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Comment

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Protesters in Seattle riot over them.[1] Farmers in France dump rotten vegetables at McDonald's to protest them.[2] Yet they are said to provide us with healthier, cheaper, produce grown with fewer pesticides – a boon for farmers, industry and consumers. Genetically modified foods are at the forefront of public attention. How they should be labeled is one of the most salient issues associated with them.[3] The number of genetically modified, or GM, foods in the marketplace has increased dramatically over the last few years, and consumers and industry leaders are split on the issue of what, if any, labels should be attached. Opinions are split between those who want mandatory labels for foods that have been genetically engineered or contain GM ingredients and those who do not want labels that identify the GM content of their foods.

This Note discusses the current distinctions between labeling requirements in the U.S. and Europe, and proposes a means for reaching a workable labeling protocol. Part I describes the distinct approaches taken by the U.S. and Europe for labeling GM foods. This section also describes the science involved in GM food products, such as techniques used in the creation of these products, and the distinctions between these products and foods created through traditional plant breeding methods. Part II analyzes the comparative strengths and weaknesses of the strict labeling requirements of the European

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1. *See* Michael Elliott, *The New Radicals*, NEWSWEEK, Dec. 13, 1999, at 36, 38.

2. *See* Jeffrey Kluger, *Bad Seeds: The Battle Heats up between the U.S. and Europe over Genetically Engineered Crops*, TIME INTERNATIONAL, Sept. 20, 1999, *available in* WL 25725566.

3. *See* Rob Hotakainen, *Farmers in Crossfire of Fight Over Labeling Genetically Altered Food*, STAR TRIB. MINNEAPOLIS, Nov. 13, 1999, at A1.

approach, and relaxed standards of the U.S. approach, including the respective effects on consumers, producers, and the biotechnology industry. It also discusses the growing difficulties in international trade resulting from these distinct approaches.

This Note proposes that the most appropriate method of resolving the labeling issue involves developing a new, international, voluntary labeling standard for products that have not been developed through genetic engineering techniques or do not contain genetically engineered ingredients. This system would strike a balance between the strict labeling requirements of the European system and the relaxed standards of the U.S. system.

I. BACKGROUND

A. GENETICALLY MODIFIED FOOD PRODUCTS

1. Scientific Background on Genetic Engineering in Agriculture

The practice of modifying plants for agricultural use is not new. Over 10,000 years ago agriculturalists worked to domesticate crops such as wheat and corn from wild varieties.[4] The process was revolutionized in the nineteenth century by the work of Gregor Mendel.[5] Based on his work, farmers and plant breeders began to selectively breed plants to produce crops with higher yields, enhanced disease resistance, and higher nutritional levels.[6] While traditional plant breeding

4. *See* Michael A. Whittaker, Comment, *Reevaluating the Food and Drug Administration's Stand on Labeling Genetically Engineered Foods*, 35 SAN DIEGO L. REV. 1215, 1218 (Fall 1998). For example, approximately 5,000 years ago farmers combined the genetic material from three different plants to create wheat. *See* Diter von Wettstein, *Perspectives for the Genetic Engineering of Plants for Agriculture, Horticulture and Industry*, 13 PLANT MOLECULAR BIOLOGY 313, 313 (1989).

5. In 1865, Gregor Mendel's experiments led to the discovery of genetic heredity. He discovered that by selectively breeding plants he could produce progeny with genes yielding desirable traits, or eliminate genes yielding unwanted characteristics. *See* Sara M. Dunn, Comment, *From Flav'r Sav'r to Environmental Saver? Biotechnology and the Future of Agriculture, International Trade, and the Environment*, 9 COLO. J. INT'L ENVTL. L. & POL'Y 145, 149 (Winter 1998).

6. *See id*. This has traditionally been accomplished through the development of hybrid plants, created by breeding two closely related varieties

methods have successfully developed new and improved plant varieties, these methods have several limitations. First, selective breeding is a somewhat "clumsy" and lengthy process. It may result in the addition of unwanted characteristics along with the desired ones.[7] Successfully developing a new line of plants that contain the desirable traits of their ancestors without the unwanted characteristics may require several years and numerous generations of cross-breeding.[8] Second, hybridization is also limited to closely related species, such as different strains of tomatoes.[9] Thus, hybridization cannot be used to transfer desirable characteristics between species, and may even prevent domesticated crops from being crossed with their wild ancestors. Third, hybrid plants often suffer from reduced vigor.[10] As a result, the desired characteristics are not passed on to subsequent generations, and producers cannot collect seeds from the plants for replanting the following season.

Advances in biotechnology have allowed researchers to overcome many of the weaknesses of traditional plant breeding methods. The cells of all organisms contain long strings of deoxyribonucleic acid, commonly referred to as DNA, which make up numerous genes, the basic units of heredity.[11] Genes function by causing the organism to produce specific proteins[12]

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to develop progeny with the desired characteristics, such as enhanced yields or disease resistance. *See id*. For example, by breeding a variety of tomato that is especially tasty but susceptible to disease with another variety of tomato that is not as flavorful but is more disease resistant, plant breeders can create a new line of tomatoes that possess the best qualities of both lines. *See* David J. Earp, Ph.D., Comment, *The Regulation of Genetically Engineered Plants: Is Peter Rabbit Safe in Mr. McGregor's Transgenic Vegetable Patch?*, 24 ENVTL. L. 1633, 1644 (Oct. 1994).

7. *See* Earp, *supra* note 6, at 1644. For example, the aforementioned tomato may end up with enhanced resistance to pests, but may also have reduced flavor when compared to the tasty original variety.

8. *See id.*

9. *See* INDUSTRIAL BIOTECHNOLOGY ASS'N, AGRICULTURE AND THE NEW BIOLOGY 1 (1987)).

10. *See* Natalie M. Derzko, Comment, *Plant Breeders' Rights in Canada and Abroad: What Are These Rights and How Much Must Society Pay for Them?*, 39 MCGILL L.J. 144, 148 (1994).

11. *See* Earp, *supra* note 6, at 1645 n.61 (citing OFFICE OF TECH. ASSESSMENT, U.S. CONGRESS, COMMERCIAL BIOTECHNOLOGY: AN INTERNATIONAL ANALYSIS 3 (1984)).

12. The information contained within a gene is expressed in an organism through the processes of transcription and translation. In the transcription of a gene, a messenger ribonucleic acid (RNA) copy of the DNA gene segment is produced. This copy is translated in an organism's cells to produce sequences

that confer particular characteristics upon an organism.[13] Researchers have utilized this knowledge to enhance agricultural products, allowing desired characteristics to be enhanced with much greater precision. Using recombinant DNA technologies, researchers are able to identify the particular gene that causes a desired characteristic and transfer it into the original variety without additionally transferring unwanted characteristics.[14] The precise nature of this technique also eliminates the need for lengthy periods of time for cross-breeding.[15] Another benefit is that genetic engineering allows researchers to introduce characteristics not only from closely related organisms, as in traditional plant breeding, but also from very different, unrelated plants, animals, or microorganisms.[16] Additionally, because the modification to the plant is much more precise than with traditional plant breeding, the plants do not possess the same reduced vigor of many hybrids, and the desired characteristic can be passed on to successive generations.[17]

2. Application of biotechnology to agricultural products

The use of GM crops has increased dramatically since 1996, when they first became widely available.[18] In 1998 one-third of the corn and 45% of the soybeans planted in the U.S. were genetically modified.[19] More than 4,500 GM plants have been tested, and at least 40 have passed government reviews.[20] Major crops such as GM cotton, corn, and potatoes are

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of amino acids that polymerize to form unique proteins. *See id*.

