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Genetically Modified Foods: More Reasons to Label than Not

by

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GENETICALLY MODIFIED FOODS: MORE REASONS TO LABEL THAN NOT

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I. INTRODUCTION

Genetics have played an incredible role in the evolution of agriculture in the twentieth century and has the potential to become the paramount issue of this century. Indeed biotechnology and genetically modified foods have become two of the most controversial issues in the world. Today genetically modified ("GM") crops are prevalent in the United States. Specifically, GM crops now make up "at least forty-five percent of cotton, thirty-eight percent of soybeans, and twenty-five percent of

corn grown."[1] As of yet, however, the United States does not require mandatory labeling of GM foods.[2] The Food and Drug Administration ("FDA") has deemed them essentially safe.[3] So why do genetically modified foods remain such a controversial issue? This note will explore several reasons why labeling should be mandatory and further examine the benefits the United States would reap from creating a regulatory scheme that deals expressly with labeling and liability issues.

II. THEN AND NOW

A. *History of Food Modification*

The modification of foods using microorganisms dates back several centuries.[4] The human race has employed microbes to produce and preserve food for almost 10,000 years.[5] Wine and bread production through fermentation is one example of this "traditional biotechnology."[6] Another traditional use of biotechnology is creating novel variants of plants through selective breeding.[7] Selective breeding is restricted to two organisms that are able to breed together, whereas modern biotechnology has surpassed this limitation.[8] Through modern biotechnology, scientists are now capable of crossing genes to produce new products and to perform services that are well beyond the organismal level.[9] One of the fundamental concepts of modern biotechnology is recombinant DNA technology, which is the process of removing individual genes from one organism and transplanting them into another organism.[10]

These new advances in technology have created great skepticism and fear among many people as society has traveled into an area of unknown dimension; an area that many feel should be left to nature rather than man.[11] As early as 1906, years

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1. Jonathan H. Adler, *More Sorry Than Safe: Assessing the Precautionary Principle and the Proposed International Biosafety Protocol*, 35 TEX. INT'L L.J. 173, 177 (2000).
2. *See* Philip Brasher, *Labeling of Biotech Food Urged*, DES MOINES REG., Dec. 19, 2000, at 2D.
3. *See* Scott Killman, *Biotech Scare Sweeps Europe, and Companies Wonder if U.S. is Next*, WALL ST. J., Oct. 7, 1999, at A1.
4. *See* Jeffrey K. Francer, *Frankenstein Foods or Flavor Savers?: Regulating Agricultural Biotechnology in the United States and European Union*, 7 VA. J. SOC. POL'Y & L. 257, 261 (2000).
5. *See id.*
6. *See id.*
7. *See id.* at 261-62.
8. *See id.* at 262.
9. *See id. See also* Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products into the Environment, 57 Fed. Reg. 6753, 6754 (Feb. 27, 1992).
10. *See* Francer, *supra* note 4, at 262.
11. *See Quotable Quotes from Scientists and Other Folks on the Dangers of Genetically*

before modern advances of bioengineering occurred, plant geneticist Luther Burbank advised that genetics were evolving "in a way never intended by nature. We must proceed with utmost caution in the application of this new found knowledge."[12] These fears are still very real today, as testified to by Dr. George Walk, professor emeritus in biology from Harvard and Nobel laureate in medicine, who voiced the concern of many by saying:

> Up to now living organisms have evolved very slowly, and new forms have had plenty of time to settle in. Now whole proteins will be transposed overnight into wholly new associations, with consequences no one can foretell, either for the host organism or their neighbors. It is all too big and is happening too fast. So this, the central problem, remains almost unconsidered. It presents probably the largest ethical problem that science has ever had to face. Our morality up to now has been to go ahead without restriction to learn all that we can about nature. Restructuring nature was not part of the bargain.[13]

This area of science is scary because it is not only crossing species lines, but also crossing lines that divide living organisms, which involves making irreversible, permanent changes for future generations.[14]

This basic fear of interfering too much with nature is only one of the reasons the American public wants GM foods to be labeled.[15] Yet the FDA apparently has not come across any reason which it feels is important enough to mandate labeling. To better understand why labeling GM foods should be required the current structure of regulation under the FDA, the United States Environmental Protection Agency ("EPA"), and the United States Department of Agricultures ("USDA"), must first be discussed.

B. *The Government's Current Philosophy on Genetically Modified Foods*

According to the FDA, there is "no material difference in nutrition, composition, or safety" between genetically modified food and food that has not been genetically modified.[16] In fact GM foods are deemed the substantial equivalent, hence there is no reason for labeling to be required.[17] The FDA primarily regulates both GM foods and non-GM foods through the general safety clause of FDCA section

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Engineered Foods and Crops, *at* http://www.purefood.org/ge/sciquotes.htm (last visited Sept. 4, 2001).

12. Adler, *supra* note 1, at 179.

13. *Quotable Quotes*, *supra* note 10.

14. *See generally id.* (taking pieces from various quotes given by scientists on the subject of genetic engineering).

15. *See* Frederick H. Degnan, *The Food Label and the Right-to-Know*, 52 FOOD & DRUG L.J. 49, 55 (1997).

16. *Id.* at 49.

