batalion, *50 Harmful Effects of Genetically Modified Food* (2000), <http://www.cqs.com/50harm.htm>.

<sup>23</sup> Arpad Pusztai, *Genetically Modified Foods: Are They a Risk to Human/Animal Health?* (June 2001), <http://www.actionbioscience.org/biotech/pusztai.html> (noting that safety test technology is inadequate to assess potential harm, that GM foods can carry unpredictable toxins, and that GMOs may increase the risk of allergenic reactions).

<sup>24</sup> DONNA U. VOGT & MICKEY PARISH, FOOD BIOTECHNOLOGY IN THE UNITED STATES: SCIENCE, REGULATION, AND ISSUES (CRS Rep. RL30198) (Jan. 19, 2001) [hereinafter CRS REPORT], available at <http://ncseonline.org/NLE/CRSreports/science/st-41.pdf>.

<sup>25</sup> *Id.* (citing Jose L. Domingo, *Health Risks of Genetically Modified Foods: Many Opinions But Few Data*, 288 SCI. 1748 (2000)).

<sup>26</sup> Pusztai, *supra* note 23; see also Batalion, *supra* note 22. But see ROYAL SOCIETY UPDATE, *supra* note 18 (“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)).

<sup>27</sup> Pusztai, *supra* note 23. For a related examination of the health issues, see, for example, MARIE-CLAIRE CORDONIER SEGGER & ASHFAQ KHALFAN, SUSTAINABLE DEVELOPMENT LAW: PRINCIPLES, PRACTICES, AND PROSPECTS (Oxford Univ. 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,

Some of the potential hazards of bioengineered foods already have been revealed in several cases. One of the first GM products brought to market—a genetically altered version of the dietary supplement L-tryptophan—illustrated the risks of toxicity to humans. When Showa Denko, Japan's third largest chemical company, introduced the GM version of L-tryptophan into the United States in the late 1980s, at least 1500 people were permanently disabled and thirty-seven died from neurological problems connected with eosinophilia-myalgia syndrome. It took months before the doctors who treated the syndrome noticed the link to patients taking tryptophan produced by Showa Denko, which contained a toxic contaminant determined to be a byproduct of the increased tryptophan production of the genetically engineered bacteria.<sup>28</sup> If the supplement had been labeled as genetically engineered, the source of the problem might have been discovered sooner and the product removed from the market more promptly.<sup>29</sup>

Allergies also are a significant concern with GM food, especially if these ingredients are not labeled, but “there are no reliable ways to test GM foods for allergies.”<sup>30</sup> When Pioneer Hi-Bred spliced Brazil nut genes into a soybean to improve its protein content, the altered soybean provoked severe allergic attacks in eight individuals sensitive to Brazil nuts but not soybeans.<sup>31</sup> Fortunately, due to unique circumstances, including awareness that this type of nut could be a serious allergen and serum samples from persons allergic to the donor species were available for testing, the testing was done premarket and the company withdrew the product.<sup>32</sup> This case illustrates the dangers of the absence of labeling; without a label alerting consumers that a soybean could contain genes from a highly allergic nut, even individuals aware of their severe allergies would have no warning.<sup>33</sup>

There have been suggestions that certain ingredients in GM foods may even be linked to cancer.<sup>34</sup> In 1994, the Food and Drug Administration (FDA) approved Monsanto's recombinant Bovine Growth Hormone (rBGH), also known as, bovine somatotropin

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AND PROSPECTS (Oxford Univ. 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. INT'L 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).

<sup>28</sup> Arthur N. Mayeno & Gerald J. Gleich, *Eosinophilia Myalgia Syndrome and Tryptophan Production: A Cautionary Tale*, 12 TRENDS BIOTECHNOLOGY 346 (1994).

<sup>29</sup> Batalion, *supra* note 22 (citing Arthur N. Mayeno & Gerald J. Gleich, *Eosinophilia Myalgia Syndrome and Tryptophan Production: A Cautionary Tale*, 12 TRENDS BIOTECHNOLOGY, 346 (1994)); *see also* Jean Hal-loran & Michael Hansen, *Why We Need Labeling of Genetically Engineered Food*, 18 SYNTHESIS/REGENERATION (1999), available at <http://www.consumersunion.org/food/whywenny798.htm> (detailing potential allergic, toxic, and antibiotic resistance effects of genetically altered food).

<sup>30</sup> Puzstai, *supra* note 23.

<sup>31</sup> Julie A. Nordlee et al., *Identification of a Brazil Nut Allergen in Transgenic Soybeans*, 334 NEW ENG. J. MED. 688 (1996).

<sup>32</sup> Marion Nestle, *Allergies to Transgenic Foods: Questions of Policy*, 334 NEW ENG. J. MED. 726 (1996).

<sup>33</sup> “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 22. Because the typical focus is on “food with genes transferred from the 8 to 10 most commonly allergenic foods, public-interest groups have cautioned that existing rules inadequately protect people against lesser-known transgenic allergens to which they might be sensitive.” Nestle, *supra* note 32.

<sup>34</sup> 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 glufosinate 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. Batalion, *supra* note 22.

(BST), a genetically produced growth hormone, for injection into dairy cows, disregarding warnings from scientists of the resulting increase of IGF-1, a potent chemical hormone with evidence indicating 400% to 500% higher risks of human breast, prostate, and colon cancer.<sup>35</sup> 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 cows and humans—particularly children—that has been linked to cancer.<sup>36</sup> Despite these concerns, FDA has repeatedly defended its approval of rBGH, publishing a review of the data and concluding that rBGH “presents no increased health risk.”<sup>37</sup> In May 1994, FDA’s Food Advisory Committee and Veterinary Medicine Advisory Committee discussed whether foods should be labeled as containing supplemental rBGH; the committee report stated that “deliberations indicate that any method for instituting labeling for food from BST-supplemented cows would have to resolve many difficult scientific and policy questions.”<sup>38</sup> To date, no such labeling of milk products is required by FDA.<sup>39</sup> Furthermore, the courts have deferred to the agency position on the nonlabeling of rBGH.<sup>40</sup>

The potential impact of GMOs on ecosystems was dramatically exhibited by a study of biotech corn and monarch butterflies at Cornell University.<sup>41</sup> When scientists applied pollen from Bt-corn to milkweed, a crop that the butterflies eat and that grows near cornfields, forty-four percent of the monarch larvae died.<sup>42</sup> None of the monarch larvae in the study that were fed corn pollen from nonengineered plants died.<sup>43</sup> Some scientists caution that additional research needs to be done, for example, in the monarch butterfly’s natural habitat, before concluding that widespread harm to the ecosystem will result.<sup>44</sup> Still, the

<sup>35</sup> *Id.*

<sup>36</sup> Press Release, 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](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 SERVS. 73 (1990); National Institutes of Health, *Technology Assessment Conference Statement on Bovine Somatotropin*, 265 JAMA 1423 (1991).

<sup>37</sup> CRS REPORT, *supra* note 24. On December 15, 1998, the nonprofit organization Center for Food Safety petitioned FDA to withdraw approval of rBGH due to possible health effects not addressed by the agency. As of January 2001, this issue was pending within FDA. Critics continue to question the data upon which FDA founded its reports and the agency’s close ties with Monsanto. See, e.g., David I. Aboulafia, *Pushing rBST: How the Law and the Political Process Were Used to Sell Recombinant Bovine Somatotropin to America*, 15 PACE ENVTL. L. REV. 603 (1998).

<sup>38</sup> *Id.*

<sup>39</sup> *Id.* Moreover, FDA rejected the request by some companies to label their milk products as “BST-free,” determining that because BST (BGH) is a normal constituent of milk, such labeling would be misleading.

<sup>40</sup> In *Stauber v. Shalala*, 895 F. Supp. 1178, 1193 (W.D. Wis. 1995), the court deferred to FDA’s finding that there was no difference between dairy products from rBGH or nontreated cows. Thus, the court upheld FDA’s determination that it would not require labeling disclosing that dairy products came from rBGH-treated cows. When the state of Vermont sought to require mandatory disclosure of rBGH use in milk production, the U.S. Court of Appeals for the Second Circuit struck down the Vermont law on grounds that “consumer curiosity” was not “substantial” enough to justify the intrusion on commercial free speech under the First Amendment. Int’l Dairy Foods Ass’n v. Amestoy, 92 F.3d 67, 74 (2d Cir. 1996). See Emily Marden, *Recombinant Bovine Growth Hormone and the Courts: In Search of Justice*, 46 DRAKE L. REV. 617 (1998).

<sup>41</sup> Arjun Makhijani, *Ecology & Genetics: An Essay on the Nature of Life and the Problem of Genetic Engineering*, ch. 5 (Apex Press 2001). See John E. Losey, Linda S. Rayor & Maureen E. Carter, *Transgenic Pollen Harms Monarch Larvae*, 399 NATURE 214 (1999), available at <http://www.biotech-info.net/transpollen.html>.

<sup>42</sup> *Id.*

<sup>43</sup> *Id.*; see also Danielle Knight, *Environment: New Report Fuels Debate on GMO’s*, ENVTL. BULL., June 4, 2001, at 1, 2.