13. *See id*. at 1645 n.61 (citing BOARD ON AGRIC., NAT'L RES. COUNCIL, GENETIC ENGINEERING OF PLANTS: AGRICULTURAL RESEARCH OPPORTUNITIES AND POLICY CONCERNS 15-18 (1984)). For example, a particular protein may be an enzyme that catalyzes a specific biochemical reaction and causes a plant to be resistant to pests, or have a longer shelf life. *See id.*

14. *See* Earp, *supra* note 6, at 1645.

15. *See id*. For example, rather than having to breed several generations of hybrids to ensure that the desired characteristic is expressed, recombinant DNA techniques allow the gene to be expressed consistently and immediately, eliminating the need for this step. *See id.*

16. *See id*.

17. *See* Dunn, *supra* note 5, at 150.

18. *See* Sharon Schmickle, *Genetic Engineering of Foodstuffs Sows Debate Over Labeling: Advocates of Labeling Say Not Enough Is Known About The Effects Of Biotechnology*, Oct. 18, 1999, STAR TRIB. MINNEAPOLIS, at A1.

19. *See id*.

20. *See* Kluger, *supra* note 2.

currently being produced commercially.[21] As a result of this widespread use, as much as 70% of processed foods contain GM components.[22] The rapid increase in use of GM crops is largely due to the benefits they provide producers and consumers.

Researchers have applied these techniques to agriculture using two primary techniques: enhanced seed systems and transgenic seeds.[23] Enhanced seed systems are those where a seed and an herbicide are designed to work together,[24] while a transgenic seed is one modified with the inclusion of a gene from another species.[25] Both enhanced seed systems and transgenic crops benefit producers by providing greater yields with the use of fewer herbicides or pesticides. For example, because of their resistance to Roundup Ultra herbicide, genetically modified Roundup Ready soybeans allow producers to control weeds with significantly fewer herbicides than are required for standard soybeans, reducing production costs and limiting exposure to a variety of herbicides. Industry advocates

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21. *See* Peter Fritsch et al., *Seed Money: Huge Biotech Harvest is a Boon for Farmers - And for Monsanto Co.*, WALL ST. J. EUR., Oct. 28, 1996, at A1.

22. *See* Schmickle, *supra* note 18.

23. *See* Dunn, *supra* note 5, at 150.

24. *See id*. Monsanto's Roundup Ready soybeans are the leading example of an enhanced seed system. *See id.* Monsanto manufactures Roundup Ultra, a broad-spectrum herbicide (i.e., one that kills plants indiscriminately rather than targeting a particular variety of plant). Roundup contains glyphosate, a chemical that kills plants by inhibiting their nutrient uptake. Roundup Ready soybeans are glyphosate-resistant because they have been genetically engineered to code for an alternate nutrient uptake system. This resistance allows farmers to apply Roundup to the entire crop, killing undesirable weeds but not harming the soybean crop. *See id.*; s*ee also Roundup Sure Shot Foam Weed and Grass Killer: FAQ's*, (visited Mar. 8, 2000) <http://www.roundup.com/questions/faqshot.html#9>.

25. *Bacillus thuringiensis* corn varieties (Bt corn), offered by nearly all major seed suppliers, are a leading example of transgenic seeds. *See* Dunn, *supra* note 5, at 151. These corn varieties have been genetically modified to provide resistance to the European corn borer and other insect pests through the inclusion of a gene from the soil bacterium *Bacillus thuringiensis*. The European corn borer has an enzyme that interacts with the *Bacillus thuringiensis* protein to form a new protein that destroys the lining of the borer's digestive tract. *See id.* at 151 (citing *YieldGard Corn Hybrids Can Help Recover Lost Income*, HIGH PLAINS J., Feb. 17, 1997, at 9-A). Bt bacteria have been used in soil or foliar insecticides by gardeners and organic producers for over 30 years. *See id.* at 151 (citing *Golden Harvest to Offer Monsanto's YieldGard Gene* (Sept. 17, 1996) <http://www.monsanto.com/MonPub/InTheNewsReleases/96-09-7GoldenHarvest.html>). By splicing the Bt gene into corn, researchers have been able to confer the insect-resistant properties of the bacterium to corn plants. *See id.* at 151.

also argue that Roundup Ultra is beneficial because of its low toxicity to animals and its short duration on the ground.[26] Because of its resistance to insect pests, Bt corn, another GM plant, allows producers to minimize the application of insecticides to corn crops, reducing the costs and health risks associated with insecticide use.[27]

3. Concerns Arising From the Use of Genetically Modified Foods

Despite these benefits, not everyone is convinced of the purported benefits of GM foods. Concerns over health issues, potential environmental harms, and unknown aspects of genetically modified foods and agricultural products have produced a backlash against the widespread use of these products.[28] Genetically engineered foods may pose health risks not associated with similar foods created through traditional plant breeding mechanisms. The actual addition of DNA to a plant does not itself pose any threat; DNA is a natural constituent of any food,[29] and the DNA inserted into a plant's genome becomes "an integral part of its genetic information," indistinguishable from the other DNA in the plant.[30] Rather, the health concern associated with these plants arises from the changes in proteins coded for by the genetic modification, which can cause unexpected allergic reactions for people who normally would not have an allergy to the food.[31] Genetic modifications that trigger these unexpected allergies arise through any of several changes to a plant's genetic code.[32] A GM plant may contain an allergenic protein not normally found

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26. *See* Whittaker, *supra* note 4, at 1219 n.24 (citing Peter R. Day, *Genetic Modification of Plants: Significant Issues and Hurdles to Success*, 63 AM J. CLINICAL NUTRITION, 651S, 653S (1996)).

27. *See* Tom Morgan, *Bt Corn Gives Cost-Effective Control*, FARM CHEMICALS 98, 99 (Jan. 1997).

28. *See* Kluger, *supra* note 2.

29. *See* Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,990 (1992).

30. Food Labeling; Foods Derived From New Plant Varieties, 58 Fed. Reg. 25,837, 25,839 (1993).

31. *See* Whittaker, *supra* note 4, at 1221. Note that food allergies can be particularly serious. Some reactions to food allergies include asthma, rhinitis, dermatitis, urticaria, and anaphylaxis. Only avoiding the threatening food can prevent these reactions. *See id*. at 1221 n.33 (citing E.R. Pearl, *Food Allergy*, *in* 1 LIPPINCOTT'S PRIMARY CARE PRACTICE 154 (1997)).