17. *See id.*

402(a)(1).[18] This clause defines adulteration and provides that food containing substances that "may render it injurious to health" is subject to being taken, while marketers of this "adulterated food are subject to injunction and criminal prosecution."[19] However, this provision does not entitle the FDA to conduct premarket reviews of foods.[20] The FDA "may require food manufacturers to petition for premarket approval unless the food is 'generally recognized as safe' ("GRAS")."[21] Although the FDA points out in its 1992 policy statement that it has "encouraged producers of new food ingredients to consult with FDA when there is a question about an ingredient's regulatory status," it is the manufacturers who actually decide whether GM foods are GRAS.[22] As a result, there is no way of knowing if manufacturers are applying the substantial equivalence doctrine on their own. This honor system method of regulation tends to be very "business-friendly."[23] Presently the FDA only provides "a detailed flowchart that attempts to aid manufacturers in determining the appropriateness of engaging in a formal consultation with the agency in assessing safety."[24] If the FDA receives a notification request from a manufacturer, a team of scientists then reviews and discusses the data the manufacturer has submitted and decides whether to approve the new food substance.[25] The FDA policy presumes, however, that the addition of genetic material from substances already existing in the food supply are GRAS.[26]

This regulatory process is also complicated by the fact that the EPA and USDA possess regulatory duties, along with the FDA, in assuring the safety requirements for biotechnology in food are met.[27] The EPA plays a role in biotechnology regulation because it has partial jurisdiction over the production and release of microbial products and pesticides into the environment.[28] While the FDA is authorized to regulate areas such as "substances intended to increase a plant's resistance to chemical herbicides," the EPA has the ultimate duty to oversee substances that are supposed to protect plants from infections.[29] As a result it is hard to create clear boundaries between these areas.

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18. *See* Francer, *supra* note 4. at 268.
19. *Id.*
20. *See id.*
21. *Id.* at 269.
22. Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,989 (May 29, 1992).
23. *See Editorial: Biotech Food--New Rules Won't Help Credibility, available at* http://www.startribune.com/...i/qview.cgi?template=opinion_a&slug=ED (Jan. 27, 2001).
24. Francer, *supra* note 4, at 271.
25. *See id.*
26. *See id.* at 270.
27. *See id.* at 266.
28. *See id.*
29. *Id.* at 270.

The EPA and the USDA also share duties of regulating GM foods.[30] Both agencies help regulate the "research and marketing of food biotechnology."[31] This splitting of authority and jurisdiction is confusing for the agencies themselves, as well as for biotech companies seeking registration and approval of their products. As technology continues to advance in crop production scientists are unsure of certain long term effects.[32] The EPA, FDA, and USDA are equally unsure of these effects. Sometimes it is hard to know exactly who should be testing, or even what exactly they should be testing.

Opponents of GM foods declare that this intra-regulatory approach is too full of holes, which can be attributed to the fact that biotech "companies have used their political power over the legislative and executive branches of government to block the consumer's right to know and to choose."[33] As a result, this policy of dividing authority between three agencies is too relaxed and secretive. Therefore, because biotechnology and genetically modified foods are topics that ignite so much public debate, labeling should be required.

III. REASONS BEHIND LABELING

A. *The Consumers' Right to Know*

The First Amendment has proven to be a successful defense so far for GM companies challenging state imposed labeling requirements. In *International Dairy Foods Ass'n v. Amestoy*,[34] the court recognized the right not to speak under the First Amendment. [35] The Second Circuit Court of Appeals, in *International Dairy*, stated that a statute that compelled disclosure of dairy products produced with the hormone rBST would likely be struck down.[36] The court ruled, "Vermont's statute was an unconstitutional government restriction on commercial free speech under the test articulated in *Central Hudson Gas v. Public Service Commission*."[37] When the compelled speech is a food labeling statute the test used is: (1) whether the compelled

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30. *See id.* at 266.

31. *Id.*

32. *See Quotable Quotes, supra* note 10.

33. Ralph Nader, *Forward to* MARTIN TEITEL, PH. D., & KIMBERLY A. WILSON, GENETICALLY ENGINEERED FOOD: CHANGING THE NATURE OF NATURE, at ix, xi-xii (1999), *available at* http://www.purefood.org/ge/presonbiotech.cfm.

34. Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67 (2d. Cir. 1996).

35. *See id.* at 71. *See also* Kirsten S. Beaudoin, Comment, *On Tonight's Menu: Toasted Cornbread with Firefly Genes? Adapting Food Labeling Law to Consumer Protection Needs in the Biotech Century*, 83 MARQ. L. REV. 237, 253 (1999) (discussing labeling of GM products).

36. *See Int'l Dairy Foods*, 92 F.3d at 74. *See also* Beaudoin, *supra* note 34, at 253.

