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Caveat Venditor: Products Liability and Genetically Modified Foods

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CAVEAT VENDITOR: PRODUCTS LIABILITY AND GENETICALLY MODIFIED FOODS

COMMENT

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I. INTRODUCTION

Genetically modified organisms (GMOs) have become a lightning rod for conflict between farmers,[1] corporations,[2] shareholders,[3] government agencies,[4] and other concerned groups.[5] Supporters tout GMOs as a solution to the problems of diminishing returns from traditional crop plants and the rising demand for greater

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1. *See generally* Monsanto Canada Inc. v. Schmeiser, [2001] F.C. 256, *aff'd in part, rev'd in part*, [2004] 1 S.C.R. 902.

2. *See id.*

3. *See, e.g.*, Sysco Corp., Securities and Exchange Commission No-Action Letter, [2002 Transfer Binder] Fed. Sec. L. Rep. (CCH) ¶ 78,323 (Sept. 4, 2002) (regarding a shareholder proposal requesting Sysco Corp. to report to its shareholders regarding its policies for food products containing "genetically modified ingredients").

4. *See generally* Testimony of Janet L. Anderson, Director of Biopesticides and Pollution Prevention, Environmental Protection Agency, Before the Comm. on Agriculture, Nutrition, and Forestry of the United States S., Oct. 7, 1999, *available at* http://www.epa.gov/ocirpage/hearings/testimony/106_1999_2000/100699ja.htm [hereinafter Anderson].

5. *See, e.g.*, Organic Consumers Association, *About the OCA: Who We Are and What We're Doing*, *at* http://www.organicconsumers.org/aboutus.htm#Background (last visited Mar. 22, 2006).

quantities of food.[6] Opponents criticize GMOs for potential toxic and allergic reactions in humans, loss of biodiversity, and pesticide and antibiotic resistance in other plants and insects.[7] As the understanding of potential applications of biotechnology broadens, the risks and benefits of such products are being scrutinized more closely.[8]

Biotech companies, such as Monsanto Company[9] and Syngenta AG,[10] invest a significant amount of resources developing GMOs[11] and protect those investments by obtaining patents for the organisms and by licensing seed products to farmers.[12] Monsanto, Syngenta, and other similar companies also license certain farmers to

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6. *See* Richard A. Repp, Comment, *Biotech Pollution: Assessing Liability for Genetically Modified Crop Production and Genetic Drift*, 36 IDAHO L. REV. 585, 586 (2000).

7. *See id.* at 587.

8. Earle Nestmann, Todd Copeland & Jason Hlywka, *The Regulatory and Science-Based Safety Evaluation of Genetically Modified Crops - A USA Perspective*, *in* GENETICALLY MODIFIED CROPS: ASSESSING SAFETY 1, 1 (Keith T. Atherton ed., 2002).

9. Monsanto Co., SEC Form 10-Q, at 6 (Jan. 9, 2006), *available at* http://www.sec.gov/Archives/edgar/data/1110783/000111078306000002/a10q2006final.txt [hereinafter Monsanto 10-Q].

> Monsanto Company, with its subsidiaries, is a leading global provider of agricultural products for farmers. Monsanto produces leading seed brands, including DEKALB, ASGROW, SEMINIS[,] and STONEVILLE, and develops biotechnology traits that assist farmers in controlling insects and weeds. Monsanto provides other seed companies with genetic material and biotechnology traits for their seed brands. The company also manufactures ROUNDUP herbicide and other herbicides. Monsanto's seeds, biotechnology trait products[,] and herbicides provide growers with solutions that improve productivity, reduce the costs of farming, and produce healthier food for consumers and better feed for animals. *Id.*

10. Syngeta AG, SEC Form 20-F, at 9 (Mar. 25, 2004), *available at* http://www.sec.gov/Archives/edgar/data/1123661/000095010304000439/mar1804_20f.htm (stating that Syngenta is a Swiss company created by Novartis AG and AstraZeneca PLC through the spin-off and merger of the Novartis crop protection and seeds businesses and the Zeneca agrochemicals business). Syngenta "is a world-leading agribusiness that is involved in the discovery, development, manufacture and marketing of a range of products designed to improve crop yields and food quality." *Id.* at ii. "It is Syngenta's intention to devote an appropriate, sustained and competitive level of resources to pursuing the opportunities it believes biotechnology can deliver." *Id.* at 14.

11. *See, e.g.*, Monsanto 10-Q, *supra* note 9, at 11 (disclosing that Monsanto had a "carrying amount" of "acquired biotechnology intellectual property" of approximately $652 million).

12. MONSANTO CO., 2005 ANNUAL REPORT 26 (2004), *available at* http://www.monsanto.com/monsanto/content/media/pubs/2005/MON_2005_Annual_Report.pdf (stating that Monsanto licenses seed biotechnology traits to more than 250 seed partners).

grow patented, genetically modified seeds.[13] Despite the attempt to control such traits via licenses, sometimes the pollen from the GMO crop drifts to neighboring lands and commingles with the crops on that land—a process called "genetic drift."[14] Once the crops are harvested, the retailer or wholesaler who purchases them inherits a potential products liability lawsuit for any harmful effects suffered by those who ingest those products.[15]

This comment provides a brief synopsis of the history of genetics and emergence of GMO food markets.[16] Also provided is a map of the various regulatory agencies and their respective roles in the general regulation of GMOs.[17] In particular, this comment addresses the Food and Drug Administration's proposed rule requiring pre-market notification of a manufacturer's intent to market GMO food products[18] and contrasts that proposed rule with the regulation of organic foods.[19] Next, this comment briefly discusses the process of bringing GMO food products to the market[20] and some of the issues raised by GMOs which have been litigated, primarily GMO drift and labeling.[21] The comment also briefly explores the implications of the Food Allergen Labeling and Consumer Protection Act with regard to the litigation regarding GMOs.[22] Then the comment argues that both of the standard tests for liability for defective food products—the foreign-natural and consumer expec-

13. *See* Yolanda Massieu Trigo, *Transgenic Crops for Small Farmers: A Dream or a Nightmare?*, *in* TRANSGENIC CROP PROTECTION CONCEPTS AND STRATEGIES 351, 367 (Opender Koul & G.S. Dhaliwal eds., 2004) (stating that large biotechnology companies are becoming more interested in having access to genetic information in the form of intellectual property rights).

14. Hillary Preston, Note, *Drift of Genetically Engineered Crops: Rethinking Liability Theories*, 81 TEX. L. REV. 1153, 1154 (2003) (describing genetic drift as the inadvertent spreading of GMOs from a farm choosing to use GMOs to farms which have not chosen to use them). Other possible sources of commingling include transportation, storage, and processing facilities. *See* In re StarLink Prod. Liab. Litig. v. Aventis CropScience USA Holding, Inc., 212 F. Supp. 2d 828, 834 (N.D. Ill. 2002) (stating that corn pollen can "drift over considerable distances").

15. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 7 (1998) (stating that one who sells or distributes a food product that is defective is subject to liability for harm caused by the defect).

16. *See infra* Section II.

17. *See infra* Section III.A.1.

18. *See infra* Section III.A.2.

19. *See infra* Section III.B.

20. *See infra* Section IV.

21. *See infra* Sections V.A. & V.B.1.

22. *See infra* Section V.B.2.

tations tests—are inadequate in the context of GMOs.[23] Then the comment discusses general products liability theories (such as manufacturing and design defects) in the context of GMOs and suggests that issues regarding allergies still remain to be decided by the courts.[24] This comment concludes by stating that due to legal uncertainties regarding GMOs, and the implications of the Food Allergen Labeling and Consumer Protection Act,[25] a company desiring to sell GMOs does so at its own risk.[26]

II. THE HISTORY OF A FUTURISTIC SCIENCE

Gregor Johann Mendel is considered to be the father of modern genetics for discoveries he made while breeding peas in his monastery garden over a century and a half ago.[27] "Mendel was the first to understand that characteristics such as height, color, and shape depend on the presence of determining *factors* . . . ."[28] In 1905, these factors were dubbed "genes" by Wilhelm Johannsen.[29] Colloquially, the word gene refers to both the location on a chromosome and the information contained at that location.[30] Genes are the basic language of life, and when combined in certain patterns they form the building design of an organism, its properties and capabilities.[31] This design is comprised of chains of deoxyribonucleic acid (DNA) molecules.[32] The two general kinds of genetic ma-

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23. *See infra* Section VI.

24. *See infra* Section VII.

25. Pub. L. No. 108-282, 118 Stat. 905 (2004) (codified in scattered sections of 21 and 42 U.S.C.).

26. *See infra* Section VIII.

27. *See* PETER PRINGLE, FOOD, INC.: MENDEL TO MONSANTO—THE PROMISES AND PERILS OF THE BIOTECH HARVEST 9 (2003).

28. *Id.* (emphasis in original).