32. *See id*. at 1221.

in the plant. For example, a biotech company inserted genetic material from the Brazil nut into soybeans in an effort to increase the amino acid levels in the beans.[33] However, the modified soybeans began producing Brazil nut allergens in addition to the increased amino acids.[34] Genetic modifications may also increase the levels of a normal protein in a food to the point where it may trigger an allergy.[35] Modifications may also eliminate proteins in a food, increasing the relative proportion of other proteins to the point where they could trigger an allergic reaction.[36] Moreover, genetic modifications may also introduce novel proteins that are new to food products in general, making potential allergenic reactions to the food completely unpredictable.[37]

Opponents of genetically modified crops also cite a variety of environmental concerns. Some fear that the overuse of genetically modified seeds such as Bt corn may cause insects to develop resistance to the toxins produced by Bt corn.[38] Although experiments have not yet demonstrated that corn borers or other insects are developing resistance, growers have been advised to plant at least 20% of their crop with non-Bt corn to prevent development of resistance.[39] Another environmental concern is that the modified gene will escape into closely-related wild plant populations.[40]

Finally, others are concerned about the unknown aspects of GM foods. Although scientific analyses have not identified negative effects from consuming GM foods, this does not mean that they do not exist.[41] Scientific methods are slow and

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33. *See* Kluger, *supra* note 2.

34. *See id*. This is not the only example of the transfer of potential allergens. In 1993, the FDA acknowledged that several experimental plants under development contained genes from foods known to be commonly allergenic, such as fish or tree nuts. *See* Food Labeling; Foods Derived From New Plant Varieties, 58 Fed. Reg. at 25,840.

35. *See* Kluger, *supra* note 2.

36. *See id*.

37. *See id*.

38. *See* J.F. WITKOWSKI ET AL., BT CORN & EUROPEAN CORN BORER, at 9 (K.R. Ostlie et al. eds., 1997).

39. *See id*. at 11.

40. *See* Whittaker, *supra* note 4, at 1220. For example, if Roundup Ready soybeans were to breed with closely-related weeds, the gene conferring resistance to Roundup Ultra herbicide could be introduced to the weed population, creating herbicide-resistant weeds. *See id.*

41. *See* Schmickle *supra* note 18. Even opponents of GM foods acknowledge that "[t]here is no evidence that the genetically engineered foods

deliberate, and require statistically valid data, technically sound methods, and careful peer review before an idea or finding can be considered valid. As a result, findings that an item or material is harmful can be delayed for years, resulting in widespread exposures to dangerous or harmful elements. One need only consider the examples of DDT[42] or cigarettes[43] to be reminded of the fact that science does not always keep up with risks and dangers.

Because of these concerns, opponents of the widespread use of genetically modified foods have argued for labeling requirements for foods that have been genetically modified.[44]

B. LABELING REGULATIONS IN THE UNITED STATES

1. Coordinated Framework

The federal government established a framework for the regulation of biotechnology in 1984.[45] The Reagan administration recognized its responsibility to address the concerns associated with biotechnology, but also wished to "minimize the uncertainties and inefficiencies that can stifle

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now on the market present safety problems." *Id.* However, they argue that these products have not yet been proven safe, either. *See id*.

42. The pesticide DDT was widely used without concern for its environmental impact until Rachel Carson galvanized public awareness of its impact on wildlife populations in her book *Silent Spring*. *See* RACHEL CARSON, SILENT SPRING (1962).

43. Consumers were not informed of the connection between smoking and lung cancer until the 1950s. *See* James C. Thornton, Comment, *The Liability of Cigarette Manufacturers for Lung Cancer: An Analysis of the Federal Cigarette Labeling and Advertising Act and Preemption of Strict Liability in Tort Against Cigarette Manufacturers*, 76 KY. L.J. 569, 570 (1988). Tobacco company advertisements in the 1930s encouraged consumers to believe that their products promoted health. *See* Wegman, *Cigarettes and Health: A Legal Analysis*, 51 CORNELL L.Q. 678, 680 (1966), *cited in* Thornton, *supra* this note, at 571 n.18. In 1936 Camel introduced the idea of a "T-Zone," "promising the smoker that both his taste and his throat would react favorably to Camel's mildness." *Id*. The statement that "More Doctors Smoke Camels" also implied the health aspects of Camel cigarettes. *See id*.

44. *See, e.g.* Greenpeace Int'l, *We Want Natural Food!* (visited Oct. 21, 1999) <http://www.greenpeace.org/~geneng/structur/food.htm>.

45. *See* Proposal for a Coordinated Framework for Regulation of Biotechnology, 49 Fed. Reg. 50,856 (1984) (reporting establishment, conclusions, and regulatory proposals of an interagency working group proposed by the White House Cabinet Council on Natural Resources and the Environment in April 1984).

innovation and impair the competitiveness of U.S. Industry."[46] An interagency working group evaluated existing laws for the regulation of products developed through traditional means and determined that "for the most part these laws as currently implemented would address regulatory needs adequately" for GM products.[47] Based on this finding, the administration chose to regulate biotechnology through the "Coordinated Framework," a set of guidelines for interagency use that utilized existing statutes and agencies, instead of enacting a broad new statute or establishing a new agency.[48] Thus, the FDA's labeling responsibility under the Federal Food, Drug, and Cosmetic Act (FFDCA), was exercised through the Coordinated Framework to address labeling requirements for GM foods.[49]

2. FDA Approaches to Labeling Requirements for Genetically Modified Foods

The FDA's approach to labeling is consistent with the policy goals described in the establishment of the Coordinated Framework, i.e. addressing safety concerns while minimizing the stifling effect of regulation on the biotechnology industry. In 1992, the FDA issued a statement of policy on foods derived from new plant varieties to discuss the safety and regulatory status of plants derived by genetic engineering.[50] Most significantly, the FDA stated that it does not consider the method by which a new plant variety is created to be material information.[51] The FDA believes that new methods and techniques for developing plant varieties are "extensions at the molecular level of traditional methods,"[52] and it "is not aware of any information showing that foods derived by these new methods differ from other foods in any meaningful or uniform way."[53] The FDA does not believe that foods produced through

46. *Id*. at 50,857.

47. *See* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,303 (1986).

48. *See id*.

49. *See id.*

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

51. *See id*. at 22,991.

52. *Id*.

53. *Id*.

biotechnology present safety risks or concerns greater than those derived from traditional plant breeding methods. Consequently, the FDA decided it would not require per se labels to alert consumers to the presence of GM ingredients in their food.[54]

However, there are two exceptions to this general rule. First, the FFDCA requires producers to describe products by their common and usual name, or in the absence thereof, by an appropriately descriptive term.[55] Thus, a label would be required if, as a result of genetic modifications, a food differed from the traditional counterpart to the extent that the common name was no longer applicable.[56]

Second, the FFDCA also requires producers to reveal all facts that are material in light of representations made or suggested by labeling or "with respect to consequences which may result from use."[57] Foods such as milk, eggs, fish, crustacea, tree nuts, wheat and legumes commonly cause allergic reactions. If a gene from one of these foods were spliced into a food to which people normally were not allergic, the FDA would require a label if the inserted gene were known to cause an allergic reaction.[58] If the producer did not know if the inserted gene were one that triggers food allergies, the FDA considers it prudent practice to assume that the transferred gene would confer allergic properties to the new food.[59] According to the industry guidance section of the FDA's policy statement, the agency will work with producers in situations like these to determine labeling requirements on a case-by-case basis.[60]

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54. *See id*.

55. *See* Identity Labeling Of Food In Packaged Form, 21 C.F.R. § 101.3 (1999).

56. *See* Statement Of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. at 22,991.

57. *Id*. (citing 21 U.S.C. §§ 321(n), 343(a)).

58. *See id*. at 22,987.

59. *See id*. For example, if a gene from a peanut were inserted into a tomato, and there was not sufficient information to prove that the peanut gene did not code for an allergen, FDA would require a label to warn consumers who are allergic to peanuts to avoid the tomato.