37. Karen A. Goldman, *Labeling of Genetically Modified Foods: Legal and Scientific Issues*, 12 GEO. INT'L ENVTL. L. REV. 717, 732-733 (2000). *See also* Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 562-63 (1980) (discussing the constitutionality of labeling laws).

speech concerns lawful activity and is not misleading; (2) whether the government interest is substantial; (3) whether the labeling law serves that interest; and (4) whether the law is no more extensive than necessary.[38] In the Vermont case the court concluded that the state had no substantial interest in requiring labeling.[39] Vermont did not present any health or safety issues in their argument, rather they addressed the sole issue of consumer concern.[40] The court declared that consumer interest or curiosity by itself is never sufficient to constitute substantial interest, and that if it were, there would be "no end to the information that states could require manufacturers to disclose about their production methods."[41]

In most commercial speech cases, courts have applied a strict standard of review because the state issued a complete ban on speech.[42] The Vermont statute, however, should be distinguished because it compelled disclosure of speech.[43] Disclosure requirements have a somewhat lower constitutional status in recent judicial history, and courts normally consider them to be within a state's legitimate power.[44]

Cases dealing with disclosure requirements, rather than outright bans on commercial forms of speech, demonstrate this method of handling.[45] For example, package labeling is categorized as advertising and therefore should be submitted to a more lenient standard of review and does not deserve the high standards of full First Amendment rights.[46] Commercial speech cases such as *Zauderer v. Office of Disciplinary Counsel*[47] and *Bates v. State Bar of Arizona,*[48] seem to indicate that consumer interest may demand disclosure when it is deemed to be a preventative measure against consumer deception.[49] Consumers are currently being misled. Many think they are buying products that are GM free yet much of what they are buying is not.[50] People who want and need foods that are strictly non-GM are not currently

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38. *See Cent. Hudson Gas*, 447 U.S. at 566. *See also* Michael A. Whittaker, *Reevaluating the Food and Drug Administration's Stand on Labeling Genetically Engineered Foods*, 35 SAN DIEGO L. REV. 1215, 1230 (1998) (discussing labeling of genetically engineered foods).

39. *See Int'l Dairy Foods*, 92 F.3d at 72-74. *See also* Whittaker, *supra* note 37, at 1230.

40. *See Int'l Dairy Foods*, 92 F.3d at 73-74. *See also* Goldman, *supra* note 36, at 733.

41. *Int'l Dairy Foods*, 92 F.3d at 74. *See also* Beaudoin, *supra* note 34, at 254.

42. *See generally* 44 Liquormart Inc. v. Rhode Island, 517 U.S. 484 (1996) (applying "special care" to a blanket prohibition on the price of alcoholic beverages' retail prices); Rubin v. Coors Brewing Co., 514 U.S. 476 (1994) (noting the regulation must "directly advance the governmental interest and be no more extensive than necessary to serve that interest"); Virginia State Bd. of Pharm. v. Virginia Citizens Consumer Council Inc., 425 U.S. 748 (1975) (striking down a state law forbidding the advertisement of pharmaceutical prices).

43. *See Int'l Dairy Foods*, 92 F.3d at 73.

44. *See* Beaudoin, *supra* note 34, at 259.

45. *See id.*

46. *See id.*

47. Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626 (1985).

48. Bates v. State Bar of Arizona, 433 U.S. 350 (1976).

49. *See* Beaudoin, *supra* note 34, at 259-60.

50. *See Biotech in Trouble (Part I)—Rachel's Environment & Health Weekly,* (May 4, 2000), *at* http://www.purefood.org/ge/rach695.cfm.

provided with adequate information. GM disclosure must begin in order to end the existing deception. Moreover, the consumer is the best person to assess the materiality of information when making decisions involving food products.[51]

Also, the necessary government interest in mandating the labeling of GM foods is not restricted to consumer concern alone.[52] Economic effects on food industries, philosophical and moral objections to biotechnology, human safety issues, and environmental concerns should all be factors in determining government interest.[53] In *International Dairy Foods*, Vermont raised none of these concerns, therefore the court struck down the labeling statute.[54]

B. *Philosophical, Religious, & Moral Concerns*

Courts must not dismiss philosophical, religious, and moral concerns if the state raises them. In the FDA's decision not to require labeling of GM foods many of these issues were undervalued.[55] Millions of consumers wishing to avoid the consumption of foods that have been genetically modified due to religious and ethical principles were over looked when the FDA considered substantial governmental interests.[56] For example, the Jewish and Muslim population must refrain from eating food substances from specific animals.[57] GM foods can be altered so that plants now can contain animal genetics, which is or could be a violation of religious principles for many.[58] There are also animal derived food substances which vegetarians and people with allergies need to stay away from, yet because of the current lack of labeling they face the potential of unknowingly eating vegetables and fruits that contain genetic material from animals.[59] In addition there are numerous consumers who are morally opposed to GM foods, believing that they are "incompatible with the integrity of nature."[60] As a result, the interests at issue here are much deeper than mere consumer concern. Right now, because there is no way to identify GM foods from natural foods, moral, religious, and dietary concerns are being flagrantly disregarded. Many restaurant chefs have also felt ignored and as a result, joined together in a recent

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51. *See* Beaudoin, *supra* note 34, at 260.
52. *See* Whittaker, *supra* note 37, at 1229-30.
53. *See* Ronnie Cummins, *Hazards of Genetically Engineered Foods and Crops: Why We Need A Global Moratorium, at* http://www.purefood.org/ge/whymoratorium.cfm (last visited Sept. 4, 2001).
54. *See Int'l Dairy Foods*, 92 F.3d at 74.
55. *See* Goldman, *supra* note 36, at 725. According to the FDA, whether a food was created by genetic engineering is not material information, and therefore is not required to be disclosed under the Federal Food, Drug, and Cosmetic Act. *Id.*
56. *See* Beaudoin, *supra* note 34, at 258.
57. *See id.*
58. *See id.*
59. *See id.*
60. *Id.*

lawsuit against the FDA, claiming that they no longer have control over the purity of the food at their own restaurant.[61]