29. Nick Smith, Chairman on the Subcommittee on Basic Research, United States General Accounting Office, *Seeds of Opportunity: An Assessment of the Benefits, Safety, and Oversight of Plant Genomics and Agricultural Biotechnology* 11 (Apr. 13, 2000), *available at* http://www.house.gov/science/smithreport_041300.pdf. [hereinafter Smith].

30. Rebecca M. Bratspies, *Biotechnology Environmental, Health, and Safety Regulation*, A.L.I.-A.B.A. CONTINUING LEGAL EDUCATION, Oct. 16-17, 2003, available on Westlaw at SJ033 ALI-ABA at *8.

31. Physicians and Scientists for Responsible Application of Science and Technology (PSRAST), *A First Introduction to Genetic Engineering*, *at* http://www.psrast.org/gefirstintro.htm (last visited Mar. 22, 2006) [hereinafter PSRAST].

32. *Id.*

terial are DNA and ribonucleic acid (RNA) and, between the two, DNA is the "unit of heredity and reproduction."[33]

In 1953, James Watson and Francis Crick described the double-helix shape of DNA, a discovery that led to the deciphering of genetic code which, in turn, led to "rapid advances in the practical applications of genetics."[34] A significant technique was developed in 1972 by Paul Berg and a group of researchers from Stanford University who were able to "cut" DNA from separate sources and splice the different pieces together into a functional molecule.[35] One year later, Stanley Cohen and Herbert Boyer[36] took the process a step further and transferred a spliced, or recombinant,[37] molecule into a bacterium where the molecule functioned with the bacterium's own genes.[38] This discovery became the "first phase of a new industrial era and a new technological field."[39]

Genetic engineering, in the simplest of explanations, is the intermingling of certain portions of the DNA code of one organism with the DNA code of another organism.[40] Desirable traits are selected from one organism and transferred between species, or even between plants and animals.[41] The terms "transgenic,"[42] "genetic engineering,"[43] and "recombinant DNA"[44] are used to describe this process and are used interchangeably throughout this comment.

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33. *See* Bratspies, *supra* note 30, at 4-5.

34. *See* Smith, *supra* note 29, at 11.

35. *Id.* at 12.

36. Boyer co-founded the world's first biotechnology company, Genentech, which used genetically engineered bacteria to produce human therapeutics and diagnostics. *Id.*

37. *See infra* note 44 and accompanying text.

38. *See* Smith, *supra* note 29, at 12.

39. Jesper Norus, *Biotechnology Organizations in Action: Turning Knowledge Into Business*, 20 PROGRESS IN BIOTECHNOLOGY 29 (2002).

40. *See* PSRAST, *supra* note 31.

41. *See* Preston, *supra* note 14, at 1155.

42. THE AMERICAN HERITAGE COLLEGIATE DICTIONARY 1436 (3d ed. 1993). "Carrying genes transferred from another species or breed." *Id.*

43. "Scientific alteration of the structure of genetic material in a living organism, used, for example, to create bacteria that synthesize insulin." *Id.* at 566.

44. "Genetically engineered DNA prepared by transplanting or splicing genes from one species into the cells of a host organism of a different species." *Id.* at 1141.

III. THE REGULATORY STRUCTURE

A. GMOs

For years, biotechnology has been used in different industries to develop more than a thousand products ranging from human insulin to enzymes used in food production.[45] Companies have been applying techniques of genetic engineering to agricultural products for widespread commercial use since the early 1980s.[46] For example, Calgene's Flavr Savr tomato was one of the first GMO, consumer-ready foods to be produced and marketed in the United States.[47] Since then, over fifty other GMO products have been determined to be substantially equivalent[48] to their conventional counterparts, including soybeans, corn, and cotton.[49] Soybeans, corn, and several other crops[50] are commonly modified to generate their own pesticide.[51]

The regulation of GMOs in the United States has been vested primarily in the Department of Agriculture (USDA),[52] the Food and Drug Administration (FDA),[53] the Environmental Protection Agency (EPA),[54] and various subdivisions of those agencies. In 1986, the Coordinated Framework for Regulation of Biotechnology (Coordi-

45. *See* Smith, *supra* note 29, at "Letter of Transmittal."

46. *See* Anderson, *supra* note 4.

47. Donna U. Vogt & Mickey Parish, *Food Biotechnology in the United States: Science, Regulation, and Issues*, CRS Report for Congress, at 4, Jan. 19, 2001, *available at* http://www.cnie.org/NLE/CRSreports/science/st-41.pdf [hereinafter Vogt & Parish].

48. For a brief discussion of substantial equivalence see *infra* notes 74-76 and accompanying text.

49. Linda Bren, *Genetic Engineering: The Future of Foods?*, FDA CONSUMER MAG. (Nov.-Dec. 2003), *available at* http://www.fda.gov/fdac/features/2003/603_food.html.

50. Other transgenic crops that are currently in the market include cotton and canola. *See* Colorado State University, *Transgenic Crops: An Introduction and Resource Guide*, *at* http://cls.casa.colostate.edu/TransgenicCrops/current.html (last visited Mar. 22, 2006). Crops currently being researched for market in the future include tomato, rice, canola, sunflower, grapes, tobacco, coffee and tea. *See id.*

51. Vogt & Parish, *supra* note 47, at 3.

52. Pursuant to 7 U.S.C. §§ 7701-7772 (2000), and 7 U.S.C. §§ 2321-2583 (Supp. 2004). For general information regarding USDA, see http://www.usda.gov/wps/portal/usdahome.

53. Pursuant to 21 U.S.C.S. §§ 301-399 (Supp. 2004). For general information regarding the FDA, see http://www.fda.gov.

54. Pursuant to 7 U.S.C.S. §§ 135-136y (Supp. 2004). For general information regarding the EPA, see http://www.epa.gov.

nated Framework)[55] stated that "[A]t the present time existing statutes seem adequate to deal with the emerging processes and products of modern biotechnology."[56] Furthermore, Coordinated Framework proposed that genetically modified products be regulated according to their characteristics and not by the methods by which they are produced.[57]

1. The "Coordinated" Framework In Action[58]

a. The USDA's Role

Essentially, the USDA's role in the regulation of GMOs is aimed at plants and plant pests.[59] No fewer than eight USDA agencies, including the Animal and Plant Health Inspection Service (APHIS),[60] collaborate to fulfill the USDA's tasks in regulating GMOs.[61] APHIS reviews plants containing, or plants produced using, biological control organisms.[62] This statutory authority extends to GMO crops

55. The Coordinated Framework is a basic network of federal agencies having jurisdiction over the research and products derived from biotechnology. *See generally* 51 Fed. Reg. 23,302 (June 26, 1986). The Coordinated Framework is supposed to evolve with the experiences of the industry and the agencies. *Id.* at 23,302.

56. *Id.* at 23,306.

57. *See* Vogt & Parish, *supra* note 47, at 6. Although there was reference to regulating "processes" in this release, the FDA's approach regarding the regulation of GMOs since has been to only regulate the "product" and not the process. 57 Fed. Reg. 6753, 6753 (Feb. 27, 1992).

58. Critics of Coordinated Framework claim that it is flawed because it was created before the completion of a comprehensive review of potential risks. *See* Gregory N. Mandel, *Gaps, Inexperience, Inconsistencies, And Overlaps: Crisis In The Regulation Of Genetically Modified Plants And Animals*, 45 WM. & MARY L. REV. 2167, 2202, 2258 (2004) (suggesting realignment of the regulation of genetically modified products because the risks of GMOs are better understood now than they were when the Framework was created).

59. A plant pest is defined broadly to include a parasitic plant, bacterium, fungus, virus, or other infectious agent. 7 U.S.C. § 7702(14) (2000).

60. APHIS is responsible for protecting United States agricultural health from agricultural pests and diseases. *See* http://www.aphis.usda.gov/about_aphis/ (last visited Mar. 22, 2006).

61. *See* USDA, *Agriculture: Biotechnology, at* http://www.usda.gov/agencies/biotech/role.html (last visited Mar. 23, 2006).

62. 7 U.S.C. § 7712(g) (2000); 7 C.F.R. § 371.3 (2004); *see also* 7 C.F.R. § 340.2 (2005). A biological control organism is colorfully defined as an "enemy, antagonist, or competitor used to control a plant pest or noxious weed." 7 U.S.C. § 7702(2) (2000).

that are designed to be resistant to plant pests or could themselves become pests for other plants.[63]

A plant pest can be either a substance or organism that directly or indirectly causes disease or damage to plants.[64] APHIS maintains a list of organisms considered to be plant pests that are subject to regulation; APHIS also maintains the procedures required to petition to amend the list, to recognize a certain substance as non-regulated, as well as container requirements for the movement of regulated organisms.[65]

b. The EPA's Role

The EPA's authority to regulate chemical and biopesticides is granted under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).[66] The role of EPA in regulating GMOs is to ensure that substances used as pesticides, such as plant incorporated protectants (PIPs), are safe for the environment. PIPs are pesticidal substances intended to be produced, or produced by, and used in living plants or their products.[67] In general, all pesticides require registration with EPA prior to sale or distribution in the United States.[68]

Nevertheless, a significant exemption from the EPA approval requirement. A PIP is exempted from registration if its genetic material comes from a plant with which it is sexually compatible—including plants where the targeted genetic material has never been derived from a source that is not sexually compatible with the recipient plant.[69] The reason for this exemption is that maintaining a sexually compatible genetic pedigree does not trigger the fears cre-

63. 7 U.S.C. § 7712(g) (2000); *see also* 7 C.F.R. § 340.2 (2005) (referring to organisms that *are* or *contain* plant pests).