60. *See id*. at 22,998.

3. First Amendment Issues Regarding Compulsory Labeling Requirements

In addition to the goals and policies set forth in the Coordinated Framework, labeling requirements for genetically modified food products are subject to First Amendment constraints. The Second Circuit addressed the issue of labeling requirements for foods derived through biotechnology in a 1996 opinion.[61] The state of Vermont had enacted a statute that required retailers to provide notification to consumers if milk they sold had been derived from cows treated with recombinant bovine somatotropin (rBST).[62] Retailers were required to post a sign in the dairy case, or post a blue shelf label, or attach a blue sticker to the milk containers.[63]

Several dairy manufacturers sued, asserting that the labeling requirement was unconstitutional, and moved for injunctive relief to enjoin enforcement of the statute.[64] The federal district court refused to grant the injunction,[65] but on review the appellate court held that the labeling requirement violated the appellants' First Amendment rights by requiring them "to speak when they would rather not."[66] The court applied the Central Hudson four-prong test for commercial speech,[67] and determined that Vermont had not asserted an interest substantial enough to establish the second prong of the

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61. International Dairy Foods Ass'n v. Amestoy, 92 F.3d 67 (2d Cir. 1996).

62. Vt. Stat. Ann. tit. 6, § 2754 (1993) (repealed). Bovine somatotropin (BST) is a natural cattle growth hormone. Recombinant BST (rBST) is a genetically modified version of the hormone which, when injected into dairy cows, increases milk production of up to 20%. *See* Whittaker, *supra* note 4, at 1227 n.72. FDA approved the use of rBST in 1993, and declined to require labeling of products derived from cows receiving the hormone on the grounds that the milk they produce is indistinguishable from that produced by untreated cows. *See* International Dairy Foods Ass'n, 92 F.3d at 69.

63. *See* 92 F.3d at 70.

64. *See id*.

65. *See id*.

66. *Id*.

67. The Supreme Court has applied a four-prong test to determine whether a government restriction on commercial speech is constitutional. Under this test, a reviewing court must determine (1) whether the speech regards lawful activity and is not misleading; (2) whether government has a substantial interest; (3) whether the labeling law directly serves the asserted interest; and (4) whether the labeling law is no more extensive than necessary. *See* Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n, 447 U.S. 556, 566 (1980).

test.[68] Although the court was sympathetic to the desire of Vermont consumers to know which products were derived from treated cows, and believed that consumer desires were sincere, it held that "consumer curiosity alone is not a strong enough state interest to sustain the compulsion of even an accurate, factual statement."[69] The court also expressed concern that if consumer interest alone were sufficient to warrant compulsory labeling, states could require producers to disclose all aspects of their production measures, such as what grains cows are fed, or with what medicine they are treated, and suggested that concerned consumers should search out products by producers who voluntarily reveal such information.[70]

4. Developments in U.S. Labeling Policy

Although the FDA considers its 1992 statement of policy its "working policy," it contends that a policy to address the rapidly evolving biotechnology field should be flexible enough to permit modifications needed to address new innovations or concerns.[71] The agency requested data and information on its labeling policy in 1993, specifically with regard to required or voluntary labeling regimes.[72] First, it sought input regarding whether all foods developed using genetic engineering techniques should be required to be labeled as such.[73] Second, the FDA sought information regarding whether labels describing the source of introduced DNA should be required.[74]

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68. *See* 92 F.3d at 73.

69. *Id*. at 74.

70. *See Id*.

71. *See* Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, *FDA's Policy for Foods Developed by Biotechnology*, AMERICAN CHEMICAL SOCIETY SYMPOSIUM SERIES NO. 605, at 3 (1995), *available at* <http://vm.cfsan.fda.gov/~lrd/biopolcy.html> (visited Oct. 21, 1999).

72. *See* Food Labeling; Foods Derived From New Plant Varieties, 58 Fed. Reg. 25,837, 25,839 (1993).

73. Specifically, FDA sought information on how "genetic engineering" should be defined; what characteristics of food from genetically engineered plants distinguish them from other foods; what labeling should be required for fresh food or processed food; what labels should be required for foods derived from multiple plant varieties; what text is appropriate for such labels; and how a labeling system could be enforced. *See id*. at 25,839-40.

74. FDA sought information regarding criteria that should be used as a basis for source labeling; the relevancy of genes common between plants, animals, and microorganisms; if labels should be required for foods derived

Third, the FDA sought information regarding under what circumstances ingredient labeling would be appropriate.[75] Fourth, the FDA sought information on how labeling for food allergies could be accomplished for whole foods, processed foods, and fabricated foods.[76] Fifth, the FDA sought information regarding practical difficulties and economic impacts of labeling genetically engineered foods.[77]

Following the publication of the FDA's 1992 policy statement, the Office of Technology Assessment of the U.S. Congress published a report that addressed voluntary labeling standards.[78] The report suggested that Congress could encourage niche markets to satisfy consumers who are willing to pay higher prices for food that has been labeled as not containing genetically engineered food.[79] The FDA sought information on the proposed niche markets, such as whether they would support consumer needs; whether they would supply fresh or processed foods, or both; what standards should apply to these markets; and whether voluntary labeling would imply that these products are better.

Although the FDA has not yet published answers to these questions, officials have hinted that a new labeling system is being contemplated,[80] and news media have reported that such a system is currently being developed.[81]

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from plants containing introduced human genes; what text is appropriate for these labels; and how the system could be enforced. *See id*. at 25,840.

75. FDA sought information on whether there is a scientific basis to distinguish between constituents added through genetic engineering and those added through traditional breeding methods; what criteria should be used to classify constituents as native or added; and whether labels should be required on whole foods, or processed foods. *See id*.

76. FDA acknowledged that consumers were particularly concerned that point of sale labels would not protect them from hidden allergens in foods served at restaurants or social functions. *See id*.

77. FDA sought information on the feasibility and cost of labeling throughout the food chain genetically engineered grains, vegetables, or foods derived from genetically engineered plants. *See id*.

78. *See id*. at 25,841 (citing OFFICE OF TECH. ASSESSMENT, U.S. CONGRESS, A NEW TECHNOLOGICAL ERA FOR AMERICAN AGRICULTURE (1992)).

79. *See id*.

80. *See* Dan Glickman, How Will Scientists, Farmers, and Consumers Learn to Love Biotechnology and What Happens If They Don't?, Remarks as Prepared for the National Press Club (July 13, 1999), *available at* <http://www.usda.gov/news/releases/1999/07/0285> (visited Sept. 12, 1999).

81. *See Genetic Food Labels Reportedly Ok'D*, CHI. TRIB., Sept. 24, 1999, at 1.

C. EUROPEAN APPROACHES TO GM FOODS

1. Cultural Distinctions

European consumers have a different attitude toward GM food products than Americans. They are generally much less approving of these foods, and the most vehement opponents have even staged protests against them. Farmers in France recently dumped manure and rotting vegetables in front of McDonald's restaurants to protest the pervasiveness of GM foods.[82] An alliance of European Parliament Greens and EuroCommerce, an organization that represents retail, wholesale, and trade interests, claimed that Europeans were concerned with GM products because they were ill-informed about them, and launched a campaign in 1996 to boycott products made from GM soybeans.[83] This opposition to GM foods is not limited to special interest groups; polls of Europeans consistently indicate opposition to the use of GM foods.[84]

This attitude is partially explained by European cultural attitudes toward food that differ significantly from those of U.S. citizens.[85] European culture favors traditional foods and minimal processing.[86] For example, European consumers and regulators approve of products, such as fresh cheese derived from raw milk and traditional cured meats, that are typically

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82. *See* Kluger, *supra* note 2.