The trend towards organically grown food in recent years is another showing of consumer mistrust of GM foods.[62] The organic market has grown to $4.2 billion a year "with a growth rate of twenty percent per year" for the past decade.[63] Organic foods traditionally could only be purchased at health food stores or co-ops, now they can be found in almost any popular grocery chain.[64] This is largely based on the fact that the modern organic consumer is no longer from the stereotypical hippie population.[65] More and more consumers want to know that what they are eating is healthy and natural.[66]

In general consumers are confused as to why they are not being given the choice to decide whether or not to eat GM foods.[67] It seems illogical that the FDA requires labeling of whether or not juice is made from concentrate, but does not require labeling as to whether foods have been genetically altered.[68] A consumers' right to know what they are eating should be an essential right. This right alone is substantial enough to require labeling of GM foods. However, aside from the consumers' right, there are also other interests material enough to require labeling.

C. *Safety Concerns*

Many consumers also desire labeling because of health and safety concerns.[69] Even though the FDA has concluded that GM foods are safe and the substantial equivalent of their natural counterparts, many consumers feel that there are still health risks involved with GM consumption.[70] Because GM foods have not been around for a long period of time there has been no way to conduct tests on the possible long term adverse effects of GM foods.[71] This is the case not only for long term testing on humans, but on the farmland environment as well as on the entire ecosystem. Gordon McVie, the head of the Cancer Research Campaign, one of many worried consumers,

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61. *See* Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 170 (D.D.C. 2000).
62. *See* Beaudoin, *supra* note 34, at 249.
63. *Id.* at 250.
64. *See id.*
65. *See id.*
66. *See Biotech in Trouble (Part I) —Rachel's Environment & Health Weekly* (May 4, 2000) *available at* http://www.purefood.org/ge/rach695.cfm.
67. *See Consumer Warning: If You are Concerned About Genetically Engineered Foods in Your Shopping Cart, You Better Act Now!, at* http://www.purefood.org/ge/consumerwarn.htm (last visited Sept. 4, 2001).
68. *See* Goldman, *supra* note 36, at 720 (citing *Seeds of Change: In the U.S. and Elsewhere, the Food Supply is Being Genetically Altered. Here's Why You Should Care,* CONSUMER REP., Sept. 1999, at 41).
69. *See id.*
70. *See* Degnan, *supra* note 14, at 55.
71. *See Quotable Quotes, supra* note 10.

has expressed this concern by stating: "I'm more worried about humans than about the environment to be honest. One of the problems is that because it's a long-term thing, you need to do long-term experiments."[72]

The FDA does not feel the safety issues associated with GM foods are substantial enough to require labeling and refuses to acknowledge that GM products have the possibility of being toxic and dangerous to human health.[73] Many scientists warn that GM foods may produce dangerous toxins, set off allergies, increase cancer risks, produce antibiotic-resistant pathogens, and damage food quality.[74] These warnings should be taken seriously because previous unheeded warnings have been proven in the past. For example, in 1989 a popular dietary supplement, which was also a genetically engineered brand of L-tryptophan, killed over thirty Americans and disabled more than 5,000 other people with Eosinophilia Myalgia Syndrome, a potentially fatal blood disorder.[75] The chemical company which produced the supplement believed that the GM bacteria used to produce it became contaminated during the recombinant DNA process.[76]

Recombinant Bovine Growth Hormone ("rBGH"), the GM recombinant hormone at issue in the Vermont case previously discussed, was approved by the FDA in 1994 despite scientists warnings that dangerous levels of a strong chemical hormone, Insulin-Like Growth Factor ("IGF-1"), present in the milk of cows injected with the hormone, could cause significant hazards for breast, colon, and prostate cancer.[77] The U.S. Congressional watchdog agency, the General Accounting Office, even advised the FDA not to approve rBGH, declaring that the increased antibiotic residues in the milk of injected cows created too great of a risk for public health.[78] In fact, no other industrialized country has approved its use.[79]

In 1999 a British scientist, Dr. Arpad Puszati, discovered that GM potatoes that have been spliced with DNA from the snowdrop plant and the Cauliflower Mosaic Virus are poisonous to mammals.[80] Dr. Puszati found that the GM potatoes damaged the vital organs and immune systems of lab rats, and that the damage done to the rats' stomach linings was most likely caused by the Cauliflower Mosaic virus, a viral promoter which is spliced into nearly all GM foods and crops.[81] Now more and more scientists fear that genetic manipulation may increase the levels of natural plant toxins or allergens in foods, and may even create completely new toxins.[82] Currently

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72. *Id.*
73. *See* Cummins, *supra* note 52.
74. *See Consumer Warning, supra* note 66.
75. *See* Cummins, *supra* note 52.
76. *See id.*
77. *See id.*
78. *See id.*
79. *See id.*
80. *See id.*
81. *See id.*
82. *See id.*

the FDA does not require thorough testing, similar to Dr. Pusztai's.[83] In fact there are no defined tests that GM products are required to go through to determine substantial equivalence and the tests that are available are "so undiscriminating that unintended changes, such as toxins and allergens, could easily escape detection."[84]

This lack of defined testing procedures has most recently become evident with the appearance of StarLink corn in grocery stores. StarLink corn is a clear example of the results born from the precarious testing and regulations currently provided by the FDA policy. StarLink corn is a genetically engineered corn variety that has not been approved for human consumption by the EPA.[85] The corn, marketed by Aventis Crop Science, is allowed in animal feed but is not considered fit for human consumption due to the uncertainty over whether it can cause allergic reactions in humans.[86] Companies have recalled millions of packages of taco shells after tests proved StarLink was present in the corn used.[87] This could be an indication of what is to come in the future, as products are quickly being put on grocery store shelves to be sold without mandatory testing.