64. *See* 7 U.S.C. § 7702(14) (2000); 7 C.F.R. § 340.1 (2005).

65. 7 C.F.R. §§ 340.0-9 (2005). A full exploration of the APHIS regulations is beyond the scope of this comment.

66. 7 U.S.C. §§ 135-136y (2000).

67. 40 C.F.R. § 174.3 (2005). *Bacillus thuringiensis*, or *Bt*, is an example of a PIP. *Bt* is a common soil microbe which is used to create a protein called Cry9C (made famous in the StarLink controversy) which "kills certain destructive pests of corn." Alejandro E. Sagarra & Jean M. Rawson, *StarLink Corn Controversy: Background*, CRS Report for Congress (Jan. 10, 2001), *available at* http://www.ncseonline.org/nle/crsreports/agriculture/ag-101.cfm (last visited Mar. 22, 2006) [hereinafter Sagarra & Rawson]. A list of PIPs, or biopesticide active ingredients, regulated by the EPA can be found at EPA, *Biopesticide Active Ingredient Fact Sheet*, *available at* http://www.epa.gov/pesticides/biopesticides/ingredients/index.htm.

68. 40 C.F.R. § 152.15 (2005).

69. 40 C.F.R. § 174.25(a),(b) (2005).

ated by juxtaposing genetic traits from sexually incompatible organisms.[70] However, any person who produces a PIP that is exempted from reporting and subsequently receives any information about adverse effects on human health or the environment must submit the information to EPA within thirty days of first possessing or learning of the information.[71]

c. The FDA's Role

The majority of the regulatory authority regarding genetically modified foods is vested in FDA to ensure the safety of all food and food components.[72] Sections of the Federal Food, Drug and Cosmetic Act (FDCA) regarding intentional and unintentional adulteration of foods and substances added to foods are especially relevant to GMOs.[73]

The FDA's longstanding approach has been that GMOs can be regulated using the "generally recognized as safe" (GRAS) standard for food additives.[74] In 1992, FDA further clarified that genetically

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70. *See* 66 Fed. Reg. 37,771, 37,783 (July 19, 2001).

> EPA, nonetheless, recognizes that plant breeding in the United States has a good record of providing a safe food supply and that plant breeders employ accepted standards of practice to maintain this record. This good record provides support to the [EPA's] determination that it can exempt plant-incorporated protectants derived through conventional breeding from sexually compatible plants from almost all regulatory oversight, relying only on the post-market reporting of adverse effects. *Id.*

71. 40 C.F.R. § 174.71(a) (2005).

72. *See* Kelly A. Leggio, Comment, *Limitations of the Consumer's Right To Know: Settling the Debate Over Labeling of Genetically Modified Foods in the United States*, 38 SAN DIEGO L. REV. 893, 910 (2001).

73. FDCA, 21 U.S.C. §§ 342 and 348 (2000).

74. 51 Fed. Reg. 23,309, 23,310 (June 26, 1986). The requirements of what is generally recognized as safe are discussed at length in 21 C.F.R. § 170.30 (2005). The FDA's decision that GMOs are generally recognized as safe has been the subject of extensive debate and criticism. The debate over whether GRAS status is appropriate mirrors the debate over the advocated advantages and disadvantages of GMOs previously discussed. One interesting argument is that GMO developers are speaking from both sides of their mouths by telling FDA that their GMO products are substantially similar to traditional crops and therefore do not require additional regulation, but they then plead with the United States Patent and Trade Office that the GMO is entirely different and needs a new form of treatment (i.e., is patentable). *See* Richard Caplan & Skip Spitzer, *Regulation of Genetically Engineered Crops and Foods in the United States*, at 4 (Mar. 2001), *available at* http://www.panna.org/resources/documents/geRegulation.pdf. However, this argument neither properly addresses the argument made by the companies nor addresses the FDA's longstanding approach to evaluating GMOs based upon their

modified plant products with "new" genes added via genetic engineering are generally recognized as safe because they are "substantially equivalent" to their conventional counterparts.[75] This "substantial equivalence" approach to GMOs is the current regulatory approach in the United States.[76]

FDA reiterated its approach to genetically modified foods in May 2000, but it also proposed a mandatory consultation process so companies that desire to market genetically modified foods would be required to consult with FDA.[77] However, the FDA's proposal was not implemented; furthermore, FDA also determined that because there was insufficient evidence to prove risk of harm to the public from genetically modified foods, mandatory labeling of GMOs was inappropriate.[78]

In 2001, however, FDA determined that GMO breeding required greater scrutiny than that of traditional breeding stating, "[t]he confluence of the increasingly broader use of [recombinant DNA] techniques . . . suggest[s] that FDA needs to be aware of the various foods developed using [recombinant DNA] technology."[79] Most likely, this renewed FDA attention to GMOs was heightened because traces of genetic material from StarLink[80] corn was discov-

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impact rather than on the manner in which they were designed. *See* Douglas A. Kysar, *Preferences For Processes: The Process/Product Distinction And The Regulation Of Consumer Choice* 118 HARV. L. REV. 525, 557 (2004). Thus, the argument made to FDA is that the *impact* of the GMO is essentially the same as its traditional counterpart so as not to require specific additional warnings or labels, while the argument to the United States Patent Office is that the *method* by which the GMO is made is sufficiently different to justify patent protection of that method. *Id.*

75. 57 Fed. Reg. 22,984, 22,985 (May 29, 1992).

76. *See id. See also* Paul R. Mayers et al., *The Concept of Substantial Equivalence, in* GENETICALLY MODIFIED CROPS: ASSESSING SAFETY 63, 63-64 and n.1 (Keith Atherton ed., 2002) (describing the concept of substantial equivalence as embodying the idea that existing food sources could be used as a basis for comparison when assessing the safety of GMOs and that the United States was a member of an international organization that developed the concept).

77. *See* Leggio, *supra* note 72, at 911.

78. *Id.* Interestingly, FIFRA preempts any claims based on the inadequacy of labeling or failure to warn about products approved by EPA. *StarLink*, 212 F. Supp. 2d at 835-36 (stating "[FIFRA] expressly authorizes states to regulate pesticide use . . . . But it also prohibits states from imposing any labeling requirements beyond those imposed by the EPA.") (citations omitted).

79. Pre-Market Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706, 4712 (Jan. 18, 2001).

80. *See* Sagarra & Rawson, *supra* note 67. "StarLink hybrids contain a plant pesticide protein (Cry9C) derived from a common soil microbe [*Bacillus thuringiensis*, or *Bt*], which kills certain destructive pests of corn such as the European corn borer." *Id.*

ered in taco shells sold in grocery stores.[81] The problem was that when EPA originally approved StarLink, it was approved for use as livestock feed or industrial purposes only, and not for human consumption.[82]

2. The FDA's Modest Proposal: Pre-Market Notification

In January 2001, FDA issued a proposal to create a mandatory consultation process so that GMO developers would be required to consult with FDA at least 120 days prior to the commercial distribution of GMOs.[83] The proposed regulations define bioengineered foods as foods derived from plants developed through transformation events.[84] A transformation event is the introduction of genetic material that has been manipulated in vitro into a plant.[85] Although these proposed regulations have not been promulgated in the form of a final rule, similar results are being pursued by other legislative means.[86] For example, a bill presented in the Arkansas Senate in 2005 was particularly concerned about genetically engineered plants containing human DNA.[87] However, on the judicial front, courts have been unreceptive to claims that GMOs should be labeled as such.[88]

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81. *See id.*

82. *Id.*

83. Pre-Market Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706, 4712 (Jan. 18, 2001).

84. *Id.* at 4730 (proposed rule 21 C.F.R. § 192.1(a)).

85. *Id.* (proposed rule 21 C.F.R. § 192.1(e)).

86. *See, e.g.*, Genetically Engineered Foods Act, S. 2546 108th Cong. § 421(a) (2004) (calling for the requirement of GMO producers to obtain pre-market approval before introducing any GMO into interstate commerce).