83. *See* Nyaguthii Chege, Comment, *Compulsory Labeling of Food Produced From Genetically Modified Soya Beans and Maize*, 4 COLUM. J. EUR. L. 179, 180 (1998) (citing *EU/Biotechnology-EuroCommerce and the EP Greens Urge EU Consumers to Boycott American Genetically Modified Soya Bean Products Until They Are Adequately Labeled*, AGENCE EUR., Sept. 28, 1996, *available in* LEXIS, Intlaw Library, ECnews File).

84. According to an Angus Reid poll for *The Economist*, the European public is deeply suspicious of GM foods. The poll indicated that 80% of Germans are less likely to purchase a food if it were genetically modified. The English and French were only slightly less opposed to GM foods. *See* Blech: A Poll on Genetically Modified Food, ECONOMIST, Jan. 15, 2000, at 69.

85. *See* Marsha A. Echols, Comment, *Food Safety Regulation in the European Union and the United States: Different Cultures, Different Laws*, 4 COLUM. J. EUR. L. 525, 528 (1998).

86. *See id*. Many researchers believe this attitude is derived from centuries of experience. *See* Mireille Vincent-Cassy, *Sur les Traces*, *in* MILLE ET UNE BOUCHES: CUISINES ET IDENTITES CULTURELLES 12 (Sophie Bessis ed., 1995), *cited in* Echols, *supra* note 84, at 528.

rejected by U.S. consumers and regulators as unsafe.[87] "Regulators and consumers believe that these practices and the foods they produce are safe and, importantly for most European consumers, close to nature and naturalness,"[88] based on centuries of experience instead of laboratory science.[89] While Europeans are accepting of time-honored, traditional methods of food production, they are skeptical of new techniques.[90] For example, "genetically engineered corn and soybeans created well-publicized opposition to this new technology and demands for segregation and labeling."[91]

2. EU Regulatory Approach

These different attitudes are manifested in the regulatory regime applied to GM foods. The European Union first addressed the issue of genetically modified organisms (GMOs) in a 1990 directive regarding the deliberate release of GMOs into the environment.[92] The directive specifically addressed live organisms, and was virtually silent on labeling issues.[93]

This directive was amended in 1997 to include mandatory labeling requirements.[94] The modification requires that all GM products placed into the market be labeled. The product must include a label or documentation to indicate that it contains or consists of GMOs, or if it contains a mixture with non-genetically modified organisms, it must contain information addressing the possibility that it contains GMOs. The label must identify the name of the product and names of the GMOs contained therein, and contain instructions to avoid the unintentional release of the GMOs into the environment.[95]

The EU adopted a comprehensive regulation of novel foods in 1997.[96] This regulation applies to a variety of novel foods

87. *See* Echols, *supra* note 85, at 529.

88. *Id.* at 528.

89. *See id*.

90. *See id*.

91. *Id*.

92. Council Directive 90/220/EEC on the Deliberate Release into the Environment of Genetically Modified Organisms, 1990 O.J. (L 117) 25.

93. *See id*.

94. Commission Directive 97/35/EC Adapting to Technical Progress for the Second Time; Council Directive 90/220/EEC on the Deliberate Release into the Environment of Genetically Modified Organisms, 1990 O.J. (L 169) 72.

95. *See id*.

96. Regulation (EC) No. 258/97 of the European Parliament and of the

and food products, including foods or food ingredients not in existence before the adoption of the regulation that: (a) consist of GMOs as defined in a prior regulation; (b) are produced from, but do not contain GMOs; (c) have a new or intentionally modified molecular structure; (d) consist of or are isolated from microorganisms; (e) consist of or are isolated from plants or food ingredients isolated from animals; and (f) were produced through a novel process that affects their nutritional value, metabolism, or level of undesirable substances.[97] This broad list of foods is subject to a panoply of labeling requirements. These foods must contain a label to inform consumers of: (a) characteristics such as composition, intended use, or nutritional value that renders a novel food no longer the equivalent of the existing food; (b) the presence of materials with health implications for certain segments of the population; (c) the presence of materials that give rise to ethical concerns; (d) the presence of a GM organism.[98] Because this regulation applies only to foods introduced after it was passed, it did not regulate foods introduced before it was enacted. This left genetically modified corn and soybeans unregulated. The EU closed this exception with regulation 97/1813,[99] which was superseded by regulation 98/1139.[100] As a result, virtually all products in the European marketplace that contain GM ingredients, or were derived from GM plants or other sources, are subject to some form of labeling requirement.

II. ANALYSIS

Regulators in the U.S. and Europe have taken distinct approaches to labeling GM foods. The U.S. approach

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Council of January 27, 1997 Concerning Novel Foods and Novel Food Ingredients, 1997 O.J. (L 043) 1.

97. *Id.* at 2. The regulation does allow an exception for foods in this last category that are obtained by traditional breeding practices and have a history of safe food use, and allowed a broad exception for food additives, flavorings, and extraction solvents. *See id*.

98. *Id.* at 5.

99. Commission Regulation (EC) No. 1813/97 of September 19, 1997 Concerning the Compulsory Indication on the Labeling of Certain Foodstuffs Produced from Genetically Modified Organisms of Particulars Other Than Those Provided for in Directive 79/112/EEC, 1997 O.J. (L 257) 7.

100. Council Regulation (EC) No. 1139/98 of May 26, 1998 Concerning the Compulsory Indication of the Labeling of Certain Foodstuffs Produced from Genetically Modified Organisms of Particulars Other Than Those Provided for in Directive 79/112/EEC, 1998 O.J. (L 159) 4.

represents a minimalist, "hands off" labeling regime, while the European approach is an all-encompassing, intensive system. Each of these approaches has strengths and weaknesses, but neither adequately addresses the broad range of issues associated with labeling GM foods.

A. CRITICISM OF CURRENT APPROACHES

1. Strengths and Weaknesses of the U.S. System

The hands-off labeling standard utilized in the U.S. has numerous strengths. It is based on scientific analysis, and it has benefits for farmers, producers, consumers, and the biotechnology industry. The strengths of this standard are countered, though, by weaknesses inherent in reliance on scientific analysis. As a result, it is not adequate to address the concerns raised by opponents of GM foods.

The current U.S. labeling requirements are based on scientific analysis of known risks.[101] The FDA's opinion, based on known scientific information, is that GM foods are not materially different from food produced through traditional breeding methods.[102] According to the FDA, Roundup Ready soybeans are still soybeans, and Bt corn is still corn. Both traditional breeding methods and genetic engineering techniques develop new plant varieties by including different genes; new methods simply allow more specificity and a greater variety of modifications than traditional methods.[103] Situations where labels are required, such as when a known allergen is transferred to a food that is not normally allergenic, are based on scientific determinations.[104] Rather than following the "precautionary principle" and alerting consumers to unknown effects, the FDA's requirements represent an evaluation of what is safe for consumers based on the best available scientific information.