<sup>44</sup> For example, researchers point out that most milkweed on which monarch larvae feed does not grow close enough to cornfields to be exposed to significant amounts of corn pollen. Further, the timing is important and the monarch larvae would have to be emerging and feeding at the same time the corn is pollinating; they would have other food choices as well. Additional research is underway to determine whether Bt-corn poses



fact that ingesting Bt-corn had this effect is troubling. A report from the nongovernmental Institute for Energy and Environmental Research (IEER) concluded from this study, "Whether Bt corn will actually have severe impacts on monarch butterfly populations is less important to the overall issue than the fact of the unanticipated toxicity of Bt corn pollen. It should serve as a huge warning signal of the possibility of ecosystem disruption due to the widespread introduction of engineered species."<sup>45</sup>

Outcrossing also could have a direct impact on human health and food safety, as was demonstrated when traces of a maize type that was only approved for feed use appeared in maize products for human consumption in the United States.<sup>46</sup> StarLink, a corn genetically engineered with a [Cry9C] protein to protect crops against certain insects, was considered suitable only for animal feed because of concerns that it could cause allergic reactions in humans; but StarLink accidentally entered the food supply, prompting a large scale recall of about 300 corn products.<sup>47</sup> In addition, the cross-contamination had an impact on international trade, causing a drop in Japanese imports of U.S. corn by 1.3 million metric tons (eight percent in volume terms) in 2001. The Japanese government now mandates the segregation of unapproved biotechnology food and feed ingredients from the export channel, allowing a one percent tolerance for the unintended presence of these components.<sup>48</sup>

Further concerns about the U.S. food supply come from the latest use of biotechnology in crops to generate the production of drugs. A small biotechnology company, Ventria Biosciences, plans to insert human genes into rice plants to produce two proteins normally found in breast milk, tears, and saliva, in turn generating "therapeutic food products to treat stomach disorders."<sup>49</sup> Several other biotechnology companies are experimenting with drugs grown in plants because using this GM method to produce drugs in mass quantities of field plantings is less costly than a traditional biotechnology factory.<sup>50</sup> A consulting firm forecasts that the first plant-manufactured drugs will reach the U.S. market next year and expand into a \$2.2 billion-per-year industry by 2011.<sup>51</sup>

Consumer and environmental advocates, and many farmers (i.e., American Farm Bureau and National Farmers Union), fear that pollen from GM drug plants could drift into fields containing food crops and create contaminated hybrids.<sup>52</sup> Moreover, a bird could ingest the bioengineered seeds and deposit them in a field hundreds of miles

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a significant danger to the monarch butterfly in the long run. See Novartis, Q & A: Monarch Butterflies and Bt Corn, Syngenta Cuts (2000), [http://www.checkbiotech.org/blocks/dsp\\_document.cfm?doc\\_id=83](http://www.checkbiotech.org/blocks/dsp_document.cfm?doc_id=83); U.S. Dep't of State, *Fact Sheet: Monarch Butterflies and Bt Corn: A Review of the Research*, 4 *ECON. PERSP.* (1999), <http://usinfo.state.gov/journals/ites/1099/ijee/bio-monarch.htm>.

<sup>45</sup> Press Release, Inst. for Energy and Env'tl. Research (IEER), 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> (statement of Arjun Makhijani, President, IEER).

<sup>46</sup> WHO, Questions on GM Foods, *supra* note 4, at Q5.

<sup>47</sup> Martin A. Lee, *Food Fight: International Protests Mount Against Genetically Engineered Crops*, S.F. BAY GUARDIAN, June 25, 2001, available at <http://www.gefoodalert.org/News/news.cfm?News-ID=w2780> ("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.")

<sup>48</sup> James Stamps, *Trade in Biotechnology Food Products*, INT'L ECON. REV. 5, 13-14 (2002); see also StarLink Information Center, StarLink History, StarLink—What Happened?, <http://www.starlinkcorn.com/History/What%20Happened.htm> (last visited May 11, 2006).

<sup>49</sup> Arlene Weintraub, *What's So Scary About Rice? Biotech Crops Can Make Drugs—But They Must Be Kept Out of the Food Chain*, BUS. WK., Aug. 1, 2005, at 58.

<sup>50</sup> "A traditional biotech factory might cost Ventria ... \$125 million," but rice yields "the same output for \$4 million." Chief Executive Officer Scott Deeter says "he intends to pass the savings to consumers. *Id.*

<sup>51</sup> *Id.*

<sup>52</sup> *Id.*

away.<sup>53</sup> Even others in industry resist the use of biotech crops for drug production; Anheuser-Busch has waged a battle against this development in Missouri, fearing contamination of the rice plants that are a key ingredient in the company's beer.<sup>54</sup> Margaret Mellon, Director of the Food and Environment program for the Union of Concerned Scientists in Washington, D.C. warns that it is "virtually certain this stuff will make it into food-grade rice."<sup>55</sup>

Along with risks to the consumer and the environment come significant potential consequences for international trade. Some \$1.3 billion in annual U.S. rice sales to foreign countries are at stake.<sup>56</sup> If drugs migrate into commodity crops, many of these countries, already wary of biotech crops, would buy their agricultural products elsewhere.<sup>57</sup> These fears are not unfounded, as revealed by an incident in 2002, when a drug-producing corn made by ProdiGene Inc. began sprouting in soybean fields near its Nebraska and Iowa sites.<sup>58</sup> The U.S. Department of Agriculture (USDA) seized 500,000 bushels of contaminated soybeans and charged ProdiGene nearly \$3 million in fines and disposal costs. Unless companies and the agencies that regulate them implement safeguards to prevent these food-safety fears from becoming a reality, this biotech method of drug production faces an unsteady future.<sup>59</sup>

The favored method of the U.S. industry has been to make comparisons between the compositions of 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. As discussed *infra*, FDA relies on this substantial equivalence for its view that no additional labeling or animal testing is required. Substantial equivalence is an unscientific concept, however, that has never been properly defined or provided with a legal standard for implementation.<sup>60</sup> The IEER report states that:

Tests have not been performed because the regulatory apparatus has bought into the scientifically unfounded doctrine of "substantial equivalence," according to which there are assumed to be no differences between genetically engineered and traditionally bred foods. Today we want to emphasize that this erroneous notion of "substantial equivalence" at the level of food composition has its analog at the level of ecological impacts.<sup>61</sup>

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<sup>53</sup> *Id.*

<sup>54</sup> *Id.* In April 2004, when Anheuser-Busch threatened to boycott all Missouri rice, Ventria shifted its plans; in June 2005, USDA approved Ventria's application for plants in North Carolina instead.

<sup>55</sup> *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*, BUS. WK., July 26, 2005, [http://www.businessweek.com/magazine/content/05\\_31/b3945092mz018.htm](http://www.businessweek.com/magazine/content/05_31/b3945092mz018.htm).

<sup>56</sup> Weintraub, *supra* note 49.

<sup>57</sup> *Id.*; *Online Extra*, *supra* note 55.

<sup>58</sup> Weintraub, *supra* note 49, at 58; *see also Spotlight Pharming Reaps Regulatory Changes*, AGBIOTECH BUZZ, May 14, 2003, <http://pewagbiotech.org/buzz/display.php3?StoryID=101> (seeds inadvertently left behind in former test sites mingled with soybeans that were harvested and stored before the situation was discovered). Two months earlier, Prodigene had to destroy 155 acres of corn in Iowa because wind-blown pollen from its drug-producing may have contaminated that too. Take Action, <http://www.seedsofdeception.com/Public/TakeAction/index.cfm> (last visited May 17, 2006).

<sup>59</sup> Weintraub, *supra* note 49, 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).

<sup>60</sup> Pusztai, *supra* note 23 (citing Erik Millstone et al., *Beyond Substantial Equivalence*, NATURE, OCT. 7, 1999, AT 525).

<sup>61</sup> IEER Press Release, *supra* note 45 (statement of Martha R. Herbert, M.D., Ph.D., Pediatric Neurologist, Harvard Medical School).

It is for this reason that this approach has been rejected in Europe, where the capability to classify a novel food as being substantially equivalent no longer justifies a lack of safety assessments.<sup>62</sup>

According to some of the major regulatory and scientific agencies in the world, GM crops possess greater dangers than traditional crop breeding methods.<sup>63</sup> Scientists have identified the following as key issues in the environmental assessment of GM crops: putative invasiveness; vertical or horizontal gene flow; other ecological impacts; effects on biodiversity; and the impact of the presence of GM material in other products.<sup>64</sup> In view of the complexities of these issues, skilled ecologists and other scientists with expertise in developing the necessary predictive tools for risk assessment must have a voice in the public debate.<sup>65</sup>

A National Academies of Sciences (NAS) National Research Council report clarifies 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.”<sup>66</sup> Distinguishing between genetic engineering methods<sup>67</sup> and nongenetic engineering methods<sup>68</sup> of modifying plants and animals, the report has suggested some possible mechanisms of unintended change for organisms genetically engineered using rDNA techniques. For example, chromosomal changes may occur depending on where the genes were inserted, there may be a loss or gain of whatever function the gene provided, and spontaneous mutation may occur. As a result, the committee concluded that genetic engineering presented the greatest likelihood of unintended health effects on its scale in comparison to nongenetic engineering methods. The National Research Council report observed that targeted, quantitative analysis—the traditional approach of determining the presence or amount of compounds produced to assess changes and potential harm to health—has become much more sophisticated in detecting small molecules, but “more improvements are still needed.”<sup>69</sup>

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<sup>62</sup> See ROYAL SOCIETY UPDATE, *supra* note 18.

<sup>63</sup> NATIONAL RESEARCH COUNCIL, GENETICALLY MODIFIED PEST-PROTECTED PLANTS: SCIENCE AND REGULATION (Nat'l Acad. 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 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).

<sup>64</sup> Anthony J. Conner et al., *The Release of Genetically Modified Crops Into the Environment*, 33 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).

<sup>65</sup> Alan J. Gray, *Ecology and Government Policies: The GM Crop Debate*, 41 J. APPLIED ECOLOGY 1 (2004). 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).

<sup>66</sup> NRC SAFETY, *supra* note 3, at 1.