87. S.B. 318, 85th Gen. Assembly, Reg. Sess. (Ark. 2005) (recommending the prohibition of growing, raising, or cultivating certain genetically engineered plants). This bill proposed that the "State Plant Board" be empowered to impose a civil penalty of not less than $25,000 and not more than $100,000. *Id.* § 2-15-203(a)(2). In determining the severity of the civil penalty, the State Plant Board would be asked to consider the gravity and magnitude of the violation, any actual or potential threat to human health or safety, the amount of benefit the violator realized from the violation, and the past history of the violator. *Id.* § 2-15-203(b)(1)-(3). The bill appeared to be a response to an announcement by Ventria Bioscience that it would collaborate with Northwest Missouri State University to use self-pollinating plants, like rice, as "factories to produce therapeutic proteins and peptides." News Release, Ventria Bioscience, Northwest Missouri State University and Ventria Bioscience Announce Collaboration to Create Northwest Missouri Center of Excellence for Plant-Made Pharmaceuticals (Nov. 18, 2004), *available at* http://www.ventria.com/news/11-18-04%20PR.pdf.

88. *See infra* Section V.B. and accompanying notes.

B. A Brief Contract With the Regulation of Organic Foods

In recent years, the organic food market has been growing at a rate five times faster than food sales in general and has now become an $11 billion-a-year business.[89] Consumers cite perceived health benefits as their primary reason for purchasing organic foods, but, ironically, organic foods are not demonstrably better for consumers because organic foods still pose their own risks (e.g., higher potential for foodborne bacteria such as *E. coli*).[90] Organic food farmers generally use methods such as crop rotation, controlling weeds through cultivation, and livestock grazing management to preserve soil quality and, therefore, food quality.[91]

GMOs and organic foods are treated in the same manner for FDA oversight purposes.[92] However, additional requirements must be met in order to market foods as "organic." The Organic Foods Production Act of 1990 (OFPA)[93] requires farmers who gross more than $5,000 annually to be certified in order to sell or label their foods as organic.[94] In 2002, USDA provided that "organically produced" foods are those products which are produced in accordance with OFPA.[95] Furthermore, products that qualify, may be labeled as either "100 percent organic," "organic," or "made with organic [particular ingredient]" as long as they meet the requisite definitions of

89. *See* Andrew J. Nicholas, Comment, *As The Organic Food Industry Gets Its House in Order, The Time Has Come For National Standards For Genetically Modified Foods*, 15 LOY. CONSUMER L. REV. 277, 278 (2003).

90. *See, e.g.*, Thompson v. East Pac. Enter., Inc., No. 49924-6-I, 2003 WL 352914 (Wash. App. Div. 1 Feb. 18, 2003) (regarding a plaintiff who suffered a severe allergic reaction after ingesting an almond chicken dish containing trace amounts of peanut oil); *see also* Thomas P. Redick, *Stewardship for Biotech Crops: Strategies for Improving Global Consumer Confidence*, 44 JURIMETRICS J. 5, 18 (Fall 2003) ("[E]xisting organic corn growing methods may increase carcinogenic mycotoxin risk compared to biotech corn varieties."); Geoffrey Cowley, *Certified Organic; Stamp Of Approval: New Government Rules Will Define* 'Organic,' NEWSWEEK, Sept. 30, 2002, *available at* http://www-schneider.viscom.ohiou.edu/photoshop6/certified_organic.htm.

91. *See* Nicholas, *supra* note 89, at 278-79.

92. *See generally id.* at 283.

93. 7 U.S.C.S. §§ 6501-23 (Supp. 2004).

94. 7 U.S.C. § 6505 (2000).

95. *Id.* § 6502(14).

each category.[96] Use of this label is determined by the percentage of organic ingredients in the product.[97]

In summary, while the federal government has determined that the labeling of foods as containing GMOs is not necessary, it has determined that organic foods should be specifically labeled as such—presumably to protect consumer expectations.[98] The most reasonable explanation of the inconsistency appears to be that labeling GMO foods would unnecessarily demonize the product, potentially harming the GMO food market, while requiring labels for organic foods establishes consumer trust in those products and, therefore, also protects the organic food market.[99]

IV. THE GMO BUSINESS

Biotechnology companies continuously explore potential uses for biotechnology ranging from a single banana chip that acts as an oral vaccine for one-fifteenth of the cost of an injection[100] to medicines engineered to regenerate human tissues.[101] Some companies are also exploring the possibility of using biotechnology to break down groundwater contaminants.[102] For each of the last ten years, the amount of acreage dedicated to the growth of biotech crops[103] has seen double-digit growth rates.[104] In 2003, the global area in-

96. 7 C.F.R. § 205.301 (2005). *See also* 7 C.F.R. §§ 205.303, 205.304, 205.305 (2005).

97. 7 C.F.R. § 205.301 (2005). For a more in depth discussion of these labeling requirements and the requisite proportions see Nicholas, *supra* note 89.

98. *See* 66 Fed. Reg. 37,772, 37,783 (July 19, 2001) (referring to the recognized safety of breeding sexually compatible plants).

99. *See id.*; 57 Fed. Reg. 22,984, 22,295 (May 29, 1992) (declaring that GMOs that are substantially similar to traditional counterparts are generally recognized as safe).

100. FRANÇOISE SIMON & PHILIP KOTLER, BUILDING GLOBAL BIOBRANDS: TAKING BIOTECHNOLOGY TO MARKET 4 (2003).

101. *Id.* at 5 (describing Apligraf, a product by Organogenis, which was the first engineered skin and was approved by FDA for leg ulcers and another tissue engineering company, Gentis, which uses products to build new cartilage).

102. *Id.* (referring to the company Regenesis, whose products can be reviewed *at* http://www.regenesis.com/products).

103. International Service for the Acquisition of Agri-Biotech Applications uses the term "biotech crop" in its research and includes such items as genetically modified maize, soybean, and cotton. *See generally* Clive James, *Global Status of Commercialized Biotech/GM Crops: 2005*, at 3, *available at* http://www.isaaa.org/kc/CBTNews/press_release/briefs34/ESummary/Executive%20Summary%20(English).pdf.

104. *Id.*

creased by fifteen percent to approximately 167 million acres, in 2004, it increased twenty percent to an estimated 200 million acres, and in 2005, it increased about eleven percent to an estimated 222 million acres.[105] These crops were grown by an estimated 8.5 million farmers in twenty-one countries.[106]

Eighty percent of the conflicts surrounding biotechnology are related to the agricultural application of the science, but agricultural biotechnology only accounts for less than fifteen percent of total private biotechnology research and development.[107] The reason for the focused attention has been attributed to environmental liabilities and other vulnerabilities of first generation biotech crops—particularly those using *Bacillus thuringiensis* (*Bt*).[108]

A company must notify EPA before it can perform certain tests to develop a plant that contains genetically modified microbial pesticides,[109] but notification is not required when the testing is conducted in a facility with adequate containment controls.[110] For example, to minimize the risk of genetic drift, EPA imposed a 660 foot buffer zone between StarLink corn and neighboring fields to minimize the effect of genetic drift.[111] Meanwhile, the developer also is encouraged to consult with FDA to determine whether the GMO introduces any new potential allergens.[112]

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105. *Id.*

106. *Id.*

107. Frederick H. Buttel, *Assessing the Environmental Implications of Agricultural Biotechnologies: A Sociological Perspective, in* AGRICULTURAL BIOTECHNOLOGY AND ENVIRONMENTAL QUALITY: GENE ESCAPE AND PEST RESISTANCE 47, 51 (Ralph W.F. Hardy & Jane Baker Segelken eds., 1998).

108. *Id. Bt* works as a midgut toxin that is effective only when ingested by insects. Hari C. Sharma et al., *The Utility and Management of Transgenic Plants with* Bacillus thuringiensis *Genes for Protection from Pests, in BACILLUS THURINGIENSIS*: A CORNERSTONE OF MODERN AGRICULTURE 53, 55 (Matthew Metz ed., 2003).

> Insect mortality may occur in hours to days, and takes much longer than for synthetic insecticides. In transgenic crops having Bt genes, the plant tissues produce specific Cry proteins in a soluble form that . . . bind to specific receptors on the insect midgut epitheluem, forming pores and leading to loss of the transmembrane potential, cell lysis, leakage of the midgut contents, paralysis, and death of the insect. Insects that develop resistance to Bt most commonly exhibit decreased or altered receptor binding or even proteolytic inactivation. *Id.* (citations omitted).

109. 40 C.F.R. § 172.45 (2005).

110. 40 C.F.R. § 172.45(d)(2) (2005).

111. *StarLink*, 212 F. Supp. 2d at 834.

112. *See generally*, 66 Fed. Reg. 4706 (Jan. 18, 2001) (proposing a mandatory consultation with FDA prior to market release).

Plant breeding programs are conducted by various state agricultural agencies, colleges and universities, USDA, and private companies.[113] Based upon "agronomic" need, a choice is made as to which trait will be introduced to a certain plant.[114] Then, if the trait is among the genetic resources available, the next decision is how to impart it to the crop—either through sexual hybridization, cross-pollination techniques, or recombinant DNA.[115]

V. THE LITIGATION

Despite efforts to test, develop, harvest, and market a GMO under controlled circumstances, there have been instances where GMOs were discovered in the food supply or otherwise growing on neighboring lands.[116] GMO proponents argue that GMO developers are not presented with any new or additional legal liabilities beyond those faced by developers of traditional crops.[117] Despite that argument, there has been scant litigation where plaintiffs claim to have suffered bodily harm as a result of GMOs. As of late 2005, there were no documented cases of illness due to consumption of GMO food products which resulted in litigation.[118] Therefore, the GMO

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113. *See* Smith, *supra* note 29, at 18.