The FDA's current labeling requirements benefit farmers and producers. First, by not distinguishing GM crops from non-GM crops, farmers are free to produce either variety or some combination thereof. Thus, if GM plants are cheaper to

101. *See supra* Part I.B.2.
102. *See supra* Part I.B.2.
103. *See supra* Part I.B.2.
104. *See supra* Part I.B.2.

produce because they require fewer pesticides or herbicides, or because they produce greater yields than non-GM plants,[105] farmers are better able to realize profits without worrying whether they will be subject to the burdens of a labeling requirement. Also, because they are not considered different from non-GM crops, farmers are not required to segregate the GM and non-GM crops at harvest time.[106] This carries through to food processors: they are not forced to address whether or not the food they are processing contains ingredients derived from GM plants, which is beneficial given the prevalence of foods derived from GM ingredients in the U.S. marketplace.[107] A labeling requirement would require processors to keep detailed records of these foods in order to comply with these standards.[108] Such a system could be burdensome and expensive.

Consumers also benefit from the current FDA labeling requirement. First, they are provided with warnings in situations where they are needed based on proven or suspected allergic reactions.[109] A person with an allergy to peanuts is warned under the current system if the GM food he or she would eat contains a gene transferred from an allergenic source, such as nuts or fish.[110] Second, the current regulations also prevent unwarranted consumer fears of GM foods. Labels are usually associated with foods or products that are health risks, and are typically not required to alert consumers when something is safe. Most labels warn consumers of potentially dangerous situations, such as warnings about health risks associated with cigarettes, or about safety concerns associated with automotive airbags and infant seats. The principles behind genetic engineering are technical and complex, and are not well understood by most consumers.[111] As a result, they

105. *See supra* Part I.A.2.

106. This is especially relevant since farmers growing Bt corn are advised to plant a percentage of their field with non-GM corn. *See supra* note 37.

107. These include not only products such as fresh tomatoes, but also processed foods ranging from corn muffins to soft drinks. *See* Kluger, *supra* note 2.

108. In order to ensure that the foods used in their products were properly labeled, producers would need to carefully track each ingredient back to the original source, i.e., the seed producer, to determine whether or not it was produced through genetic engineering processes.

109. *See supra* Part I.B.2.

110. *See supra* Part I.B.2.

111. *See* Thomas J. Hoban, *Anticipating Public Reaction to the Use of*

may fear that foods created through these new processes will harm them in some unforeseen way.[112] Human beings have been genetically modifying agricultural products for thousands of years, and while modern genetic engineering techniques are distinct from traditional methods, they perform essentially the same task, albeit in a more efficient and effective manner.[113] Most consumers are not aware of this, however, and if presented with a choice between a product labeled as containing GM food and one without such a label, they would probably choose the unlabeled item. An unsubstantiated concern may lead them to purchase an item that will rot more quickly, or was produced using greater quantities of herbicides or pesticides than a comparable GM product.[114]

Of course, the biotech industry stands to benefit the most from the current labeling requirements. Because the FDA has not distinguished GM and non-GM plants,[115] it has ensured that GM foods will readily assimilate into the market. Everyone has to eat, and consumers will keep eating GM foods if they cannot distinguish them from non-GM foods. As a result, the industry is free to pursue new developments and patents without the fear that there will be no market for them. Because the current standard does not give consumers a chance to reject GM foods, the current labeling standard allows biotechnology companies to continue development of GM foods without fear that consumers will reject them.

There are, however, some weaknesses to the FDA's approach. The biggest weakness is that it does not provide consumers with the full knowledge that they may want regarding their food supply.[116] Certain consumers have reasons to avoid GM foods. For example, under the current system, a

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Genetic Engineering in Infant Nutrition, 63 AM. J. CLINICAL NUTRITION 655S at 658S-59S, *cited in* Whittaker, *supra* note 4, at 1222-23.

112. The "Frankenfood" moniker associated with GM foods is a perfect example of this. This term has been widely used by Europeans critics of GM foods. *See, e.g.,* Kenneth Klee*, Frankenstein Foods?*, NEWSWEEK, Sept. 13, 1999, at 33, 33. In a way, the comparison to Frankenstein's monster may actually have a little merit. Contrary to common knowledge, the "monster" created in Mary Shelly's novel was not a dim-witted beast, but an articulate, well-read, and quite misunderstood creation. *See* MARY SHELLY, FRANKENSTEIN (1818). Of course, the GM foods described in this article will not come to life and kill human beings should they ultimately be rejected.

113. *See supra* Part I.A.1.

114. *See supra* Part I.A.2.

115. *See supra* Part I.B.2.

116. *See supra* Part I.B.2.

novel protein introduced for the first time into a consumer product would not require a label.[117] Although this protein may not cause an allergic reaction in most consumers, those who are sensitive to foods or are prone to food allergies would consume it without having means to know whether it is safe. Of course, if allergenic characteristics are discovered in the food, a label would be required,[118] but this would be a reactionary response, rather than a proactive step to allow consumers to avoid the food in question. Other consumers concerned with the environmental issues associated with GM crops[119] may simply want to avoid supporting the market for them. Under the current labeling standard, these consumers have no way of knowing if the food they are purchasing contains GM products.[120]

The FDA's reliance on established scientific knowledge could also be considered a weakness. Because this approach is based on known risks, it is reactionary, rather than precautionary. Although scientific research has not yet discovered potential harms associated with these foods, this does not mean they do not exist;[121] unknown or yet-undiscovered risks may indeed be associated with these foods. Current FDA labeling requirements do not alert consumers to the presence of GM foods, and consumers have no way to search out products that do not contain them.[122] Because GM foods have already become so prevalent, if concerns are later discovered through scientific analysis, a widespread exposure would have already occurred before consumers were alerted.

2. Strengths and Weaknesses of the European System

The European labeling requirements also have both positive and negative aspects. The biggest advantage of this system is that the broad labeling requirements and the broad categories of foods to which they apply provide consumers with detailed information regarding the origin of their food.[123] This allows consumers to make informed decisions regarding which

117. *See supra* Part I.B.2.
118. *See supra* Part I.B.2.
119. *See supra* Part I.A.3.
120. *See supra* Part I.B.2.
121. *See supra* note 41 and accompanying text.
122. *See supra* Part I.A.3.
123. *See supra* Part I.C.2.

food they wish to buy or avoid. Thus, consumers who wish to avoid GM food consumption are able to do so.

Despite this benefit, there are several weaknesses with this system. First, consumers who have little to fear about GM foods may avoid healthy, tasty, fresh foods that are cheaper to produce and involve the use of fewer herbicides or pesticides simply because the food has a GM label. This is especially relevant in Europe, where consumers have a preference for foods produced through traditional means.[124] Even traditional foods produced through genetic engineering, such as cheese produced by cows treated with rBST,[125] or produce such as Roundup Ready soybeans[126] or Bt Corn,[127] are likely to be shunned by consumers because of the label.

If GM foods do find a home in the European marketplace, the broad labeling requirements could result in confusion over what products could actually harm certain sections of the population. Overly broad labeling requirements may actually make it more difficult to distinguish foods that have been modified and contain an allergen; this information could simply get lost in the required label. The European regulation requires labels to inform consumers of composition, intended use, or nutritional value that renders a food no longer the equivalent of an existing food or ingredient; the presence of materials that give rise to ethical concerns; the presence of genetically modified organisms; and the presence of materials with health implications for certain segments of the population.[128] This last piece could get lost in a sea of information. Consequently, a consumer who regularly purchases GM foods without scrutinizing the label too carefully might end up ignoring a warning that the GM potato chips he or she just purchased contain a peanut gene. If this person has a peanut allergy, these chips could be potentially deadly.