<sup>67</sup> Two GE methods (targeted) were described: microbial vectors, a method that 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.*

<sup>68</sup> Non-GE methods (nontargeted) 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.*

<sup>69</sup> *Id.* at 2.

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 a safety assessment prior to commercialization and postmarket surveillance to monitor unanticipated compositional changes and health effects of genetically engineered foods.<sup>70</sup> 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.<sup>71</sup>

### III. A CAUTIOUS APPROACH: EUROPEAN UNION AND INTERNATIONAL LAW

In the face of such significant concerns in the scientific community as to the safety of GMOs in food, how do regulatory systems proceed? Viewing this level of risk to be unacceptable, Europeans and the international community take a more cautious approach than the United States. In seeking an explanation for the greater opposition to food biotechnology in Europe, a study found that different histories of media coverage and regulation combined with public perceptions that reflected deeper cultural sensitivity not only toward food and novel food technologies but also toward agriculture and the environment.<sup>72</sup> Until recently, consumers in the United States have appeared to be relatively trusting and uninformed of a technology that in Europe has triggered extensive public debate, due in part to a history of food and environmental concerns, lack of transparency, and suspicion towards the government.<sup>73</sup>

The divergent legal approaches reflect this cultural difference in attitudes through the level to which scientific uncertainty is factored into risk assessment as part of the regulatory process. The international community gives greater weight to this uncertainty than does the U.S. government in its treatment of GMOs.<sup>74</sup> Because U.S. regulators do not view biotechnology as posing special risks in and of itself, the regulatory treatment of biotech products has been limited to fitting them within existing laws addressing known physical risks of new products.<sup>75</sup> In contrast, European regulators have dealt with biotechnology as “a novel process requiring novel regulatory provisions,” and, as a consequence, have launched a complex series of European and international initiatives that take into account a wider range of both known and unknown risks to human health and the environment.<sup>76</sup>

To provide international consistency in the assessment of GM foods, the Codex Alimentarius Commission—an international standard setting body for food safety jointly administered by two United Nations agencies, the Food Agriculture Organization (FAO) and WHO—adopted principles that set a uniform standard for assessing food safety for foods derived from modern biotechnology.<sup>77</sup> The Codex principles set forth a premarket

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<sup>70</sup> *Id.*

<sup>71</sup> *Id.* at 3; see also *infra* note 212 and accompanying text.

<sup>72</sup> 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).

<sup>73</sup> *Id.*; Ahmed, *supra* note 12, at 215; see also Alexander G. Haslberger, *Monitoring and Labeling for Genetically Modified Products*, 287 *SCI.* 431 (2000).

<sup>74</sup> Haslberger, *supra* note 73.

<sup>75</sup> Gaskell et al., *supra* note 72.

<sup>76</sup> *Id.*

<sup>77</sup> 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](http://www.codexalimentarius.net/download/standards/10007/CXG_044e.pdf).

assessment, implemented 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 risks previously identified, namely, toxicity, allergenicity, specific components having nutritional or toxic properties, the stability of the inserted gene, the nutritional effects of the specific gene modification, and any unintended effects from the gene insertion.<sup>78</sup> Treaties such as the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization (WTO) embrace the Codex principles, even though the Codex does not in itself have a binding effect on national legislation. These principles are further referred to as a standard in cases of trade disputes, including those involving the United States.<sup>79</sup>

In evaluating this approach to biotechnology and food safety, WHO in its recent study concluded that the risk assessment guidelines specified by the Codex Commission are “thought to be adequate for the safety assessment of GM foods currently on the international market.”<sup>80</sup> The study determined that GMOs and GM foods should be assessed on a case-by-case basis for potential risks, while taking into account their characteristics and possible differences in the receiving environments. In particular, relevant consequences must be investigated for specific crops and strategies for risk management explored to detect potential risks from outcrossing or contamination from GM crops. A better understanding of the impact and interaction of food with the immune system also is required to ascertain how and whether conventional and GM foods cause specific health and safety problems. WHO supported the Codex Commission in its expectation that improvements in risk assessment techniques will be included in the premarket approval process launched by many countries under this international guidance.<sup>81</sup>

As the only international regulatory instrument established to protect biological diversity from the risks of biotechnology, the Cartagena Protocol on Biosafety of the Convention on Biological Diversity<sup>82</sup> expressly focuses on the potential adverse effects of “living modified organisms” (LMOs) on the environment, while also taking into account the risks to human health as a secondary consideration.<sup>83</sup> The Cartagena Protocol, an environmental treaty legally binding on its parties, regulates the trade and transfer of LMOs across borders, including labeling on shipments of GM commodities.<sup>84</sup> Through an Advance Informed Agreement (AIA), an exporter must inform potential

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<sup>78</sup> WHO STUDY, *supra* note 14, at 12.

<sup>79</sup> The United States has participated in Codex since it was formed in 1962. *Id.*; Stamps, *supra* note 48, at 5, 7; *see also* WHO, Questions on GM Foods, *supra* note 4.

<sup>80</sup> WHO STUDY, *supra* note 14, at 24.

<sup>81</sup> *Id.*

<sup>82</sup> Cartagena 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/Cartagena Protocol on Biosafety, <http://www.biodiv.org/world/parties.asp> (last visited May 13, 2006).

<sup>83</sup> WHO STUDY, *supra* note 14, at 19.

<sup>84</sup> 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).

participatory countries of all of the information associated with these organisms before permitting their import.<sup>85</sup>

The Cartagena Protocol incorporates a precautionary approach in keeping with the language of the Rio Declaration on Environment and Development, 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.”<sup>86</sup> It provides risk scientific detection methods and assessment techniques, and allows governments to prohibit the import of GM foods because of safety concerns. Reflected in the Cartagena Protocol’s approach is the recognition that, although the risks may be unknown,

[I]ack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or feed, or for processing, in order to avoid or minimize such potential adverse effects.<sup>87</sup>

Lastly, the Cartagena Protocol establishes a Biosafety Clearing-House “to facilitate the exchange of scientific, technical, environmental, and legal information, and experience with, living modified organisms” and to assist countries in the implementation of the Protocol.<sup>88</sup>

According to the WHO study, the Cartagena Protocol is only the first step in the international regulation of bioengineered foods.<sup>89</sup> Although the Cartagena Protocol is the key basis for international regulation of LMOs, the Protocol’s scope does not consider GM foods that do not meet the definition of an LMO.<sup>90</sup> GM foods are within the scope of the Cartagena Protocol only if they contain LMOs that are capable of transferring or replicating genetic material. Moreover, the primary focus on biodiversity limits its consideration of human health issues; consequently, “the Protocol alone . . . is not sufficient for the international regulation of GM foods.”<sup>91</sup> In addition, the WHO study reported the possibility of implementing postmarket surveillance in the future, but tools to identify and trace GMOs or products derived from GMOs in the environment and food chain are needed; detection techniques in a number of countries already facilitate monitoring of GMOs, and attempts to standardize analytical methods for tracing GMOs have been initiated.<sup>92</sup> Lastly, WHO hopes that “this report could form the basis for a future

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<sup>85</sup> Cartagena Protocol, *supra* note 82; see Aarti Gupta, *Advance Informed Agreement: A Shared Basis for Governing Trade in Genetically Modified Organisms?*, 9 IND. J. GLOBAL LEGAL STUD. 265 (2001).

<sup>86</sup> Comisión Nacional de Recursos Fitogenéticos, Frequently Asked Questions About the Cartagena Protocol on Biosafety, <http://www.conarefi.ucr.ac.cr/Bioseguridad1.htm> (last visited May 13, 2006).

<sup>87</sup> Cartagena Protocol art. 11, para. 8.

<sup>88</sup> See Cartagena Protocol art. 20, para. 1. The Biosafety Clearing House is located at <http://bch.biodiv.org/>. 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).

<sup>89</sup> WHO STUDY, *supra* note 14, at 19-20.

<sup>90</sup> 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 modern biotechnology” and living organism means “any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids.” Cartagena Protocol art. 3(g)-(h).

<sup>91</sup> WHO STUDY, *supra* note 14, at 19-20.

<sup>92</sup> *Id.* at 23 (citing European Network of GMO Laboratories (2002), available at <http://engl.jrc.it/>).

initiative towards more systematic, coordinated, multi-organizational and international evaluation of certain GM foods.”<sup>93</sup>

Sharing this initiative, the Organization for Economic Cooperation and Development (OECD) established the Internal Coordination Group on Biotechnology in 1993 to aid international coordination in the areas of agriculture, technology, and trade. The OECD BioTrack 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.<sup>94</sup> This OECD effort seeks to promote international harmonization in the safety assessment and regulation of biotechnology food products, including conforming food labeling practices, which otherwise would have a potential to impede international trade in food products as nontariff trade barriers.<sup>95</sup>

With its precautionary approach, the European Union (EU) has taken a relatively proactive role in enacting strict legislation to control the spread of GMOs. Most significantly, the EU introduced a new Directive, 2001/18/EC,<sup>96</sup> regulating and restricting the distribution of GMOs and foods containing GM ingredients. The Directive 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.<sup>97</sup>

As a result, the Directive mandates 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].”<sup>98</sup> Directive 2001/18/EC provides a notification procedure before a GM product is placed on the market, a period of public comment, an assessment report, and principles for environmental risk assessment. Following a “step-by-step” principle, the scale of release is increased gradually only with proper evaluation at each step, providing first that

[n]o GMOs, as or in products, intended for deliberate release are to be considered for placing on the market without first having been subjected to satisfactory field testing at the research and development stage in ecosystems which could be affected by their use.<sup>99</sup>

The Directive also sets forth specific provisions for labeling and packaging, including a requirement that the words “this product contains genetically modified organisms” shall appear either on a label or in an accompanying document.<sup>100</sup> For products where

<sup>93</sup> WHO, Questions on GM Foods, *supra* note 4, at Q20.