114. *See id.*

115. *Id.*

116. *See generally* SmithKline Beecham Corp. v. Apotex Corp., 365 F.3d 1306 (Fed. Cir. 2004) (regarding patent infringement of GMO anti-depressant drug) (Gajarsa, J. concurring) (discussing the possibility of GMO blue corn blowing across the country at 1030-31); *StarLink*, 212 F. Supp. 2d 828 (N.D. Ill. 2002) (involving StarLink corn discovered in human food supply); Campbell v. AG Finder Iowa Neb., Mgmt. Consultants, Inc., 683 N.W.2d 126 (Iowa Ct. App. 2004) (regarding a breach of contract for sale of in nonconformity where purchaser-farmer unknowingly bought GMO seed and could not sell it due to its GMO status). *See also Bentgrass May Spell Trouble*, L.A. TIMES, Sept. 25, 2004, Science File (discussing the EPA's discovery of GMO grass developed for golf courses 13 miles away from the course).

117. *See* Drew Kershen, *Legal Liability Issues in Agricultural Biotechnology*, at 4 (Nov. 2002), *at* http://www.nationalaglawcenter.org/assets/articles/kershen_biotech.pdf (last visited Mar. 23, 2006) (stating that "the United States leaves the issue of legal liability for agricultural biotechnology products . . . to the laws applicable generally to agricultural products . . . primarily the common law of torts"). An interesting argument raised by Kershen in an earlier article is that manufacturers of traditional crops may be held liable for harms caused by the traditional crops when plaintiffs bring an action on a design defect theory and introduce the GMO as proof of a reasonable alternative design to traditional crops. Drew Kershen, *The Risks of Going Non-GMO*, 53 OKLA. L. REV. 631, 633-37 (2000).

118. *See* David Hegewood, *Remarks on Regulating Genetically Modified Foods in the United States*, 10 RICH. J.L. & TECH. 10, at *12 (2004) (stating that as of late 2004 no such instances have occurred). The author's research has not discovered any new

developer or anyone who desires to sell or market foods that may contain GMOs needs to assess the risks of liability should the product cause harm.[119] To assess those risks, several cases and the Restatement (Third) of Torts provide some insight into the potential liability for claims based upon the various theories of products liability.[120]

A. Escape

In September 2001, a consumer group called the Genetically Engineered Food Alert[121] reported that a variety of corn not approved for human consumption had made its way into the food supply—specifically in certain taco shells.[122] FDA began an investigation after hearing allegations that the taco shells contained StarLink corn.[123] The producer of the taco shells initiated its own investigation and voluntarily recalled millions of taco shells as soon as the presence of the Cry9C gene was independently verified.[124] It was subsequently confirmed that StarLink was present in the taco shells.[125]

Naturally, the presence of proteins unapproved for human consumption invokes concerns of whether the proteins may cause aller-

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developments as of late 2005. However, the possibility may remain. *See Brazil Nut Project Shows Modified Foods Can Inherit Troubles of Genes They Receive*, STAR TRIB., May 2, 2000, at 12A (noting the spread of allergic proteins from a brazil nut into a genetically modified soybean where the GMO soybean product triggered allergic responses to persons known to be allergic to brazil nuts) [hereinafter Brazil Nut Article].

119. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 7 (1998) (stating that one who sells or distributes a food product that is defective is subject to liability for harm caused by the defect).

120. *See infra* Sections V.A., V.B., VI, and VII.

121. For general information regarding the Genetically Engineered Food Alert see http://www.gefoodalert.org/pages/home.cfm.

122. Raymond Formanek, Jr., *Proposed Rules Issued for Bioengineered Foods, at* http://www.fda.gov/fdac/features/2001/201_food.html (last visited Mar. 23, 2006) [hereinafter Formanek].

123. *Id. See also* Sagarra & Rawson, *supra* note 67 ("StarLink hybrids contain a plant pesticide protein (Cry9C) derived from a common soil microbe [*Bt*], which kills certain destructive pests of corn such as the European corn borer."). The problem is that when StarLink was originally approved by the EPA, it was permitted to be used only as livestock feed or industrial purposes and not for human consumption. *See id.*

124. *Id.* Cry9C is used with corn and is intended to provide protection from certain pests. 66 Fed. Reg. 17,706, 17,707 (Apr. 3, 2001).

125. 66 Fed. Reg. at 17,708.

gic reactions or other dangerous effects when they are consumed.[126] Some commentators argue that the new proteins in GMOs can lead to the creation of new food toxins or to antibiotic resistance because marker genes[127] might be transferred to bacteria, and thereby lead to antibiotic-resistant pathogenic bacteria.[128]

However, such a conclusion is hardly well-settled. Some researchers disagree, citing that technical approaches used to test GMOs for potential allergenicity prevent GMO foods from posing any harmful effects beyond what is posed by any other food product.[129] In fact, some researchers claim that there is even a greater likelihood of predicting whether a GMO plant will cause an allergic reaction than its traditional counterpart.[130]

B. Labeling

1. Litigation

The creation of food definitions and standards is justified by the need to protect a consumer's ability to judge the quality of a food product.[131] Conflicts between consumers and GMO developers generally revolve around the tension between assertions of consumers' right to know what ingredients are in the food they consume

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126. *See* Sharma, *supra* note 108 (discussing the effects of *Bt* on insects which ingest it).

127. A marker gene is a gene used to alleviate the process of identifying transformed cells and is itself resistant to antibiotics. *See* Ann E. Blechl, *Applications of Biotechnology for Improving the Healthfulness and Utility of Cerals, in* AGRICULTURAL BIOTECHNOLOGY CHALLENGES AND PROSPECTS 53, 54 (Mahesh K. Bhalgat et al. eds., 2004).

128. *See generally* ROBERT ALI BRAC DE LA PERRIÈRE & FRANCK SEURET, BRAVE NEW SEEDS: THE THREAT OF GM CROPS TO FARMERS 47-49 (2000).

129. Dean D. Metcalfe, *Allergenicity of Foods Produced by Genetic Modification, in* GENETICALLY MODIFIED CROPS: ASSESSING SAFETY 94, 107 (Keith A. Atherton ed., 2002).

> [B]ecause almost any food may be allergenic in one or a very few individuals . . . it is not reasonable to expect that modified foods will be absolutely and consistently without allergenic potential in everyone. It is reasonable to expect that the technical approaches available . . . will help prevent the marketing of a modified food with significant allergenic potential. *Id.*

130. *See* NIGEL G. HALFORD, GENETICALLY MODIFIED CROPS 67 (2003); *see also* Brazil Nut Article, *supra* note 118 (stating that some researchers claim that science can be used to control unexpected spread of allergic proteins from one organism to another).

131. Federal Sec. Adm'r v. Quaker Oats Co., 318 U.S. 218, 230-31 (1943); 35A AM. JUR. 2D *Food* § 19 (2001).

and the developer's right to sell food it claims is just as safe without having to label the product in a manner that arguably suggests it is not as safe. These issues were at the heart of the controversy in *Alliance for Bio-Integrity v. Shalala*.[132]

In *Alliance for Bio-Integrity*, a coalition of groups concerned about GMOs sought to challenge the FDA's GMO policy on several grounds.[133] One challenge was to the FDA's presumption that foods developed through recombinant DNA are generally recognized as safe, thereby making it unnecessary to impose mandatory labeling requirements for GMO foods.[134] The plaintiffs argued that FDA should have considered consumer interests when making its determination.[135] The court gave deference to FDA on the presumptive GRAS status of GMOs.[136] The court reasoned:

> The FDA's exclusion of consumer interest from the factors which determine whether a change is "material" constitutes a reasonable interpretation of the statute. Moreover, it is doubtful whether the FDA would even have the power under the FDCA to require labeling in a situation where the sole justification for such a requirement is consumer demand.137

The plaintiffs also argued that the modification of a traditional food equates to a material fact, as defined in FDCA.[138] Again, the court determined that the FDA's policy was rational and entitled to deference over plaintiff's argument.[139]

The plaintiffs' next argument was that the FDA's policy constituted a violation of their right to free exercise of religion by allowing GMOs into the market without labeling them as genetically modified.[140] The court again dismissed this claim, relying upon a prior

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132. 116 F. Supp. 2d 166 (D.D.C. 2000).

133. *Id.* at 170.

134. *See id.*

135. *Id.* at 178.

136. *Id.* at 179 (stating that plaintiffs did not "recognize the determination that a product differs materially . . . is a factual predicate to the requirement of labeling. Only once materiality has been established may the FDA consider consumer opinion to determine whether a label is required to disclose a material fact.").