Labeling requirements could also prevent consumers from even having a choice in determining whether or not they wish to purchase GM foods. Food processors faced with

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124. *See supra* Part I.C.1.

125. *See supra* note 62.

126. *See supra* note 24.

127. *See supra* note 25.

128. Regulation (EC) No. 258/97 of the European Parliament and of the Council of January 27, 1997 Concerning Novel Foods and Novel Food Ingredients, 1997 O.J. (L 043) 1.

comprehensive and expensive labeling requirements[129] may simply chose to avoid utilizing GM foods or ingredients to avoid the costs and burdens associated with the labels. Also, considering the Europeans' preference for traditional foods,[130] processors may simply chose to avoid using GM products out of fear that consumers will not purchase their products. For the same reasons, farmers may chose to avoid raising GM crops. Rather than choosing to plant seeds that have the benefits offered by genetic engineering,[131] they may choose to avoid planting them in favor of traditional seeds because of real or perceived market demands. Even if farmers plant a mixture of GM and non-GM plants, under the European regulations they have to keep them segregated from the time of planting through harvesting and storage in order to avoid having all their products labeled as potentially containing GM foods.[132]

The mandatory European labeling requirement may also inhibit the development of new biotech products. Innovations in biotechnology require a vast, substantial investment and corporate commitment; research is expensive, and as a result new products can be quite costly to develop.[133] The negative consumer perceptions aroused by mandatory labels may cause biotech industries to fear that there will not be a market for the efforts of their research and development. As a result of this fear, they may refuse to devote financial resources to the development of new products. Thus, labels may stifle innovation in a new, and potentially beneficial field.

3. Trade Issue

The distinct labeling systems have impacted agricultural trade between the U.S. and Europe. European Union regulations require that GM crops are certified before they may be imported,[134] and last year banned the importation of non-

129. *See, e.g., id*.

130. *See supra* Part I.C.1.

131. *See supra* Part I.A.2.

132. *See supra* Part I.C.2.

133. *See, e.g.*, *Biotechnological Patent Protection Act of 1991: Hearings on H.R. 1417 Before the Subcomm. on Intellectual Property and Judicial Admin. of the House Comm. on the Judiciary*, 102d Cong., 13 (1991) (justifying increased patent protection with the fact that biotechnology firms spend almost half their revenues on research and development).

134. *See* Kluger, *supra* note 2.

approved GM corn. Because GM corn grown in the U.S. is not segregated from non-GM corn, the Europeans have effectively banned all U.S. corn.[135] U.S. Agriculture Secretary Dan Glickman expressed concern that the European labeling requirements may be the equivalent of a non-tariff trade barrier.[136] The stringent labeling requirements may discourage U.S. producers from marketing their products in Europe to avoid complying with the costly and burdensome European labeling standards.

B. A VOLUNTARY LABELING SYSTEM IS THE BEST MEANS TO ADDRESS THESE ISSUES

A simple, voluntary, international standard that allows producers to label their food products as being free from genetically engineered ingredients is the best means to address the labeling issue. This system would let the marketplace determine if GM foods will continue to flourish. It would allow both U.S. and European consumers the option of seeking out foods that do not contain GM ingredients; it would not subject producers to burdensome labeling requirements unless they determined that they wanted to pursue that particular market segment; and it would not unnecessarily frighten consumers who are not experts on genetic engineering.

1. Description

Producers would affix a label to their products that describes them as being free from GM ingredients, similar to the way foods are labeled "organic,"[137] or cans of tuna are labeled "dolphin safe."[138] The voluntary labeling system would supplement the current FDA labeling requirements. Of course, such a system would require standards in order to make it effective and acceptable to consumers.

First, in order to make this standard effective, the range of procedures that constitute genetic engineering should be broadly defined. Genetic engineering should include not only

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135. *See id*.

136. *See EU May Strengthen Labeling Requirements for GM Soybeans and Corn*, FOOD LABELING NEWS, Dec. 11, 1997 *available in* 1997 WL 9737859.

137. *See infra* note 148.

138. *See infra* note 147.

recombinant DNA techniques, but a broad range of genetic manipulations used to modify foods.[139] Consumers who are seeking foods that are free from GM ingredients should be able to feel confident that the products they encounter in the market labeled as such meet these criteria. Thus, any food that contains proteins not previously found in food, proteins new to that type of food, foods that contain newly introduced but unexpressed genetic material, improved nutritional or food processing characteristics through GM techniques, or even processed foods that are chemically unchanged but contain ingredients derived from GM foods would be prohibited from being labeled as GM-free. If the ancestor of any plant was the product of genetic engineering, the plant itself should be considered genetically engineered. Thus, foods derived from plant cultivars developed by traditional breeding methods where one or both of the parent lines was developed using genetic engineering techniques would be precluded from being labeled GM-free.[140]

Second, the standard should apply to both fresh produce and processed foods.[141] If fresh foods have been genetically engineered, or mixed with those that have been, they should be precluded from being labeled GM-free. For example, if a farmer plants a mixture of GM soybeans and non-GM soybeans, but harvests them together, or transports his or her non-GM soybeans to a silo where they are mixed with soybeans that have been genetically engineered, his or her produce would be precluded from being labeled as GM-free. A rigorous standard should also apply to processed foods. If a soft drink manufacturer does not have verification that the corn syrup used to sweeten the beverage was derived from GM-free corn, it would not be allowed to label the soft drink GM-free.

Third, labels should be visible at the point of sale. The label itself should be a small symbol, or perhaps the phrase "GM-free," that would allow consumers to recognize the product as being free from genetically engineered ingredients. This could include labeling on the package of processed foods, posted signs at the grocery store for produce, and labels on restaurant

139. *See*, *e.g.,* Food Labeling; Foods Derived From New Plant Varieties, 58 Fed. Reg. 25,837, 25,839-40 (1993) (describing various results of genetic modifications).

140. *See id*. at 25,840 (describing various sources of genetic modifications).

141. *See id*.

menus.[142] This delegation would provide consumers with the ability to seek out GM-free foods in a variety of situations, such as restaurants or social events.

To make the standard effective, a federal agency should have the ability to enforce it. The USDA, which already oversees enforcement of standards for organic foods,[143] would be best suited to enforce GM-free labeling standards. This would eliminate the need for a new federal agency to oversee the regulation of biotechnology.

Fourth, the standard should be promulgated internationally. This can best be achieved through the Codex Alimentarius Commission, an international organization under the auspices of the United Nations that oversees food safety and promotion.[144] International recognition of the standard will facilitate trade by allowing widespread recognition of the product. Codex is best suited to setting this international standard because of its unique role. Although member nations are not obligated to adopt Codex standards, they may be relied on when challenging foreign standards before the World Trade Organization.[145] Thus, promulgation of a voluntary labeling standard through Codex will facilitate international recognition and acceptance.

2. Support and Application

Although a voluntary labeling standard will not solve all the problems associated with labeling GM products, it represents a workable compromise between those who want only minimal labels and those who want *per se* labeling of all GM foods. It would provide consumers with knowledge while not giving them cause to be fearful; it would allow producers and processors to determine for themselves whether they want to label; it would help facilitate trade between Europe and the U.S.; and it would allow a fair, market-based determination of the acceptance of GM foods.