<sup>94</sup> Organisation for Economic Co-operation and Development (OECD), 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](http://www.oecd.org/document/51/0,2340,en_2649_37437_1889395_1_1_1_37437,00.html) (last visited May 13, 2006).

<sup>95</sup> Stamps, *supra* note 48, at 8 (citing OECD, Biosafety—BioTrack, About, [http://www.oecd.org/about/0,2337,en\\_2649\\_34385\\_1\\_1\\_1\\_37437,00.html](http://www.oecd.org/about/0,2337,en_2649_34385_1_1_1_37437,00.html) (last visited May 13, 2006)).

<sup>96</sup> Council Directive 2001/18/EC, 2001 O.J. (L106), *available at* <http://binas.unido.org/binas/regs.php>; *see also* Facts on GMOs in the EU, *supra* note 3.

<sup>97</sup> Council Directive 2001/18/EC, *supra* note 96, at cl. 4.

<sup>98</sup> Council Directive 2001/18/EC, *supra* note 96, at cl. 5.

<sup>99</sup> *Id.* at cls. 24 and 25.

<sup>100</sup> *Id.* at art. 13, § 2, ¶ f. 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.

unavoidable traces of authorized GMOS cannot be excluded, minimum threshold levels for the labeling requirement shall be established.<sup>101</sup> Postmarket monitoring by the industry is required, as well as notifying the authorities of new information and taking immediate measures necessary to protect human health and the environment.<sup>102</sup>

Extending beyond the previous Directive 90/220/EC,<sup>103</sup> the new Directive allows a temporary ban of GM products if evidence can be provided exposing risks to human health or the environment.<sup>104</sup> 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.<sup>105</sup> The United States has filed a complaint with the WTO challenging the ban, on the grounds that it is an impediment to trade.<sup>106</sup> The ban followed an earlier action when, in November 2002, the EU approved enhanced traceability and labeling requirements for biotechnology food and feed.<sup>107</sup> The U.S. government previously had delivered a demarche to the EU in September 2002 outlining U.S. concerns about the then-pending (traceability and labeling) regulations and their likely adverse impact on U.S. bulk shipments.<sup>108</sup>

In response to a series of food safety alarms, the EU, in May 2003, created the European Food Safety Authority (EFSA) to serve as a “food safety watchdog.”<sup>109</sup> The role of the EFSA differs from its U.S. counterpart in that the EFSA deals only with

<sup>101</sup> *Id.* at art. 21, § 2.

<sup>102</sup> *Id.* at art. 19, § 2 ¶¶ f and art. 20.

<sup>103</sup> Council Directive 90/220/EEC, 1990 O.J. (L117), 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](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.

<sup>104</sup> 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).

<sup>105</sup> The Non-GMO Report, EU tightens GM food labeling requirements (Nov. 2002), [http://www.non-gmosource.com/GM\\_food\\_labeling\\_requirements.php](http://www.non-gmosource.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, GENES, TRADE, AND REGULATION: THE SEEDS OF CONFLICT IN FOOD BIOTECHNOLOGY (Princeton Univ. 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)).

<sup>106</sup> In May 2003, the United States, Argentina, and Canada filed a formal complaint with the World Trade Organization (WTO) against the European Union 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 May 13, 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).

<sup>107</sup> Stamps, *supra* note 48, at 10.

<sup>108</sup> *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).

<sup>109</sup> Geoffrey Podger, *European Food Safety Authority Will Focus on Science*, 5 EUR. AFF. (2004), available at [http://www.europeanaffairs.org/current\\_issue/2004\\_winter/2004\\_winter\\_77.php4](http://www.europeanaffairs.org/current_issue/2004_winter/2004_winter_77.php4).



the science of risk assessment (determining what risks exist), while FDA also handles the policy decisions involved in risk management (determining what to do about those risks and whether they are considered acceptable). The European Parliament wanted an organization that gave “genuinely objective, independent and public advice,” leaving the policy judgments to the European Commission.<sup>110</sup> Thus, the EFSA will not have a role in trade disputes before the WTO, but instead hopes to “help bring American and European scientists together at an early stage in the hope of reducing the political impact of such differences” because “food safety does not respect boundaries.”<sup>111</sup> Another goal is to instill “a much clearer degree of scientific input into the risk management measures adopted by the EU” by taking care not to avoid difficult scientific issues of risk assessment for fear of unpopularity.<sup>112</sup> At the same time, in light of the European sensitivity to food issues and past food scares, the EFSA seeks to achieve more transparency and restore public confidence.

To this end, the Executive Director of the EFSA, Geoffrey Podger, has taken a position in favor of the labeling approach. He explains that when GM products were clearly labeled in the United Kingdom, many people bought them and initially gave GMOs a degree of acceptability, “until commodity crops starting arriving from North America in which GMO and non-GMO varieties could not be differentiated.”<sup>113</sup> The European opposition to GMOs did not come about because the science had changed, but rather it was based on ethical grounds as a reaction to being denied a choice. As a consequence, Dr. Podger believes that the solution to regaining the support of the European public is through labeling:

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.<sup>114</sup>

Dr. Podger sees potential for the market for GMOs to open if these products have obvious advantages for consumers even in the face of some risk.<sup>115</sup> Public perceptions, he notes, are open to change with new information, as long as the regulatory process is transparent and gives people all available information on the science. “Equally, of course, we are always open to new scientific evidence and to improving the regulatory process if necessary.”<sup>116</sup>

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. As of 2000, twenty-two nations, including Great Britain, France, Australia, Japan, South Korea, and Mexico, in addition to the EU, had passed regulations that require GM food labeling.<sup>117</sup> Thus, the EU and the international community continue to pursue an aggressive policy of caution in the regulation of bioengineered foods and food products.<sup>118</sup>

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<sup>110</sup> *Id.*

<sup>111</sup> *Id.*

<sup>112</sup> *Id.*

<sup>113</sup> *Id.*

<sup>114</sup> *Id.*

<sup>115</sup> *Id.*

<sup>116</sup> *Id.*

<sup>117</sup> See Press Release, Oregon State Univ. (OSU), OSU Economist Estimates Cost of GM Food Labels (Oct. 23, 2000), available at [http://www.biotech-info.net/label\\_cost.html](http://www.biotech-info.net/label_cost.html).

<sup>118</sup> 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](http://www.wto.org/english/forums_e/ngo_e/posp47_nftc_looking_behind_e.pdf).

## IV. A LOOK AT EXISTING U.S. LAW

In contrast to the stringent premarket approval process, mandatory labeling, and moratoriums in Europe and the international community, the United States has not developed a regulatory scheme of special safeguards for GMOs because the U.S. government does not recognize biotechnology as posing special risks. As a consequence, U.S. regulation of biotechnology food products does not differ fundamentally from the regulation of conventional food products. The United States uses health and safety laws written prior to the development of modern biotechnology to review genetically engineered products. To date, the United States has not issued any new legislation for these products.<sup>119</sup> Under the 1986 Coordinated Framework for Regulation of Biotechnology, three agencies primarily share the regulatory oversight responsibility for these products: USDA and its agencies, which regulate and monitor the use of biotechnology for agriculture, restricting, among other things, the addition of potential plant pests "altered or produced through genetic engineering";<sup>120</sup> the Environmental Protection Agency (EPA), which approves new pesticidal and herbicidal substances; and 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 end product rather than on the process by which a product is made. Thus, it is immaterial that the product originated from genetic engineering.<sup>121</sup> Each agency draws on its own perspective and area of concern. For example, USDA regulates field testing and examines possible environmental consequences as to plant pests, other organisms, and weediness characteristics (e.g., the potential to become a weed through ease of seed dispersal); EPA considers the health effects by assessing allergenicity and digestibility, the environmental fate such as the potential for cross-pollination, and the effects on nontarget organisms, particularly whether the introduced pesticidal substance is toxic to wildlife; and FDA asks the developer voluntarily to address issues of food safety and allergenicity, examining "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."<sup>122</sup> However,

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<sup>119</sup> United States Regulatory Agencies Unified Biotechnology Website, Frequently Asked Questions, <http://usbiotechreg.nbio.gov/FAQRecord.asp?qryGUID=2> (last visited May 13, 2006). For a compilation of the laws currently used to regulate the products of modern biotechnology and the regulations developed under these statutes (the Plant Protection Act, the Federal Food, Drug, and Cosmetic Act (FDCA), the Federal Insecticide, Fungicide, and Rodenticide Act, and the Toxic Substances Control Act), see United States Regulatory Agencies Unified Biotechnology Website, U.S. Laws and Regulations, <http://usbiotechreg.nbio.gov/lawsregsguidance.asp> (last visited May 13, 2006). See also 1986 Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986).

<sup>120</sup> See, e.g., Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which are Plant Pests or Which There is Reason to Believe are Plant Pests, 7 C.F.R. § 340 (1997). For example, USDA's Biotechnology Regulatory Services, which is a branch of the Animal and Plant Health Inspection Service, "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 May 13, 2006).

<sup>121</sup> Stamps, *supra* note 48, at 5-6.

<sup>122</sup> U.S. Dep't 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).