When it was discovered that StarLink corn was present in human food products, the FDA took action and began to recall taco shells.[88] The FDA is empowered to protect consumers from GM plant pesticides, such as the corn not approved by the EPA.[89] Meanwhile, Aventis agreed to the USDA's order to buy back StarLink crops currently being grown across the country.[90] The commingled presence of the EPA, FDA, and USDA in this ordeal highlights the need for a standardized regulatory scheme for testing and labeling. Even greater evidence of this is the fact that StarLink corn was discovered by a private organization, Genetic ID, and not the FDA or EPA.[91] Should we have to rely on private companies to protect us from food that is unsafe?

People also have legitimate reasons to be scared of potential food allergies GM foods may create. Humans may be harmed by eating foreign proteins spliced into everyday food products.[92] People have never before been exposed to several of the

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83. *See id.*

84. MARTIN TEITEL & KIMBERLY A. WILSON, GENETICALLY ENGINEERED FOOD: CHANGING THE NATURE OF NATURE 69 (1999) (quoting Nae-Wan Ho, et al., *The Biotechnology Bubble*, 28 ECOLOGIST, May-June 1998, at 149).

85. *See* Charles A. Deacon & Emilie K. Paterson, *Emerging Trends in Biotechnology Litigation*, 20 REV. LITIG. 589, 613-14 (2001).

86. *See id.* at 614.

87. *See* Ronald E. Bailey & Linda M. Bolduan, *Genetically Modified Foods: Labeling Issues Are Driving the Regulators and Counsel*, 68 DEF. COUNS. J. 308, 314 (2001).

88. *See id.*

89. *See id.* at 310.

90. *See id.* at 314.

91. *See* Andrew Pollack, *Labeling Genetically Altered Food Is Thorny Issue*, N.Y. TIMES, Sept. 26, 2000, at A1, *available at* http://www.thecampaign.org/newsupdates/sept00q.htm.

92. *See* Sally Schuff, *Case Opens GM Food Testing Debate*, FEEDSTUFFS, Sept. 25, 2000, at 3.

foreign proteins currently being genetically spliced into foods.[93] Mandatory labeling is needed to protect people that are prone to food allergies caused by dangerous GM foods.[94]

Another safety issue that has been noted is antibiotic resistance.[95] To determine if a gene was correctly spliced into a host organism, engineers normally link it to another gene, termed an antibiotic resistance marker gene.[96] Some scientists fear that these antibiotic resistance genes may recombine with certain naturally occurring bacteria or microbes in the environment or in the stomachs of animals and people who consume GM foods, which poses a dangerous hazard of antibiotic resistance.[97] There also exists the danger of creating new infections, such as novel "strains of salmonella, e-coli, campylobacter, and enterococci," that cannot be cured with today's available antibiotics.[98]

There appears to be enough health concerns that GM crops bring to peoples' minds that it would make sense to label food produced from them. So why aren't they labeled here, in the United States, while they are labeled in most every other country? Why has Europe recognized the consumers' ethical concerns and declared GM foods not to be the substantial equivalent of their natural counterparts? Are science and technology so much further advanced in the United States that the FDA is certain GM foods are safe enough not to be labeled? Why is it that the country that was once labeled as the cultural melting pot of the world, the one country that has incorporated a policy that has dismissed the diverse cultural dietary needs of its people? Still the FDA continues to find none of these issues substantial enough to overrule biotech corporations First Amendment right not to speak.

The FDA points out that it will require the labeling of foods containing GM material if there is a reason to conclude that the introduced genes could act as allergens, or if the GM food has a distinct nutritive value from what consumers expect.[99] But this is only if companies have volunteered their products to be tested.[100] Further, this approach fails to address all we do not know about possible allergens. Finally, a federal regulatory scheme addressing both testing and labeling issues would provide a better solution to liability issues.

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93. *See* Cummins, *supra* note 52.

94. *See id.*

95. *See* Martha R. Herbert, *Feasting on the Unknown Being Exposed to One of the Largest Uncontrolled Experiments in History*, CHI. TRIB., Sept. 3, 2000, at C21.

96. *See id.*

97. *See* Cummins, *supra* note 52.

98. *Id.*

99. *See* Adler, *supra* note 1, at 182.

100. *See Report Faults U.S. Regulation of Biotech Foods* (Jan. 13, 2001), *available at* http://www.nytimes.com/2001/01/13/health/biotech-report.html.