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142. *See id*.

143. *See infra* note 148.

144. *See* John S. Eldred & Shirley A. Coffield, *What Every Food Manufacturer Needs to Know: Realizing the Impact of Globalization on National Food Regulation*, 52 FOOD DRUG COSM. L.J. 31, 31-32 (1997). The goal of the Codex is "to ensure that the world's food supply is sound, wholesome, and properly labeled." *Id*.

145. *See id*. at 33.

A voluntary labeling standard would provide consumers with an appropriate amount of information. Because labels would only be required in the U.S. when the FDA has determined there may be a health risk associated with the foods,[146] consumers who lack knowledge sufficient to make informed decisions about GM foods would not be frightened away by a label. Consumers who do wish to avoid GM foods, however, would be able to look for the label indicating a particular food was not genetically engineered or is free from GM ingredients. This would allow a truly market-based determination of whether or not consumers want to eat GM foods. This method is currently being used in labels for "dolphin-safe" tuna and organic foods labels. Tuna caught through methods that do not harm dolphins may be labeled "dolphin safe."[147] Similarly, foods produced in conformance with USDA methods for organic certification may be labeled "organic."[148] Both these methods allow market forces to

146. *See supra* Part I.B.2.

147. Dolphins typically congregate above schools of tuna. As a result, dolphins are good indicators of the location of tuna schools. Traditional fishing methods involved encircling the schools of tuna and dolphins with nets, and capturing both tuna and dolphins. Outrage by environmentalists led to federal regulations that allow tuna caught through methods that do not kill dolphins to be labeled "dolphin-safe." The label provides consumers information that allows them to choose tuna caught through the friendlier methods or through traditional means. *See* Taking of Marine Mammals Incident to Commercial Fishing Operations; Tuna Purse Seine Vessels in the Eastern Tropical Pacific Ocean, 64 Fed. Reg. 31,806 (1999). Through this label, consumers may choose whether to purchase tuna based on its effect on dolphins, allowing market forces to effectively determine tuna fishing methods. Consumers who wish to purchase tuna caught through methods that do not kill dolphins have the option of doing so. The labeling regulation has had a significant impact on tuna fishing methods. As a result of the label, fewer than 2,000 dolphins were killed in 1998 through tuna fishing, down from 133,000 in 1986. *See* H. Joseph Hebert, *Flipper vs. Charlie, Dolphin Safe Label Standard for Tuna Fishing Modified*, THE FORT WORTH STAR-TELEGRAM, May 2, 1999, *available in* 1999 WL 6232740.

148. Organic foods are subject to federal labeling requirements. The U.S. government recognized that some consumers wished to purchase food that they perceived as being healthier through organic production methods, and would be willing to pay a premium for these foods. The Organic Food Production Act of 1990 established standards by which foods can be labeled organic. 7 U.S.C. § 6504 (1990). According to the act, foods (1) must have been produced and handled without the use of synthetic chemicals, except as otherwise provided in the act; (2) must not be produced on land to which any prohibited substances, including synthetic chemicals, were applied during the three years immediately preceding the harvest of the agricultural products; and (3) must be produced and handled in compliance with an organic plan agreed to by the producer and handler of such product and the certifying

influence production methods. A voluntary labeling system for GM-free foods or GM ingredients would function in a similar way, allowing consumers to choose whether or not the importance of being GM-free is worth any additional costs GM-free production methods and labels may add to the price of the goods.[149]

Producers would be able to examine the market demand for foods labeled GM-free, and determine for themselves whether or not they want to undergo the extra burdens of labeling foods. Given the demand for GM-free foods in foreign countries,[150] and the market for organic foods in the U.S.,[151] it seems likely that producers would be willing to undertake the labeling burdens in order to tap into this market. If, however, they determine that such a market is not worth pursuing, they would not be required to follow through with the labeling requirements, as they would be required to conform to under a compulsory labeling system.

A voluntary labeling system would have much less of an impact on the biotech industry than a mandatory system. Mandatory labels would potentially scare away consumers;[152] a voluntary labeling standard would only serve as a guide for consumers who wish to consume GM-free foods. As a result, biotech companies would be less fearful that their products would be shunned in the marketplace. The companies would likely continue to invest in the development of new foods.

A voluntary labeling system would also avoid the potential First Amendment challenges facing a mandatory labeling requirement. Since producers would be compelled to speak when they wish not to, a voluntary system would not face the type of successful challenge brought in Vermont,[153] and would easily pass the four-prong Central Hudson test for commercial speech. Because the labeling is voluntary, the government's interest is not in compelling speech, but rather in making sure that speech is not misleading. Since this is already a prong of

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agent. *See id*. The statute provides that foods produced in conformance with these criteria may be labeled as meeting USDA standards for organic foods. *See id*.

149. *See supra* note 133 and accompanying text.

150. *See* Kluger, *supra* note 2.

151. *See supra* note 148.

152. *See supra* Part II.A.1.

153. *See supra* Part I.B.3.

the Central Hudson test,[154] a voluntary labeling standard would likely withstand judicial scrutiny.

A voluntary labeling system will not solve all the problems associated with labeling GM foods. It would still impose burdens on farmers and producers, but these would be much less substantial than those associated with a mandatory labeling system. Farmers and processors would have a choice of pursuing two market segments: one that demands GM-free foods, and one that is not concerned with the GM content of their foods. Farmers wishing to market to the community demanding GM-free foods would be required to segregate their crops, and producers would need to keep careful records of the sources of their ingredients. The advantage of a voluntary system, though, is that these burdens would be self-imposed if farmers and producers chose to pursue the GM-free market. Presumably, this choice would be based on the evidence that this market would be willing to pay a premium for GM-free foods. Unlike a mandatory system, farmers and processors who chose not to pursue this market would not be burdened with extra costs and record-keeping requirements. Therefore, they would be free to take advantage of the benefits of GM seeds and plants and pass any cost savings on to consumers. Under a mandatory labeling system, these groups would be burdened, and as a result would likely chose to use GM-free materials, denying themselves the positive aspects of these crops.

By having the voluntary standard promulgated internationally, U.S. food products can be more easily assimilated into the European marketplace. GM products will still have to be segregated from non-GM products, but a voluntary standard will provide European consumers confidence that the beans imported from the U.S. do not contain GM materials.

CONCLUSION

Current labeling requirements for GM foods suffer from a Goldilocks-type dilemma: the European regulations are too strict, causing unnecessary consumer fear of GM products, while U.S. regulations are too weak, withholding relevant information from consumers. The current systems result in

154. Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n, 447 U.S. 556, 566 (1980).

problems for consumers, producers, and the biotech industry, and have caused trade issues between the U.S. and Europe.

An international, voluntary labeling standard that allows easy identification of GM-free foods and food products is the "just right" compromise. This system would let the marketplace determine if GM foods will continue to flourish. It would allow both U.S. and European consumers the option of seeking out foods that do not contain GM ingredients; it would not subject producers to burdensome labeling requirements unless they determined that they wanted to pursue that particular segment; and it would provide relevant information to consumers without unnecessarily frightening them away. No proposal will completely satisfy parties on both sides of the issue, but a voluntary labeling standard would suit them best.