“each agency ... relies on industry data and rarely completes its own independent experiments comparing different foods.”<sup>123</sup>

U.S. regulations do not mandate labeling of GM foods, but instead recommend voluntary labeling of bioengineered foods and request that companies notify FDA of their intent to market GM foods at least 120 days before launch.<sup>124</sup> The inquiry focuses on whether the GM foods are substantially equivalent to their parent crops.<sup>125</sup> If so, only the general labeling requirements for all foods would apply. For all foods, section 403(i) of the Federal Food, Drug, and Cosmetic Act (FDCA) 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.<sup>126</sup> In its 1992 policy statement on foods developed from new plant varieties including bioengineered foods, FDA emphasized that, while the agency was not establishing special labeling requirements for bioengineered foods as a class of foods, this preexisting scheme would apply:

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.<sup>127</sup>

FDA offers 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.”<sup>128</sup> This information would be “a material fact” whose omission may make the label of the tomato misleading under section 403(a) of the FDCA.<sup>129</sup>

From FDA’s perspective, biotechnologically-produced products are seen as substantially equivalent to conventional food products because, in the agency’s view, there is no scientific basis to presuppose that biotech foods are more risky or substantially different from other food products. FDA states in its regulations that the agency

believes that the new techniques are extensions at the molecular level of traditional ... plant breeding. The agency is not aware of any information

<sup>123</sup> CRS REPORT, *supra* note 24.

<sup>124</sup> Ahmed, *supra* note 12, at 215. See, e.g., Premarket Notice Concerning Bioengineered Foods, 21 C.F.R. Parts 192 and 592 (2001), available at <http://www.cfsan.fda.gov/~lrd/fr010118.html>.

<sup>125</sup> 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 judgment. ROYAL SOCIETY UPDATE, *supra* note 18. 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.

<sup>126</sup> 21 U.S.C. § 343(i); *id.* § 343(a); *id.* § 321(n) (2005); see also Letter from Catalina Ferre-Hockensmith, Dep’t of Health and Human Servs. (HHS), Div. 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>.

<sup>127</sup> Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984, 22,991 (May 29, 1992).

<sup>128</sup> *Id.* For critiques of this regime, see, for example, 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).

<sup>129</sup> 21 U.S.C. § 321(n), cited in Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. at 22,991.

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.<sup>130</sup>

Accordingly, if GM soy contains the same nutritional and dietary content as its predecessor, FDA does not require that it be labeled as a biotechnologically altered food. This policy was reaffirmed by FDA in 2001 in its Draft Guidance for Industry allowing voluntary labeling indicating whether foods have or have not been developed using bioengineering.<sup>131</sup>

FDA's treatment of GM foods contrasts with its handling of the irradiation of food, which was a food processing technology considered by the agency to be a "material fact" necessary to disclose to consumers through labeling. FDA approved the use of ionizing radiation on various foods under specific conditions.<sup>132</sup> Although FDA determined that "there is no concern about the safety of such treatment," the agency concluded that labeling of irradiated foods was necessary because such processing is a material fact that must be disclosed to the consumer to prevent deception. FDA determined that irradiation is a form of processing that can produce significant changes in certain characteristics of a food, such as the organoleptic (e.g., taste, smell, texture) or holding properties, in a manner that is not obvious to the consumer in the absence of labeling. That is, in the absence of labeling indicating that the food has been irradiated, the implied representation to consumers is that the food has not been processed.<sup>133</sup>

FDA thus required that the label and labeling of retail packages or displays of foods treated with ionizing radiation include both the radura logo (the international symbol that indicates radiation treatment) and a disclosure statement (either "Treated with radiation" or "Treated by irradiation") in addition to information required by other regulations.<sup>134</sup> In mandating a disclosure on all irradiated foods, FDA was cognizant of widespread consumer concerns about food irradiation. According to the agency, "the large number of consumer comments requesting retail labeling attest to the significance placed on such information by consumers."<sup>135</sup>

Supporters of GM food labeling point to FDA's irradiated foods analysis as being applicable as well to GM foods, reasoning that "the absence of an affirmative statement that a food had been genetically modified would be viewed as an implied representation to consumers that it has been grown by traditional means."<sup>136</sup> In *Alliance for Bio-Integ-*

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<sup>130</sup> Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. at 22,991.

<sup>131</sup> CFSAN, FDA, Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering (Jan. 2001) [hereinafter FDA, Draft Guidance on Voluntary Labeling], available at <http://vm.cfsan.fda.gov/~dms/biolabgu.html>.

<sup>132</sup> Irradiation in the Production, Processing and Handling of Food, 21 C.F.R. § 179.26 (2003).

<sup>133</sup> Irradiation in the Production, Processing, and Handling of Food, 21 C.F.R. Part 179, 64 Fed. Reg. 7834 (Feb. 17, 1999), citing Irradiation in the Production, Processing, and Handling of Food, Final Rule, 51 Fed. Reg. 13,376 (Apr. 18, 1986); Irradiation in the Production, Processing, and Handling of Food; Final Rule, 53 Fed. Reg. 12, 757 (Apr. 18, 1988).

<sup>134</sup> 21 C.F.R. § 179.26(c)(1), (2).

<sup>135</sup> 51 Fed. Reg. at 13,388.

<sup>136</sup> Emily Marden, *Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture*, 44 B.C.L. REV. 733, 763 (2003); see also Frederick Degnan, *Food Labeling and the Right-to-Know*, 52 FOOD & DRUG L.J. 49 (1997).

*ity v. Shalala*,<sup>137</sup> a group of concerned citizens sued FDA claiming that the agency's refusal to require labeling and safety testing raises health and environmental concerns and makes it difficult to comply with religious dietary laws. The suit identified thirty-six genetically modified foods being consumed daily without the knowledge of U.S. consumers. Seeking to apply the food-processing reasoning used for irradiated foods, the plaintiffs demanded that FDA institute mandatory labeling of GM foods on the grounds that genetic alteration made material changes (i.e., safety, allergenicity risks) to foods. The plaintiffs took the position that the process of being genetically modified was itself a material fact. The court rejected both of these arguments, however, and affirmed FDA's position.<sup>138</sup>

In November 2004, FDA proposed a Draft Guidance for Industry for New Plant Varieties Intended for Food Use "to address the possibility that material from a new plant variety intended for food use might inadvertently enter the food supply before its sponsor has fully consulted with the [FDA]."<sup>139</sup> This draft guidance provides a scientific framework in which to evaluate the food safety of new nonpesticidal proteins produced in bioengineered plants,<sup>140</sup> and encourages developers to submit to FDA their evaluation of the food safety of their new protein. 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.<sup>141</sup>

FDA recommends that sponsors and developers of new plant varieties intended for food use "consult with 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."<sup>142</sup> The agency made it clear, however, that any concern related to such material entering the food supply would be limited to the possibility that the new protein could cause an allergic reaction in susceptible individuals or could be a toxin in people or animals.<sup>143</sup> Additionally, FDA stressed that this draft guidance

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<sup>137</sup> *Alliance for Bio-Integrity v. Shalala*, 116 F. Supp. 2d 166, 178 (D.D.C. 2000).

<sup>138</sup> *Id.*

<sup>139</sup> FDA, 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>; 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 HHS, HHS News, FDA to Strengthen Pre-Market Review of Bioengineered Foods (May 3, 2000), available at <http://www.cfsan.fda.gov/~lrd/hhbioen2.html> (announcing 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").

<sup>140</sup> This guidance concerns developers of new plant varieties that are intended for food use, describing procedures for the early food safety evaluation of such new nonpesticidal proteins. FDA notes that, because EPA is responsible for assessing the safety of pesticides including plant-incorporated protectants, those proteins are not subject to FDA review or this guidance. See FDA, 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) [hereinafter FDA, Guidance for Industry, Recommendations for Early Food Safety Evaluation], available at <http://www.cfsan.fda.gov/~dms/bioprgui.html>.

<sup>141</sup> FDA Talk Paper, *supra* note 139.

<sup>142</sup> FDA, Guidance for Industry, Recommendations for Early Food Safety Evaluation, *supra* note 140.

<sup>143</sup> 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.

does not establish legally enforceable responsibilities, but “describe[s] the agency’s current thinking on a topic and should be viewed only as recommendations . . . .”<sup>144</sup>

Note that the U.S. approach differs greatly from the international approach embodied by the Codex principles and Cartagena Protocol, most significantly by not adopting the precautionary principle that would require premarket approval conditioned upon a case-by-case risk assessment to consider the intended and unintended effects of the GM product *before* its release.<sup>145</sup> In promulgating its regulatory scheme, FDA appears to have given little weight to the scientific uncertainty and risks recognized by its EU counterparts as inherent in GMOs.<sup>146</sup> FDA’s regulations go no farther than recommendations to the industry of communication with the agency and, unlike the EU and international regulations, do not require disclosure of GM processes to the consumer. The absence of mandatory labeling and monitoring, as well as a premarket approval process, stands in stark contrast to the approach overseas.

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 labeling of biotechnology food products.<sup>147</sup> 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.”<sup>148</sup> Although H.R. 4814 gained thirty-eight cosponsors, the bill died in a subcommittee.<sup>149</sup>

H.R. 4814 was one of five bills introduced by Rep. Kucinich that sought to expand the regulation of agricultural biotechnology. H.R. 4812, the Genetically Engineered Crop and Animal Farmer Protection Act, would “provide additional protections for farmers and ranchers that may be harmed economically by genetically engineered seeds, plants, or animals,” establishing a Farmer’s Bill of Rights “to ensure fairness for farmers and ranchers in their dealings with biotechnology companies that sell genetically engineered seeds, plants, or animals.”<sup>150</sup> Among these protections, the bill would require disclosure by the biotechnology companies of the legal and environmental

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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.

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

<sup>144</sup> FDA, Guidance for Industry, Recommendations for Early Food Safety Evaluation, *supra* note 140.