137. 116 F. Supp. 2d at 179.

138. *Id.* at 178. *See also* 21 U.S.C. § 321(n) (2000) (stating that foods shall be considered to be misbranded if the label fails to reveal facts "material with respect to consequences which may result from the use of the [product] . . .").

139. *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 179-80.

140. *Id.* at 179-80. This argument raises an interesting hypothetical point. For example, what if a transgenic crop were designed to retain a trait transferred from a pig? Does the presence of the trait mean that the food is not to be consumed by followers of religions that expressly forbid consumption of products derived from pigs? *See* Alan Goldhammer, *The Regulation of Agricultural Biotechnology: An Indus-*

Supreme Court case which held that "neutral laws of general applicability do not violate the Free Exercise Clause, even if the laws incidentally burden religion."[141] Essentially, after *Alliance for Bio-Integrity*, the FDA's policy on the GRAS status of GMOs remained unscathed.

Another case regarding the labeling of GMOs is the famous *In re StarLink Corn Products Liability Litigation*[142] case where the plaintiffs sought to impose state tort liability upon a manufacturer of GMOs. In *StarLink*, the defendants argued that FIFRA preempted the state law claims brought by the plaintiffs.[143] The plaintiffs' claim for relief was rejected by the court on grounds that FIFRA preempts state pesticide labeling requirements.[144] It is important to note that the claim for failure to warn of known allergens was premised upon the requirements in FIFRA.[145] This is of particular importance in light of the labeling requirements of the Food Allergen Labeling and Consumer Protection Act of 2004 (Allergen Labeling Act).[146]

2. Food Allergen Labeling and Consumer Protection Act

In 2000, it was reported by a scientific study that certain soybeans (genetically modified with proteins from Brazil nuts) generated allergic reactions to blood serum taken from persons who were known to be allergic to Brazil nuts.[147] This discovery is particularly alarming because, as discussed earlier, GMOs are not presently required to be labeled as having been genetically modified.[148] Therefore, persons who are allergic to Brazil nuts would not be aware that

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trial Perspective, 48 FOOD & DRUG L.J. 501, 507 (1993) (stating that "mainstream Orthodox Jewish groups have accepted microbially-produced calf chymosin, an enzyme used in cheesemaking, as being kosher pareve. Thus, the source of the gene . . . does not preclude a genetically engineered food product from being classified as kosher").

141. *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 179-80. (*citing* Employment Div. v. Smith, 494 U.S. 872 (1990)). In fact, the court reasoned that if the government were to take action to further the practice of an individual's religion, the government would be "precariously close to violating the First Amendment's Establishment Clause." *Id.* at 180.

142. 212 F. Supp. 2d 828 (N.D. Ill. 2002).

143. *Id.* at 836.

144. *See id.* at 835.

145. Plaintiffs'/Intervenors' Class Action Complaint ¶ 25, 212 F. Supp. 2d 828 (N.D. Ill. 2002) (No. 1:01CV04928), 2002 WL 32600026.

146. Pub. L. No. 108-282, 118 Stat. 905-911 (Aug. 2, 2004) (codified in various sections of 21 U.S.C. and 42 U.S.C.).

147. Brazil Nut Article, *supra* note 118, at 12A.

148. *See* discussion *supra* Section V.B.1. and accompanying notes.

certain soy products might trigger their allergic reactions. This would appear to bolster the arguments of opponents of GMOs regarding the alleged hazards of potential allergic reactions in humans as one of the primary concerns raised by GMOs.[149] In 2004, Congress declared its intent to protect consumers from unforeseen allergic reactions by passing the Allergen Labeling Act.[150] By doing so, Congress inadvertently may have revived the debate about whether certain GMOs will be required to be labeled. The new labeling requirements for major food allergens became effective for all foods labeled on or after January 1, 2006.[151]

The Allergen Labeling Act includes several congressional findings such as the eight major foods or food groups that account for approximately ninety percent of food allergies,[152] the difficulty parents face in identifying potential allergens in foods,[153] and that "in some cases, the common or usual name of an ingredient may be unfamiliar to consumers, and many consumers may not realize the ingredient is derived from, or contains, a major food allergen."[154] The Allergen Labeling Act amends FDCA[155] so that a food will be deemed misbranded if it is not a "raw agricultural commodity and it *is*, or it *contains* an ingredient that bears or contains, a major food allergen."[156] This product is considered misbranded unless either (i) the product also states that it "contains" the "name of the food source from which the major food allergen is derived,"[157] or (ii) "the common or usual name of the major food allergen in the list of ingredients . . . is followed in parentheses by the name of the food source from which the major food allergen is derived . . . ."[158]

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149. *See, e.g.*, Repp, *supra* note 6, at 587.

150. Pub. L. No. 108-282, 118 Stat. 905-11 (Aug. 2, 2004) (codified in various sections of 21 U.S.C. and 42 U.S.C.). *See also* Allergen Labeling Act § 202 (2004) (regarding Congressional findings about the nature and extent of food allergens in the United States).

151. Allergen Labeling Act § 203(d)(2004).

152. *Id.* § 202(2)(A) (finding that milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans account for ninety percent of food allergies). These items are all included in the Act's definition of a "major food allergen." *Id.* § 203(c).

153. *Id.* § 202(4).

154. *Id.* § 202(5)(B).

155. 21 U.S.C. §§ 301-99 (2000).

156. Allergen Labeling Act § 203(a) (2004) (codified at 21 U.S.C. § 343(w)(1) (emphasis added).

157. Allergen Labeling Act § 203(a) (2004) (codified at 21 U.S.C. § 343(w)(1)(A)).

158. Allergen Labeling Act § 203(a) (2004) (codified at 21 U.S.C. § 343(w)(1)(B)).

The Allergen Labeling Act goes further to state that, in the case of certain foods such as a tree nut, the term "name of the food source from which the major food allergen is derived" means the "specific type of nut."[159] The scope of this requirement even reaches to flavorings, colorings, or incidental additives that are or contain a major food allergen[160] and states that they are subject to these labeling requirements regardless of "any other law."[161] An exemption from the labeling requirement may be applied for, but the applicant must "provide scientific evidence (including the analytical method used to produce the evidence) that demonstrates that such food ingredient, as derived by the method specified in the petition, does not cause an allergic response that poses a risk to human health."[162] But even that exemption does not completely escape public notice because all petitions, along with any corresponding responses, will be posted to a public site.[163]

At first glance, it would appear that the debate regarding labeling of GMOs may have been reopened by the new labeling requirements of the Allergen Labeling Act. However, the Allergen Labeling Act also forecloses on one of the stronger arguments in favor of labeling. By requiring the disclosure of information regarding major food allergens, a definition that includes products including or derived from such products,[164] Congress now has denied GMO opponents the opportunity to continue to argue consumer safety from allergic reactions as a reason to require the labeling of GMOs. Stated another way, the concern of consumers suffering unforeseen allergic reactions because of transferred allergic properties now has been addressed directly by Congress regardless of whether the food contains or is derived from genetically modified foods.[165]

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159. Allergen Labeling Act § 203(a) (2004) (codified at 21 U.S.C. § 343(w)(2)).

160. Allergen Labeling Act § 203(a) (2004) (codified at 21 U.S.C. § 343(w)(4)). Congress also signaled new regulation for spices, flavorings, colorings, or incidental additives that are, or contain, a food allergen, "other than a major food allergen," as determined by regulation, shall be labeled according to such regulation. *See* Allergen Labeling Act § 203 (2004) (codified at 21 U.S.C. § 343(x)).

161. Allergen Labeling Act § 203 (2004) (codified at 21 U.S.C. § 343(w)(4)).

162. Allergen Labeling Act § 203 (2004) (codified at 21 U.S.C. § 343(w)(6)(C)).

163. *Id.*

164. Allergen Labeling Act § 203(a) (2004).

165. *See supra* notes 147-64 and accompanying text.

VI. IS THE FOOD PRODUCT DEFECTIVE?

In food products liability cases, it is difficult to determine whether a harm-causing ingredient is actually a product defect.[166] In some jurisdictions, harm caused by substances natural to the food product will not impose liability for the harm, but harm caused by substances that are not natural to the food product will.[167] This is often called the "foreign-natural test."[168]

California was the first state to adopt this test in *Mix v. Ingersoll Candy Co.*[169] In *Ingersoll*, the California Supreme Court held that because it is well-known that chicken pies occasionally contain chicken bones and, because the bone was natural to the kind of meat being served, the bone is not a foreign substance and therefore no liability attaches to harm caused by that bone.[170] The "foreign-natural" test was revised in *Mexicali Rose v. Superior Court*[171] to provide that if the substance is natural to the *preparation* of the food, then the only cause of action for harm it caused is negligence if the seller failed to exercise reasonable care preparing it.[172] If the substance *is* foreign to the food product, then a products liability claim may be brought, and the trier of fact must decide whether the presence of the substance is (1) reasonably expected by the average consumer and (2) whether its presence rendered the food unfit or defective.[173]

The foreign-natural test has been adopted in a handful of jurisdictions, but it remains the distinct minority approach to products liability for harm caused by food.[174] The criticism of the foreign-

166. JAMES A. HENDERSON, JR. & AARON D. TWERSKI, PRODUCTS LIABILITY: PROBLEMS AND PROCESS 568 (5th ed. 2004).

167. *See infra* notes 169-76 and accompanying text.