IV. LIABILITY ISSUES

The United States has no single federal statutory scheme to regulate GMOs.[101] Because the EPA, FDA, and USDA share regulatory responsibilities, many characteristics of GMOs are still unregulated.[102] These agencies are only able to modify existing regulations to include biotechnology, which has led to questions and confusion concerning recovery of damages. [103] The release of GMOs into the environment may result in various types of harm, including cross-pollination, allergic reactions, or harm to natural resources.[104] Plaintiffs may not use federal law to recover for GMO damage, but instead are left to proceed under common law theories, while recovery for such damage exists in the plaintiffs' ability to meet the common law's difficult burden of proof.[105] Currently plaintiffs are limited to theories such as negligence, nuisance, trespass, or strict liability.[106]

A. *Genetic Drift Problems*

Crop contamination, or genetic drift, is a very real concern for farmers. Crop contamination occurs when GM crops cross-pollinate with non-GM crops of the same or related species.[107] This can hurt organic and non-GM farmers' ability to sell their crops.[108] The monetary damage caused by undesired cross-pollination has already been felt by Terra Prima, an organic tortilla chip processor.[109] DNA testing showed traces of GM corn in the tortilla chips after they had been processed and shipped to Europe.[110] The entire shipment, worth $500,000, was not accepted.[111] Terra Prima executives concluded that pollen from genetically modified corn from nearby fields was the probable cause.[112]

Studies have shown that cross-pollination can occur within substantial distances.[113] A bee specialist, working with the United Kingdom pollen research unit, discovered airborne genetically modified pollen 475 meters from a GM field, and GM

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101. *See* A. Bryan Endres, *"GMO:" Genetically Modified Organism or Gigantic Monetary Obligation? The Liability Schemes for GMO Damage in the United States and the European Union*, 22 LOY. L.A. INT'L & COMP. L. REV. 453, 459 (2000).
102. *See id.*
103. *See id.* at 481-82.
104. *See id.* at 459.
105. *See id.* at 481-82.
106. *See id.* at 482.
107. *See* Richard A. Repp, Comment, *Biotech Pollution: Assessing Liability for Genetically Modified Crop Production and Genetic Drift*, 36 IDAHO L. REV. 585, 591 (2000).
108. *See* Endres, *supra* note 100, at 455-56.
109. *See id.* at 482.
110. *See* Repp, *supra* note 106, at 591.
111. *See id.*
112. *See* Endres, *supra* note 100, at 482.
113. *See id.*

pollen in bee hives was discovered up to four and a half kilometers from GM fields.[114] Genetic ID, a GMO testing laboratory in Iowa, has also found evidence of cross-pollination.[115] The laboratory has compiled extensive data of GMO contamination of non-GM crops by wind blown pollen from nearby GM corn fields.[116] Organic farmers bear the greatest risk, as GM contamination of an organic crop may lead to expulsion from the organic market.[117] Organic food production standards mandate that foods labeled organic contain no GMOs, not even a trace amount.[118] Traditional farmers also suffer due to the decreased amount of money they can receive for contaminated crops.[119]

B. *Grain Segregation Problems*

In addition to contamination during growth, cross-contamination may occur after the crops have been harvested.[120] The lack of segregation between GM crops and non-GM crops in storage and handling facilities has caused tremendous economic damage for the United States agriculture industry.[121] Pacific Northwest wheat farmers experienced an economic loss in 1999 when scientists in Thailand rejected a shipment of wheat "because it tested positive for GMOs."[122] It was discovered that GM corn had become mixed up with the wheat during shipment.[123] Because the United States failed to segregate crops the grain industry has suffered significantly, "[t]he U.S. grain industry has lost virtually all of the $200 million annual export market for sale of corn to the EU during the past two years."[124] Corn sales from the United States to the EU have been stopped since 1997.[125] In addition soya exports from the United States to Europe have fallen from 9.85m tonnes to 6.75m tonnes between 1995 and 1999.[126]

Because United States companies have felt the impact of market restrictions in recent years, several food suppliers have developed systems to segregate GM crops from non-GM crops.[127] Companies such as Kelloggs, Kraft foods, and Quaker Oats sell GM foods in the United States but the food they sell in Europe is non-GM.[128]

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114. *See id.*
115. *See* Repp, *supra* note 106, at 591.
116. *See id.*
117. *See id.* at 594.
118. *See id.*
119. *See id.* at 593.
120. *See id.* at 592.
121. *See id.* at 592-93.
122. *Id.* at 592.
123. *See id.*
124. *Id.* at 593.
125. *See* Francer, *supra* note 4, at 257.
126. *See* John Vidal, *"Supermarket Giants Pave the Way for 'GM-free' Britain", at* http://www.guardianunlimited.co.uk/gmdebate/Story/0,2763,429581,00.html (Jan. 27, 2001).
127. *See Biotech in Trouble (Part I), supra* note 49.
128. *See id.*

For years the GM food industry has claimed that the difficulty in segregating and the costliness involved have been significant reasons not to label GM foods. Many companies alleged segregation was virtually impossible.[129] However these companies seem to have since found ways to segregate. They managed to overcome the difficulties as soon as it became in their best interests to do so.[130] By segregating the crops, companies are able to sell non-GM foods in Europe. Segregation presents other advantages as well. For example, biotech companies are researching ways to produce foods with oils lower in fats, foods that raise the levels of Vitamin A in humans, and foods with disease fighting substances from GM crops.[131] Certainly these companies will want to segregate and label these foods if they are created. However mandatory segregation and labeling scare Biotech companies because they have been able to avoid liability under the current regulatory scheme.