<sup>145</sup> In fact, in discussions of the Codex, the United States has consistently battled with Europeans over their incorporation of the precautionary principle into regulation of GM technology. *See, e.g.,* Marden, *supra* note 136, at 786 (citing FDA Public Meeting on the Codex Ad Hoc Intergovernmental Task Force on Food Derived from Biotechnology (Dec. 15, 1999)).

<sup>146</sup> The United States has vigorously resisted “any efforts to regulate GM technology based on the development process, or on grounds of *potential* health or environmental risks,” opposing the European Commission and others in the drafting of the Convention on Biological Diversity, which “permit[ted] non-scientific based measures to justify exclusion of GM products from entry into a country.” *Id.* at 786-87.

<sup>147</sup> Genetically Engineered Food Right to Know Act, H.R. 4814, 107th Cong. (2002).

<sup>148</sup> *Id.*

<sup>149</sup> 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, United States H.R. 4814 (May 2005), <http://pewagbiotech.org/resources/factsheets/legislation/bill.php?LegislationID=167>.

<sup>150</sup> Genetically Engineered Crop and Animal Farmer Protection Act of 2002, H.R. 4812, 107th Cong. (2002).

risks that the use of the genetically engineered seeds, plants, or animals may pose to the purchaser; prevent noncompetitive practices involving technology fees; preclude the biotechnology company from limiting liability for harm that may result from the release of genetically engineered material into the environment; and prohibit the sale of certain nonfertile plant seeds (a seed that is genetically engineered to produce a plant whose seeds are not capable of reproduction).

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.<sup>151</sup> This bill explicitly recognized that “genetic engineering is an artificial gene transfer process wholly different from traditional breeding” and considered adding new genes into a food as comparable to adding a food additive, thus requiring an analysis of safety factors:

Given the consensus among the scientific community that genetic engineering can potentially introduce hazards, such as allergens or toxins, genetically engineered foods need to be evaluated on a case-by-case basis and cannot be presumed to be generally recognized as safe.<sup>152</sup>

H.R. 4813 would require that all GMOs be determined safe for human consumption prior to release in the market, and would give FDA the right to impose independent testing and to seek input from the National Academy’s Institute of Medicine. Further, the bill would authorize citizen suits for genetic food additives in the event of noncompliance with these provisions.<sup>153</sup>

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.<sup>154</sup> By its terms, the bill asserted that “[t]he need for mandatory labeling, safety testing, and environmental reviews of genetically engineered foods do not constitute obstacles to the cessation of world hunger.”<sup>155</sup> The stated purpose 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 . . . .”<sup>156</sup> H.R. 4815 would support funding for international research that promotes the development of sustainable agriculture techniques with minimum artificial inputs to meet the food and fiber needs of developing countries.

Finally, H.R. 4816, the Genetically Engineered Organism Liability Act, would hold biotechnology companies liable to any party for injuries caused by the release of a genetically engineered organism into the environment.<sup>157</sup> The list of potential injuries included crop failures suffered by farmers, cross pollination of neighboring farms, and increased insect resistance, as well as health and environmental impacts on consumers.<sup>158</sup> All of these bills were referred to subcommittees with no further action.

Likewise, in the U.S. Senate, Senator Richard Durbin (D-IL) in October 2002 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.”<sup>159</sup> This legisla-

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<sup>151</sup> Genetically Engineered Food Safety Act of 2002, H.R. 4813, 107th Cong. (2002).

<sup>152</sup> *Id.*

<sup>153</sup> *Id.*

<sup>154</sup> Real Solutions to World Hunger Act of 2002, H.R. 4815, 107th Cong. (2002).

<sup>155</sup> *Id.*

<sup>156</sup> *Id.*

<sup>157</sup> Genetically Engineered Organism Liability Act of 2002, H.R. 4816, 107th Cong. (2002).

<sup>158</sup> *Id.*

<sup>159</sup> Genetically Engineered Foods Act, S. 3095, 107th Cong. (2002).

tion would require 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 (HHS) 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. S. 3095 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 apparently was no action on this bill, as it died in committee.<sup>160</sup>

Congress does not appear to be supporting initiatives to address food safety concerns and to tighten the regulatory process for bioengineered food in the United States. In the 108th Congress (2003-2004), thirteen bills and two resolutions specifically addressing agricultural biotechnology were introduced. Of those, only two nonbinding resolutions—supporting the Administration's efforts to bring a complaint against the European Union for its restrictions on GM crops—passed (H.R. Res. 252 and S. Res. 154).<sup>161</sup> The stated purpose of these resolutions was to express the support of the House of Representatives and the Senate for the United States "in its efforts within the World Trade Organization (WTO) to end the European Union's protectionist and discriminatory trade practices of the past five years regarding agriculture biotechnology."<sup>162</sup> Each resolution "supports and applauds the efforts of the Administration on behalf of the Nation's farmers, challenging the long-standing, unwarranted moratorium imposed by the European Union on the approval of agriculture biotechnology products and encourages the President to continue to press this issue . . ."<sup>163</sup>

With the U.S. Congress continuing to take relatively little action on biotechnology-focused legislation to alter the way GM foods are regulated,<sup>164</sup> state legislatures have come forward as the main venue for issues pertaining to agricultural biotechnology.<sup>165</sup> In the 2003-2004 legislative session, 170 pieces of legislation (156 bills and fourteen resolutions) were introduced in thirty-five different states, representing a seven percent increase over the amount of legislation introduced in thirty-nine state legislatures in 2001-2002.<sup>166</sup> This increase indicates a growing trend that agricultural biotechnology issues generate a high level of interest among state legislators and their constituents.

The state legislation can be classified into several broad categories: regulating biotech crops and animals, labeling, liability and agricultural contracts, studies or task forces, supporting the technology, implementing moratoria, or criminalizing crop destruction. Of the thirty-seven pieces of legislation that passed in 2003-2004, a majority (21) fell

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<sup>160</sup> *Id.* On the day it was introduced in the Senate, it was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry.

<sup>161</sup> H.R. Res. 252, 108th Cong. (2003) (introduced by Rep. Roy Blunt, R-MO); S. Res. 154, 108th Cong. (2003) (introduced by Sen. 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 PEW Legislative Activities].

<sup>162</sup> H.R. Res. 252.

<sup>163</sup> S. Res. 154, 108th Cong. (2003).

<sup>164</sup> A review of the current legislative session (109th Congress, 2005-2006) finds no pending bills or resolutions involving GMOs or food biotechnology. *See* The Library of Congress: THOMAS, <http://thomas.loc.gov/> (last visited May 13, 2006).

<sup>165</sup> PEW Legislative Activities, *supra* note 161.

<sup>166</sup> *Id.*



into the category of “supporting biotechnology.” Nationally, there was a large increase in the number of bills introduced that support biotechnology, particularly as a tool for economic development. In 2004, two states passed legislation that would “assert state preeminence over agricultural biotechnology and prevent local initiatives from countering state authorities.”<sup>167</sup>

One trend in 2003-2004 was the increase in legislation addressing “novel” applications of agricultural biotechnology, beyond the corn, cotton, and soybeans modified for herbicide or insect resistance that have proliferated in the United States: “The next generation of agricultural biotechnology products is likely to include new food or feed crops (possibly alfalfa, wheat, coffee, or rice); transgenic fish or other aquatic organisms; transgenic crops and livestock genetically modified to produce human therapeutics or industrial compounds; and other genetically modified animals.”<sup>168</sup> Regional issues appear to dominate the kinds of legislation introduced by state lawmakers. “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.”<sup>169</sup> State legislatures across the nation passed seven bills regulating biotech crops or animals,<sup>170</sup> three bills addressing labeling,<sup>171</sup> one bill on the subject of liability and agricultural contracts,<sup>172</sup> four pieces of legislation in the study/task force category,<sup>173</sup> and one bill imposing a moratorium.<sup>174</sup> These developments potentially raise issues of a constitutional dimension, such as preemption and the Commerce Clause.<sup>175</sup> In the absence of a comprehensive system of federal legislation, these state and local restrictions could result in “a patchwork of inconsistent regulatory requirements . . . .”<sup>176</sup>

## V. A MODEL OF CAUTION: LABELING AND MONITORING

Despite the benefits of biotechnology, the safety issues from unintended and unknown risks and scientific uncertainty necessitate a more effective approach to risk assessment in the United States. Without transparency as to the presence of GM products in food, informed choice cannot be realized. This lack of information also impedes the development of biotechnology in the long run. A report by the Atlantic Council of the United

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<sup>167</sup> *Id.*

<sup>168</sup> *Id.*

<sup>169</sup> *Id.*

<sup>170</sup> See Arizona HB2615, Michigan SB226, Michigan SB227, Michigan SB228, Michigan SB229, Pennsylvania HB2387, and South Dakota HB1237, cited in PEW Legislative Activities, *supra* note 161.

<sup>171</sup> See Vermont HB 777, Pub. Act No. 97 (2004) (requires all GM seed to be labeled with information describing the trait; requirements for safe handling, storage, transport, and use; and information about the manufacturer; all manufacturers of GM seed are required to report to the secretary the quantities sold annually); Minnesota SF 2843 (passed Mar. 15, 2004, but presumed dead in Committee) (provides guidelines for voluntary labeling of dairy products produced from cows not treated w rBGH (rBST) and mandates that dairy products derived from cows that have been treated with rBGH be labeled as such); Maine HP 1149 (2003) (imposes a civil violation for any manufacturer, distributor, processor, wholesaler or retailer who falsely labels any product such as commercial feed as made without genetic engineering or bioengineering).

<sup>172</sup> See Illinois HB 264, cited in PEW Legislative Activities, *supra* note 161.