168. This test was first adopted in California. HENDERSON & TWERSKI, *supra* note 166, at 570.

169. 59 P.2d 144 (Cal. 1936), *overruled by* Mexicali Rose v. Superior Court, 822 P.2d 1292 (Cal. 1992).

170. *Id.* at 148. "Bones which are natural to the type of meat served cannot legitimately be called a foreign substance, and a consumer who eats meat dishes ought to anticipate and be on his guard against the presence of such bones." *Id.*

171. 822 P.2d 1292 (Cal. 1992).

172. *Id.* at 1302-03.

173. *Id.* at 1303-04.

174. *See, e.g., id.*; Polite v. Carey Hilliards Rest., Inc., 338 S.E.2d 541, 542 (Ga. Ct. App. 1985) (stating that the possibility of finding a one-inch piece of fishbone in a food prepared from fish is a matter of common knowledge of which the consumer should be aware and guard against himself); Brown v. Nebiker, 296 N.W. 366, 369 (Iowa 1941) (affirming lower court's grant of summary judgment because a pork bone was not a foreign substance in a pork chop); *but see* Bryer v. Rath Packing Co., 156 A.2d 442, 446-47 (Md. 1959) (stating that it is common knowledge that there

natural test is that it has no logical basis for the distinction between what is foreign and what is natural.[175] In addition, the test is criticized because it fails to cover instances where a substance (such as a bone) is natural to the kind of food product but nevertheless should not be in the product because of the way the product was marketed (such as boneless).[176]

The uncertainty between natural and foreign substances would remain unresolved in the context of a case brought for harm caused by the presence of a GMO in a food product. The jury would need to hear expert testimony concerning whether the genetic material inserted into the food product is a foreign or natural substance. The trier of fact would be asked to make that determination.[177] A plaintiff would likely argue that the genetic material is unnatural to the food product because it had to be physically inserted and does not naturally occur within the product.[178] A defendant would likely argue that because the genetic material was compatible with that of the food product, it is a natural combination of the two products, and is therefore not a foreign substance.[179]

Most jurisdictions use a test that evaluates whether the consumer would reasonably expect to find the harm-causing substance in the product, regardless of whether it is foreign or natural to the food product.[180] The "consumer expectations" test is also adopted

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are ingredients in chow mein that resemble bones and make it difficult to anticipate or even guard against the presence of bones, so a canner was held liable where it represented its product as boneless).

175. *See* Clime v. Dewey Beach Enter., Inc., 831 F. Supp. 341, 348 (D. Del. 1993) (stating that the problem with the foreign-natural distinction is that it is artificial because even a natural substance such as "a small, but unforgiving, pearl from an oyster can cause as much damage as a 'foreign' piece of metal when a consumer bites down on it.").

176. *See, e.g., Bryer*, 156 A.2d at 446-47; *see also* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 7 cmt. b (1998) (stating that most courts have found the foreign-natural test inadequate).

177. *See, e.g., Mexicali Rose*, 822 P.2d at 1301-02.

178. *See Alliance for Bio-Integrity*, 116 F. Supp. 2d at 177.

179. *See, e.g.*, C. Neal Stewart, Jr. & Sarah K. Wheaton, *Urban Myths and Scientific Facts About the Biosafety of Genetically Modified (GM) Crops, in* PLANTS, GENES, AND CROP BIOTECHNOLOGY 528, 533 (Maarten J. Chrispeels & David E. Sadava eds., 2d ed. 2003) (stating that even though opponents of GMOs stress that they are unnatural, such seemingly unnatural combinations can occur in nature as well, such as crown gall disease in which bacterial DNA is incorporated into plant DNA).

180. *See* Holowaty v. McDonald's Corp., 10 F. Supp. 2d 1078, 1084 (D. Minn. 1998) (stating that a food product is defective under consumer expectations test if the harm-causing characteristic would not be expected by a reasonable consumer); Cain v. Sheraton Perimeter Park S. Hotel, 592 So. 2d 218, 221 (Ala. 1991) (reaf-

by the Restatement (Third) of Torts in the context of food products.[181] This test has a heritage similar to the theory of implied warranty of merchantability.[182]

Under the consumer expectations test, the primary issue is what a consumer is reasonably justified to expect from his or her food; this is generally a question left for the jury to answer.183 A variation on this approach allows the jury to consider the foreign-naturalness of the harm-causing substance among the factors that create reasonable expectations.184

The consumer expectations test for food products will likely remain the same for a GMO food product. That is, the plaintiff will be required to demonstrate that a consumer would not reasonably expect the food to contain the genetically altered substances.[185]

At first glance, the consumer expectations test seems sufficiently applicable to claims for harm caused by genetically modified food products. However, the manner in which the plaintiff will prove those consumer expectations presents a problem because consumers' attitudes about GMOs are closely related to their beliefs

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firming the adoption of a reasonable expectations standard as the proper standard for food products liability cases); Zabner v. Howard Johnson's, Inc., 201 So. 2d 824, 826 (Fla. Dist. Ct. App. 1967) (stating "[t]he test should be what is 'reasonably expected' by the consumer in the food as served, not what might be natural to the ingredients of that food prior to preparation."); Phillips v. Town of West Springfield, 540 N.E.2d 1331, 1333 (Mass. 1989) (determining that reasonable expectations standard is the appropriate test); Gray v. Manitowoc Co., 771 F.2d 866, 870-71 (Miss. 1985) (comparing consumer expectations standard in a defective food case to a case regarding an allegedly defective construction crane).

181. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 7 (1998). Interestingly, except for a few types of products such as food products, a product is not defectively designed under the Restatement (Third) unless it fails a risk-utility balancing and if the plaintiff cannot present a reasonable alternative design. *Id.* § 2(b).

182. Gates v. Standard Brands Inc., 719 P.2d 130, 134 (Wash. Ct. App. 1986) (stating that the concept of consumer expectations reflects the same warranty heritage found in the theory of implied warranty).

183. Spain v. Brown & Williamson Tobacco Corp., 872 So. 2d 101, 109 (quoting Allen v. Delchamps, Inc., 624 So. 2d 1065, 1068 (Ala. 1993)).

184. Jackson v. Nestle-Beich, Inc. 589 N.E.2d 547, 548-49 (Ill. 1992) (holding that naturalness of the ingredient does not bar recovery but is one factor to be considered in determining whether the product is unreasonably dangerous); Goodman v. Wenco Foods, Inc., 423 S.E.2d 444, 451 (N.C. 1992) (holding that it is not a complete bar to recovery if the harm causing substance is natural to the food product); Betehia v. Cape Cod Corp., 103 N.W.2d 64, 67 (Wis. 1960) (stating that merely classifying a substance as foreign or natural may be important in determining negligence of the processor of food, "but it is not determinative of what is unfit or harmful in fact for human consumption.").

185. *See, e.g., Alliance for Bio-Integrity*, 116 F. Supp. 2d at 177.

about the science.[186] Furthermore, consumer understanding may be an unreliable standard if forty-five percent of United States consumers do not realize that both GMO and non-GMO food products contain genes.[187] In addition, because corn and soybeans, two of the most widely grown GMOs in the United States,[188] are used in processed food, consumers may not realize that up to seventy percent of all products in the country's supermarkets may contain GMOs.[189]

It has been argued that the consumer expectations test is inappropriate when the case involves GMOs because GMOs (1) have a "design" in the same sense as "manufactured" products and (2) because consumers do not have widely shared standards about GMOs.[190] The latter part of this argument is bolstered by the lack of a labeling requirement for GMOs[191] in contrast with regulatory requirements that must be met in order to market foods as organic.[192] Without a label on the GMO product, how is a consumer supposed to determine what his or her expectations are, or in the alternative, what would such expectations be for an unlabeled, potentially-GMO product when it is on the shelf next to a product labeled as organic? In summary, although standards exist for determining whether a party is liable for harm caused by food products, the present standards being utilized are inadequate in the context of GMOs.

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186. Thomas J. Hoban, *International Acceptance of Agricultural Biotechnology, in* AGRICULTURAL BIOTECHNOLOGY AND ENVIRONMENTAL QUALITY: GENE ESCAPE AND PEST RESISTANCE 59, 71 (Ralph W.F. Hardy & Jane Baker Segelken eds., 1998).

187. *Id.* at 68.

188. *See* James, *supra* note 103.

189. *See* Stewart & Wheaton, *supra* note 179, at 532.