C. *Farmer Liability*

In the past plaintiffs have found it easier to find a cause of action against farmers who plant genetically modified crops in fields neighboring non-GM or organic crops, rather than biotech companies who often should be held accountable.[132] But because courts or the legislature have not imposed a duty on GM seed developers, farmers are placed in a precarious position.[133] Because farmers have been the ones at risk, biotech companies have little motivation "to re-engineer seeds to eliminate the chances of cross-pollination or conduct field tests to determine effective methods for pollen containment."[134]

Holding farmers accountable, however, is not advantageous to plaintiffs either. The biotech companies almost always have a deeper pocket.[135] This is evident by Terra Prima, the tortilla chip manufacturer previously mentioned, choosing not to seek damages from the farmer but instead deciding "to join Greenpeace and the Center for Food Safety as plaintiffs in a lawsuit filed against the EPA."[136]

Nevertheless, the legal theories most plaintiffs have been forced to proceed under in these genetic drift cases have been trespass, nuisance, negligence, and strict liability.[137] Under these theories the plaintiff often has a hard time proving causation and presenting evidence that contamination came from a particular person.[138] When

129. *See id.*
130. *See id.*
131. *See id. See* Franz Xaver Perrez, *Taking Consumers Seriously: The Swiss Regulatory Approach to Genetically Modified Food,* 8 N.Y.U. ENVTL. L.J. 585, 589 (2000).
132. *See* Endres, *supra* note 100, at 485.
133. *See id.*
134. *Id.*
135. *See id.* at 505.
136. Repp, *supra* note 106, at 591.
137. *See id.* at 599.
138. *See id.* at 603.

there is more than one neighboring farmer producing the same variety of a GM crop, GMO testing alone is inadequate to locate the exact source of GMO contamination.[139] The plaintiff must then present circumstantial evidence such as "testimony from expert witnesses who are able to show the potential drift range of the GMOs; evidence of the likely drift pattern in the given atmospheric conditions; and evidence of a defendant's growing practices or other conduct which would identify the defendant is the likely source of contamination."[140] Because it is so difficult to prove a case with such circumstantial evidence, more and more plaintiffs have been attempting to sue the Biotech companies and the EPA.[141] But until labeling is enforced, these suits will also be very difficult to win. And the real question still remains: who should be at fault?

D. *Biotech Liability*

Should the producer of the seeds, the biotech company, be held responsible, or should the ones planting the seeds, the farmer, be responsible? Or should no one be held accountable at all, because who really cares if cross-pollination occurs anyways, on account of the fact that GM foods are the "substantial equivalent" of non-GM foods? This nation needs and is deserving of resolution because farmers are facing very real economic loss.[142] This is because some United States food processors have begun to segregate their purchasing and processing of GM crops from non-GM crops the market has become two-tiered and non-GM corn and soybeans obtain a premium price.[143] Contaminated non-GM crops face a price penalty.[144] So organic farmers and non-GM farmers who have resisted pressure from Biotech companies to buy GM seeds risk damage from something that is no fault of their own.

V. THE FUTURE OF BIOTECHNOLOGY IN AGRICULTURE

Nearly forty percent of the world seed market belongs to just ten multinational corporations.[145] It is estimated that fifty percent of the grain industry in the United States is currently using GM seeds.[146] Another worry for non-GM farmers is that seed companies will take traditional varieties off the market or use patent laws to prevent farmers from growing these conventional varieties.[147] In *Diamond v.*

139. *See id.*
140. *Id.* at 603-04.
141. *See id.* at 604.
142. *See id.* at 593.
143. *See id.*
144. *See id.*
145. *See* Organic Consumers Association, *Ten Reasons Why GE Foods Will Not Feed the World, at* http://www.purefood.org/ge/tenreasons.cfm (last visited Sept. 5, 2001).
146. *See id.*
147. *See id.*

Chakrabarty,[148] the Supreme Court held that a live, but human-made organism is patentable.[149] This could bring about an incredible reduction in farm biodiversity.[150] By being able to patent the genes these biotech corporations find and the organisms they produce, the small, corporate elite may soon emerge and dominate and farmers may become totally reliant on the corporations for their seeds.[151] The corporations who discover genes and ways of engineering them can patent the technique as well as the genes themselves.[152] It is interesting to note that these manmade genes are unique enough to patent, but not unique enough to label. Many fear that this patenting of genetically modified foods and the overtaking of biotech food production will undermine and wipe out farming as we know it:

> [I]f the trend is not stopped, the patenting of transgenic plants and food-producing animals will soon lead to tenant farming in which farmers will lease their plants and animals from biotech conglomerates and pay royalties on seeds and offspring. Eventually, within the next few decades, agriculture will move off the soil and into the biosynthetic industrial factories controlled by chemical and biotech companies. Never again will people know the joy of eating naturally produced, fresh foods.[153]

These fears are compounded by the power of the GM food lobby in George Bush's new cabinet.[154] The secretaries of defense, heath, and agriculture, the attorney general, and the chairman of the House agriculture committee all have connections with Monsanto or the biotech industry.[155] John Ashcroft, the attorney general, who received $10,000 from Monsanto in the elections, is likely to be very active in supporting the GM industry.[156] The director of the Center for Public Integrity, Charles Lewis, warned, "it looks like Monsanto and the biotech industry has the potential to bring undue influence on the new government."[157]