<sup>173</sup> See Hawaii SB 837, Illinois SR 89, Montana SJ 8, and New Mexico SMR 62, cited in PEW Legislative Activities, *supra* note 161.

<sup>174</sup> A moratorium on transgenic fish passed in California. California SB 245, ch. 871, Statutes of 2003 (2003), cited in PEW Legislative Activities, *supra* note 161.

<sup>175</sup> See Eric Lasker, *Federal Preemption and State Anti-“GM” Food Laws*, 20 LEGAL BACKGROUNDER 1 (2005) (conflict between favorable federal law and restrictive state legislative laws may raise preemption issues); Eric Lasker, *FDA Position on Federal Preemption Consistent with Law & Public Health*, 20 LEGAL BACKGROUNDER 1 (2005) (FDA asserting in court proceedings that the agency’s labeling of FDA-regulated products, including prescription drugs, should be given preemptive effect over state law).

<sup>176</sup> PEW Legislative Activities, *supra* note 161.

States found that “[c]onsumer confidence is the most important determinant of any future market [in] ... biotechnology.”<sup>177</sup> 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 information and choice.<sup>178</sup>

With regard to GMOs, the most prevalent view is the demand for information and for choice. According to recent polls, 94.6% of Europeans want the right to choose whether or not they eat food that has been genetically modified.<sup>179</sup> Other studies in Japan and Europe indicated a decline of confidence in the biotechnology product.<sup>180</sup> 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.<sup>181</sup>

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 products.<sup>182</sup> Among the U.S. consumers recently surveyed, there appears to be little awareness concerning the genetic modification of agricultural and food products.<sup>183</sup> Only two in five Americans (forty-one percent) say that they realize that genetically modified food products currently are for sale in supermarkets.<sup>184</sup> Even so, over seventy-five percent of Americans stated that the potential danger from genetic modification is so great that strict regulations are necessary; yet sixty-three percent believe that the government does not have the tools to regulate GMOs properly.<sup>185</sup> Nine out of ten Americans said that GM foods should be labeled as such, although only about half said they actually would take time to look for foods labeled as not being genetically modified.<sup>186</sup> (This last point should be welcome news for the biotechnology industry, which may be concerned about the impact of labeling on sales.) In another poll, ninety-three percent of Americans agreed that the federal government should require labels identifying genetically modified or bioengineered foods. “Such near unanimity in public opinion is rare.”<sup>187</sup> Even among American farmers, “90 [percent] ... support labels on biotech products if they are scientifically different from conventional foods and 61 [%] support labels on biotech products even if not scientifically different.”<sup>188</sup> The increased attention from

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<sup>177</sup> DAVID AARON ET AL., RISK AND REWARD: U.S.-EU REGULATORY COOPERATION ON FOOD SAFETY AND THE ENVIRONMENT (Nov. 2002), available at <http://www.acus.org/Publications/policypapers/TransatlanticRelations/Risk%20and%20Reward.pdf>.

<sup>178</sup> *Id.*

<sup>179</sup> 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](http://europa.eu.int/comm/public_opinion/archives/eb/ebs_154_en.pdf).

<sup>180</sup> Pan, *supra* note 1, 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)).

<sup>181</sup> *Id.*

<sup>182</sup> *Id.*

<sup>183</sup> WILLIAM K. HALLMAN ET AL., PUBLIC PERCEPTIONS OF GENETICALLY MODIFIED FOODS: AMERICANS KNOW NOT WHAT THEY EAT (Food Policy Inst., Mar. 15, 2002), available at <http://www.foodpolicyinstitute.org/docs/reports/Public%20Perceptions%20of%20Genetically%20Modified%20Foods.pdf>.

<sup>184</sup> *Id.*; see also Pew Initiative on Food and Biotechnology, Public Sentiment About Genetically Modified Food (Nov. 2005 Update), available at <http://pewagbiotech.org/research/2005update/> (While knowledge of genetically modified foods has increased to 41%, fewer—25%—believe they have or are likely—40%—to eat GM foods. Those who are most informed about GM foods also oppose their introduction into the food supply, with 54% opposed among those who have heard “a great deal” about GM foods.)

<sup>185</sup> *Id.*

<sup>186</sup> *Id.*

<sup>187</sup> The GE Food Alert Campaign Center, American Public Opinion Polls on GE Foods, [http://www.gefoodalert.org/News/news.cfm?News\\_ID=3151](http://www.gefoodalert.org/News/news.cfm?News_ID=3151) (last updated Feb. 1, 2002) (citing an ABCNews.com poll, June 2001).

<sup>188</sup> *Id.* (citing Farm Foundation/Kansas State Univ., Survey of Farms Throughout the United States (Sept. 2001)).

the public and erosion of consumer confidence should compel regulators and legislators to reexamine current policies.

In the past, FDA recognized this mandate from the people but rejected mandatory labeling based on the restraints of the agency's own regulatory scheme and FDA's narrow reasoning as to the role of undetermined risks, stating that

[m]ost of the comments that addressed labeling requested mandatory disclosure of the fact that the food or its ingredients was bioengineered or was produced from bioengineered food. However, these comments did not provide data or other information regarding consequences to consumers from eating the foods or any other basis for FDA to find under section 201(n) of the act that such a disclosure was a material fact. Many of the comments expressed concern about possible long term consequences from consuming bioengineered foods, but they did not contend that any of the bioengineered foods already on the market have adverse health effects. The comments were mainly expressions of concern about the unknown.<sup>189</sup>

In reviewing the more than 50,000 written comments about its policy, FDA did acknowledge "there was general agreement that providing more information to consumers about bioengineered foods would be useful."<sup>190</sup> FDA's position rejecting mandatory labeling based mainly on "concerns about the unknown" contrasts directly with the precautionary principle embodied in the Cartagena Protocol, which does not allow the "[l]ack of certainty due to insufficient relevant scientific information and knowledge" to prevent restrictions on imports to avoid these "potential adverse effects."<sup>191</sup> The ultimate question is who bears the burden of proving that these substances are not hazardous—the companies before approval or the consumers who fear the potential hazards. Science is fallible—who do we want to bear the risk of as-yet undetected hazards? If the U.S. government does not require a rigorous pre-approval process as do the Europeans, at the very least it should require the food to be labeled so that consumers can individually make this choice. Moreover, there can then be some chance of removal from the market if, through the development of scientific assessment techniques and long-term studies, problems are discovered later.

Countries that have introduced mandatory labeling legislation for GM foods have done so to give their consumers a choice in selecting foods according to their comfort level.<sup>192</sup> Transparency can be ensured only by requiring labeling and traceability of food products derived from GM plants at all stages of production and distribution.<sup>193</sup> Realizing the potential of agricultural biotechnology in the United States and worldwide 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.<sup>194</sup> Indeed, FDA initially began investigating the

<sup>189</sup> FDA, Draft Guidance on Voluntary Labeling, *supra* note 131 (FDA's response after reviewing more than 50,000 written comments about the agency's policy regarding safety and labeling of bioengineered foods).

<sup>190</sup> *Id.*

<sup>191</sup> See *supra* note 118 and accompanying text.

<sup>192</sup> INTERNATIONAL LIFE SCIENCES INSTITUTE, DETECTION METHODS FOR NOVEL FOODS DERIVED FROM GENETICALLY MODIFIED ORGANISMS (Kevin Yates ed., 1999) (summary of a workshop held in June 1998).

<sup>193</sup> See The Non-GMO Report, EU tightens GM food labelling requirements, *supra* note 105.

<sup>194</sup> See David G. Victor & C. Ford Runge, *Farming the Genetic Frontier*, 81 FOREIGN AFF. 107 (2002); 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/uploadedfiles/Labeling\\_Trade\\_and\\_Genetically\\_Modified\\_Organi.htm](http://www.gefoodalert.org/library/admin/uploadedfiles/Labeling_Trade_and_Genetically_Modified_Organi.htm) [hereinafter Runge & Jackson, *Labeling, Trade, and*

use of voluntary labeling for GM products to ease tensions with trading partners such as the European Union.<sup>195</sup>

Industry has begun to respond as well to the perceived risks of biotechnology in food. Fearful of losing buyers, large food producers 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.<sup>196</sup> Frito-Lay made headlines when, in response to consumer worries, the company told its suppliers not to use genetically altered corn.<sup>197</sup> Additionally, 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 windborne pollen.<sup>198</sup>

In examining the regulatory options, it is important to acknowledge and evaluate the economic costs; however, mandatory GM labeling may not involve such prohibitive costs. A study by an agricultural economist at Oregon State University reported that, for other countries that label GM foods, the 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.<sup>199</sup> The analysis of these countries determined that the cost ranged from twenty-three 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 estimated costs for the more extensive GM labeling options under consideration in the United Kingdom, New Zealand, and Australia were calculated as \$3 to \$10 a year per person.<sup>200</sup> Moreover, the actual cost may be lower to the extent that product segregation, identity preservation, and labeling already are becoming routine for exporters to foreign markets where GM labeling is required.<sup>201</sup> 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.<sup>202</sup>

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 cares about the attribute. A government's choice about whether to require labeling is based in part on what proportion of their citizens

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*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).

<sup>195</sup> CRS REPORT, *supra* note 24 (citing *TDA Eyes Voluntary Label as Middle Ground in GMO Food Dispute*, FDA Wk., Mar. 26, 1999, at 3).

<sup>196</sup> Haslberger, *supra* note 73.

<sup>197</sup> Associated Press, *No Genetically Altered Corn, Frito-Lay Tells Suppliers*, SACRAMENTO BEE, Feb. 1, 2000, available at [http://www.biotech-info.net/frito\\_lay1.html](http://www.biotech-info.net/frito_lay1.html) (Frito-Lay accounts for two-thirds of PepsiCo sales).