Allergic reactions are another harm GM foods have the potential of creating. A study conducted by Pioneer Hi-Bred International in the mid 1990s showed that placing a Brazil nut gene into a soybean triggered nut allergies among test subjects who consumed the GM soybeans.[158] Pioneer terminated development of that GM soybean, but GM foods still possess the ability to produce unexpected allergic reactions.[159] Without labeling it will be extremely hard to trace the source of new

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148. Diamond v. Chakrabarty, 447 U.S. 303 (1980).
149. *See* Beaudoin, *supra* note 34, at 252.
150. *See* Organic Consumers Association, *supra* note 144.
151. *See What's Wrong with Genetic Engineering?, at* http://www.purefood.org/text.html (last visited Sept. 5, 2001).
152. *See id.*
153. *Id.*
154. Vidal, *supra* note 125.
155. *Id.*
156. *See id.*
157. *Id.*
158. *See* Repp, *supra* note 106, at 598.
159. *See id.*

illness created by GM foods.[160] This leaves open concerns about legal theories and damages as well. Is a plaintiff who has an allergic reaction supposed to bring a claim as one who suffered from food poisoning would, under the common law theory of negligence or should they be able to proceed under a strict liability claim? Again who should be held liable, the seed company or the farmer?

VI. MOVING TOWARD A SOLUTION

Some members of Congress do want to take action and solve these problems. Last year Senator Barbara Boxer of California introduced in the United States Senate the Genetically Engineered Food Right to Know Act, S2080.[161] This act would call for mandatory labeling of GM foods.[162] Representative Dennis J. Kucinich also introduced parallel legislation to the House of Representatives.[163] The S2080 bill would make it a requirement that food that contains GM material or food produced with GM material be labeled at each stage of the food production process.[164] There would be a chain of custody system from farmers to manufacturers to retailers.[165] This act "would preserve access to foreign markets by establishing a chain of custody and labeling system that would allow American producers to ensure foreign markets that their food does not contain GM material."[166] To be productive, segregation and labeling must start at the farm level, at the beginning.[167] This is because present testing only detects a single type of modified grain, and "'[u]nless you know the history of the sample, you don't know what you are testing for.'"[168] Crops need to be followed from "seed through food processing with a paper trail."[169] Legislation like this would be the start of resolving liability issues. However, this legislation has not been passed and problems remain.

Because the federal government has not offered much resolution for the numerous rising concerns related to GM foods, states are also attempting to take action. For instance, Massachusetts submitted three bills earlier this year, which would begin regulating GM foods within the state, if passed.[170] One of the bills, if enacted, would hold biotech firms liable for health problems that are shown to be

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160. *See Quotable Quotes, supra* note 10.

161. *See The Genetically Engineered Food Right-to-Know Act, S. 2080, at* http://www.foe.org/safefood/boxer-s2080.htm (last visited Sept. 4, 2001).

162. *See id.*

163. *See id.*

164. *See id.*

165. *See id.*

166. *Id.*

167. *See id.*

168. Pollack, *supra* note 90 (quoting Eluned Jones, associate professor of agriculture and agribusiness at Virginia Tech.) *available at* http://www.thecampaign.org/newsupdates/sept00q.htm.

169. *Id.*

170. *See* Naomi Aoki, *Protection from Food Technologies Sought State Lawmakers File Liability, Labeling Bills*, BOSTON GLOBE, Feb. 14, 2000, at D4.

caused by the GM foods they engineer.[171] Senator Joyce, who filed the bill, explained in a press conference in January the logic of the bill: "for years, car companies, toy companies, and more recently tire manufacturers have been held accountable for their products. Let's do the same for GM foods, and hold all manufacturers directly responsible for whatever product they bring to the public."[172] This should also make sense to the biotech companies as they are so confident GM products are safe and beneficial. The bill would clear up liability confusion, but in order to work, labeling is necessary.

Biotech companies should be responsible for health problems, such as allergic reactions, as well as for environmental harm, but the question remains if they should be held accountable for cross-pollination. It might take a major crisis before Congress answers this question. The best answer may be to create a federal regulatory scheme parallel to that of the Genetically Modified Food and Producer Liability Bill, proposed to the British parliament by Alan Simpson.[173] The bill provides strict liability for "those who are seeking to introduce alien technology to the countryside."[174] Farmers and consumers are excluded from possible liability, while Biotech companies would be held accountable for health problems, damage to the environment, as well as any economic damage resulting from crop contamination due to cross-pollination.[175] However, it must be understood that common law tort theories must still be used if farmers are truly at fault (if they fail to properly use the GM seeds).

Labeling might not solve all of the problems concerning liability or the other issues addressed in this note, but it would be a good start. Labeling will clear up some of the problems and put the more complex issues in a better light for everyone to understand. Not only will labeling tremendously aid in the area of liability, labeling will also aid in protecting consumers rights and remembering what this country should value dearly. Clearly ethnic and religious principles, as well as moral and ethical principles, are not being given the respect they deserve.

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171. *See id.*

172. *The Campaign to Label Genetically Engineered Foods: News Updates*, *at* http://www.thecampaign.org/newsupdates/jan01.r.htm. (last visited Sept. 4, 2001)

173. *See* Endres, *supra* note 100, at 473.

174. *Id.*

175. *See id.*