<sup>198</sup> Sally Lehrman, *GM Backlash Leaves US Farmers Wondering How to Sell Their Crops*, 401 *NATURE*, Sept. 9, 1999, at 107.

<sup>199</sup> OSU Press Release, *supra* note 117. The entire text of the OSU 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>.

<sup>200</sup> *Id.*

<sup>201</sup> *Id.* As mentioned previously, as of the date of this study, 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. Because some U.S. food producers and exporters already separate genetically modified foods from the rest of the foods to comply with GM labeling requirements in effect in these nations, the incremental cost would be less.

<sup>202</sup> 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).

want information about the technology.<sup>203</sup> 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.<sup>204</sup> The time has come for the U.S. government to 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.

Such labeling could be either positive labels stating that “This product may contain GMOs”; or negative labels stating that “This product (or seed) contains no GMOs.”<sup>205</sup> In the past, for companies wanting to advertise products as non-GM, FDA has indicated that it would not allow labels like “GM-free,” “GMO-Free” or “biotech-free.” The agency reasoned that guaranteeing a product to be free of GM material is virtually impossible because to establish a threshold “would require methods to test for a wide range of genetic changes at very low levels in a wide variety of foods” and “such methods are not available at this time”; but stated that the labels could say the food was “not developed using bioengineering.”<sup>206</sup> In determining the requisite labeling, the U.S. government, particularly FDA, should study the effectiveness of 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. If the labeling requirements conform to a uniform international standard in their wording and content, the costs for industry in the global marketplace will be reduced.

For these goals to be attained there must be some form of positive labeling indicating the presence or possible presence of GMOs, in order to be an effective notification mechanism both for consumers in the United States and importers from abroad. Voluntary negative labeling alone will not be adequate. A mandatory positive labeling requirement also will target the appropriate segment of the industry. The costs of such labeling thus will be borne, at least in the first instance, by those in the industry who have benefited from GM technology. Some of these costs ultimately will be passed on to the consumer, but surveys show that the U.S. consumer finds this labeling to be important and the addition of this labeling is a choice supported by the citizenry.

As food companies adapt to changes in the regulatory climate, they will need to devise marketing strategies that work with labeling policies in promoting the safety and desirability of their products.<sup>207</sup> Thus, the most effective labeling scheme would include both mandatory labels indicating those products “made with GM ingredients” or that “may contain genetically modified ingredients,” as a necessary disclosure to consumers; and voluntary labeling for foods that are “not made with GM processes” or “not produced through bioengineering,” highlighting this feature as a positive marketing tool to consumers. Note that as consumer preferences shape market forces, the costs of these voluntary negative labels will be absorbed by the successful producers (i.e., factored in as increased sales). Indeed, this type of labeling already has been sought by

<sup>203</sup> 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).

<sup>204</sup> 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).

<sup>205</sup> Runge & Jackson, *Labeling, Trade, and Genetically Modified Organisms*, *supra* note 194 (advocating negative labels for GM foods).

<sup>206</sup> FDA, Draft Guidance on Voluntary Labeling, *supra* note 131 (“FDA does not have information with which to establish a threshold level of bioengineered constituents or ingredients in foods for the statement ‘free of bioengineered material.’”); see also 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](http://www.non-gmosource.com/FDA_disallows_GMO-free_label.php) (last visited May 13, 2006).

<sup>207</sup> Caswell, *supra* note 203, at 24.

the segments of the industry that would benefit from its marketing impact. FDA supports such labeling as long as it is truthful and not misleading.<sup>208</sup>

In labeling the presence of GMOs, a minimum threshold level may be determined so that a reasonably low percentage of accidental GMO presence may be allowed before invoking the requirement of a mandatory positive label.<sup>209</sup> This practical and scientifically feasible approach is reflected in EU Directive 2001/18/EC and differs from the "GM free" certification disfavored by FDA as misleading. Still, the requirement must be workable and enforceable through credible scientific assessment and testing.<sup>210</sup>

In addition to labeling, GM products should be subject to a rigorous system of pre- and postmarket monitoring. Testing does involve additional costs for the industry, but such testing, which FDA requires premarket in other areas such as food and color additives,<sup>211</sup> is necessary to protect the public. The National Research Council report discussed *supra* proposed postmarket surveillance to identify and monitor unanticipated compositional changes and health effects of all altered foods, 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 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.<sup>212</sup>

Once monitoring is mandated in the United States, scientists will focus their efforts on the development of appropriate means to detect and track GM foods and their components. In response to EU regulations, scientists have attempted to assess and improve reliable and sensitive methods for GMO detection.<sup>213</sup> Several of these methods need further refinement to surmount their limits (e.g., heating and other processes in food production can degrade DNA and lead to false-positive rates and disappearance of marker genes).<sup>214</sup> As scientific research on the long-term human health and environ-

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<sup>208</sup> See FDA, Draft Guidance on Voluntary Labeling, *supra* note 131:

The agency is providing the following guidance to assist manufacturers who wish to voluntarily label their foods as being made with or without the use of bioengineered ingredients. While the use of bioengineering is not a material fact, many consumers are interested in the information, and some manufacturers may want to respond to this consumer desire. The guidance was developed using information from the comments and from focus groups, as well as other resources, and is intended to help ensure that labeling is truthful and not misleading.

See also CFSAN, FDA, REPORT ON CONSUMER FOCUS GROUPS ON BIOTECHNOLOGY (Oct. 20, 2000), available at <http://www.cfsan.fda.gov/~comm/biorpt.html>.

<sup>209</sup> AARON, *supra* note 177, at 32.

<sup>210</sup> *Id.* See Council Directive 2001/18/EC, *supra* note 96, at art. 21, § 2.

<sup>211</sup> 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 FDCA, 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)).

<sup>212</sup> NRC SAFETY, *supra* note 3, at 3; see *supra* notes 66 to 71 and accompanying text.

<sup>213</sup> See, e.g., Ahmed, *supra* note 12 (discussing methods for GMO detection, including "protein- and DNA-based methods employing western blots, enzyme-linked immunosorbent 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 1, at 232.

<sup>214</sup> Ahmed, *supra* note 12 (proposing a tiered approach combining several methods of detection to counteract these limitations); Pan, *supra* note 1, at 230.

mental effects of bioengineered food progresses, the postmarket monitoring of products containing GMOs will be critical in tracing, in the event that it becomes necessary to withdraw such products from the market and food chain.

Of significant concern to 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.”<sup>215</sup> These changes in the storage and transportation structure would place added costs on the U.S. farm sector. In addition, according to the State Department, 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.””<sup>216</sup> 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 simple economic costs, even if the cost of labeling and segregating proves to be considerable. If these genetic modifications cannot be monitored effectively, a more extreme remedy such as a ban may be necessary.

## VI. CONCLUSION

The United States should adopt labeling requirements modeled after international law, choosing the vigilant approach regarding the use of GMOs in food in light of the unknown scientific effects and a number of initial harmful results. The point is not that all scientists agree, as would never occur, but that there are enough negative implications with regard to GMOs to question the relatively *laissez-faire* U.S. policy. When faced with significant scientific debate, the U.S. government should err on the side of caution, particularly when it involves something as critical as the U.S. food supply. That is the position Congress and FDA have taken in the past with food and color additives and irradiated food. This apparent inconsistency raises the query, why are these governmental units treating this type of food product differently?

In view of the scientific uncertainty, risk assessment is essential to determining who should bear the risk while identifying and quantifying those risks through responsible and appropriate scientific methods.<sup>217</sup> Particularly when considering the nonquantifiable risks, public safety and health considerations should prevail.

A comprehensive system of pre- and postmarket monitoring, enhanced testing, and appropriate labeling would realize benefits for all stakeholders. Implementing these measures would aid consumers by increasing the likelihood of informed decisionmaking, 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 and labeling, industry may benefit from more streamlined and timely approval for marketing in the United States with fewer obstacles from abroad.<sup>218</sup>

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<sup>215</sup> Stamps, *supra* note 48, at 7.

<sup>216</sup> *Id.* (quoting U.S. Dep’t of State, Fact Sheet, Frequently Asked Questions About Biotechnology (Jan. 22, 2001), <http://www.state.gov/e/eb/rls/fs/1142pf.htm>).

<sup>217</sup> See VED P. NANDA & GEORGE PRING, INTERNATIONAL ENVIRONMENTAL LAW & POLICY FOR THE 21ST CENTURY (Transnat’l 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 (Transnat’l Publisher 2003)).

<sup>218</sup> 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?*

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 also involve international trade policy and economic concerns beyond matters of science.<sup>219</sup> As a matter of international trade, the biotechnology industry must “accept the challenge of developing and regulating products that take into account regional diverse needs and concerns of consumers and specificities of the environment.”<sup>220</sup>

The United States must address these critical environmental concerns and consumer demands through legislation and regulation to improve risk management. Only then will it be possible for the biotechnology industry to introduce GMOs into worldwide markets without significant opposition.<sup>221</sup> If neither the U.S. government nor industry moves forward to attend to these risks in a meaningful way, increased public awareness and pressure from abroad may further impede international trade and, eventually, necessitate a ban of GMOs in the U.S. food supply. Thus, for the sake of the biotechnology industry, as well as the consumer, adopting this more cautious approach would offer GMOs the most viability in the long run to attain some of the initial promise and secure a future in food.

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*The Precautionary Principle, Genetically Modified Organisms, and Allowing Unfounded Fear to Undermine Free Trade*, 14 *TRANSNAT'L LAW*. 295 (2001).

<sup>219</sup> 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).

<sup>220</sup> Haslberger, *supra* note 73.

<sup>221</sup> 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).