190. Katharine Van Tassel, *Adding Biotech Foods to the Tort System*, WEST MASS. L. TRIB. (Aug. 2003), *reprinted in part in* JAMES A. HENDERSON, JR. & AARON D. TWERSKI, PRODUCTS LIABILITY: PROBLEMS AND PROCESS 571-72 (5th ed. 2004).

> [Basing a claim for harm caused by GMO is] without merit when dealing with GM food. First, GM food clearly has a design like any other manufactured product. Second, while consumers may have well-informed, culturally defined and widely shared standards when it comes to some foods, they certainly do not when it comes to GM foods . . . . A recent survey conducted by the University of Richmond revealed that [sixty-two] percent of those surveyed said that they had not eaten any genetically modified foods, and very few of those surveyed were aware that more than sixty percent of the packaged foods sold in [United States] supermarkets contain bio-engineered ingredients. *Id.*

191. *See generally Alliance for Bio-Integrity*, 116 F. Supp. 2d 166 (D.D.C. 2000).

192. OFPA, 7 U.S.C. §§ 6501-23 (Supp. 2004).

VII. OTHER THEORIES OF PRODUCTS LIABILITY IN THE CONTEXT OF FOOD PRODUCTS

A claim for harm caused by a defective product can be brought primarily under theories of (1) manufacturing defect, (2) design defect, or (3) failure to warn defect.[193] Anyone who sells or distributes a food product found to be defective is subject to liability for harm caused by that defect.[194] Although there has been scant litigation on these matters concerning GMOs, a few cases addressing these forms of liability in the context of food products help analyze what would happen in a food products liability lawsuit regarding GMOs.

A. Manufacturing Defect

A manufacturing defect exists when a product departs from its intended design even though all possible care was exercised in its preparation and marketing.[195] The manufacturer or seller will be held strictly liable for harm caused by the manufacturing defect.[196] Thus, in a manufacturing defect case involving GMOs, the claim might arise when a GMO species finds its way into a product specifically branded or labeled as organic (or otherwise non-GMO) and subsequently causes harm. A good example of such an instance is the *StarLink* incident where corn unapproved for human consumption was discovered in the nation's food supply.[197]

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193. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 7 (1998). For the moment, it has been settled that GMO products will not be required to be specially labeled. *See also Alliance for Bio-Integrity*, 116 F. Supp. 2d 166 (D.D.C. 2000); *infra* notes 195-256 and accompanying text. However, some researchers claim that in certain situations if a company that does choose to warn against harm by labeling the product, it may be inviting more liability on itself because once some kind of warning is provided, it might serve as an admission by the manufacturer that an underlying duty to warn did exist. *See* HENDERSON & TWERSKI, *supra* note 166, at 328-29.

194. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 7 (1998).

195. *Id.* § 2.

196. *See, e.g.*, Shoshone Coca-Cola Bottling Co. v. Dolinski, 420 P.2d 855, 856 (Nev. 1966) (holding a bottler strictly liable when plaintiff partially consumed the contents of a bottled beverage containing a decomposed mouse).

197. *StarLink*, 212 F. Supp. 2d 828 (N.D. Ill. 2002). The plaintiffs alleged at least four points in the supply chain where the GMO corn could have entered the food supply: the farmers' supplier inventory was mingled when received, pollen drift from neighboring StarLink fields, transport or storage, or in processing. *Id.* at 842-43. However, it is important to note that no facts were found by the court in this case. It was a ruling on defendants' motion to dismiss and therefore the court was reviewing the facts in a light most favorable to the plaintiffs. *Id.* at 835.

In *StarLink*, a class action lawsuit was filed on behalf of consumers who claimed they ingested food unfit for human consumption.[198] This lawsuit resulted in a $9 million settlement against Aventis, the owner of StarLink.[199] Similarly, in *Monsanto Canada, Inc. v. Schmeiser*,[200] GMO canola was discovered in a neighboring non-GMO, canola field.[201] Again, the parties disputed the means by which the GMO canola arrived in the non-GMO field.[202] Monsanto claimed that Schmeiser acquired the GMO seed in violation of Monsanto's rights as a patent holder.[203] Schmeiser claimed that GMO pollen drifted onto his property or that seed was otherwise transferred to his property accidentally.[204]

These two cases clearly demonstrate the possibility of GMOs escaping from the confines of regulatory controls, either through their own promiscuity with other sexually compatible breeds or by other methods (i.e., transportation, storage, packaging, or processing).[205] The general concept of such a claim is that the GMOs commingled with traditional counterparts, entered the food supply, and caused harm; therefore, the person harmed might recover under a theory of manufacturing defect.[206]

B. Design Defect: Risk-Utility v. Consumer Expectations[207]

Under the Restatement (Third) of Torts, a product is defectively designed if the foreseeable risks of harm could have been re-

198. *See generally id.*
199. *See* Kershen, *supra* note 117, at 15 n.65.
200. [2001] F.C. 256, *aff'd in part rev'd in part*, [2004] 1 S.C.R. 902.
201. *Id.* ¶ 8.
202. *See id.* ¶ 11.
203. *Id.* ¶ 1.
204. *See id.* ¶ 11.
205. Processing poses a completely different problem in that GMO and non-GMO products alike are processed together. *See* Neil E. Harl, *Biotechnology Policy: Global Economic and Legal Issues*, 12 WILLAMETTE J. INT'L L. & DISP. RESOL. 1, 9 (2004) (estimating that seventy percent or more of all processed foods contain GMOs).
206. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 7 cmt. b (1998). "Food product cases . . . sometimes present unique difficulties when it is unclear whether the ingredient that caused the plaintiff's harm is unanticipated adulteration or is an inherent aspect of the product." *Id.*
207. There are many other issues that arise in a design defect case (such as whether certain kinds of GMOs should be adjudged defective as a product category or whether producing GMOs is an abnormally dangerous activity). *See generally* HENDERSON & TWERSKI, *supra* note 166, at 161-313. However, such issues are beyond the scope of this comment.

duced or avoided by using a reasonable alternative design, and failure to utilize that alternative design renders the product unreasonably unsafe.[208] Some factors considered in deciding whether a product is unreasonably unsafe for failure to adopt an alternative reasonable design include the magnitude and probability of foreseeable risks,[209] the likely effects of the alternative design on production costs, and whether the alternative design was technologically and economically feasible.[210] By contrast, some states apply a consumer expectations standard in the context of a design defect case.[211] In states that apply the consumer expectations standard for a defective design claim, the plaintiff would encounter the same obstacles as he or she would under the consumer expectations standard (i.e., defining reasonable expectations of consumers).[212]

In the context of GMOs, a plaintiff is likely to argue that the manufacturer of the GMO failed to adopt a reasonable alternative design and such failure rendered the product unreasonably safe.[213] Then, under the Restatement (Third) approach, the plaintiff must prove that the reasonable alternative design was technologically and economically feasible.[214] The plaintiff's argument at this point might be that the organic version of the product is the reasonable alternative design that was not adopted. In contrast, the defendant will likely marshal the advantages of GMOs and use risk-utility analysis as a shield from liability.[215] Furthermore, a plaintiff would encounter the same obstacles as in a food product liability case if the consumer

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208. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2(b) (1998).

209. This consideration comes from the *B* > *PL* risk-utility negligence formula coined by Judge Learned Hand in U.S. v. Carroll Towing Co., 159 F.2d 169, 173 (2d Cir. 1947) where B is the burden placed upon the defendant in preventing foreseeable harm, P is the probability of injury to the plaintiff, and L is the degree of damage that will be caused by breaching a duty owed to the injured party. *Id.*

210. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2(b) cmt. f (1998).

211. *See, e.g.*, Delaney v. Deere & Co., 999 P.2d 930, 946 (Kan. 2000) (holding that the ultimate determination is whether the product is unreasonably dangerous beyond a reasonable consumer's expectations); Green v. Smith & Co., 629 N.W.2d 727, 741 (Wis. 2001) (referring to the standard as the consumer contemplation test).

212. *See supra* notes 186-92 and accompanying text.

213. *See, e.g.*, *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 170. Although this case was not brought as a design defect products liability case, the plaintiffs brought the action to protest GMOs because of their "design" as having been produced by recombinant DNA techniques. *Id.*

214. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2(b) cmt. f (1998) (explaining that a plaintiff must prove that the reasonable alternative design is technologically and economically feasible).

215. *See infra* notes 221-236 and accompanying text.

expectations standard were applied (i.e., proving reasonable consumer expectations).[216]

One commentator has proposed that courts evaluate harm caused by the ingestion of GMOs under a "utilitarian risk/utility" theory of liability.[217] Under this proposal, which closely follows the Restatement (Third) approach to design defect liability for non-food products,[218] the case is more focused upon the conduct of the manufacturer as opposed to the reasonable expectations of the injured plaintiff.[219] Furthermore, the plaintiff would prevail if he or she could prove that a reasonable alternative design (made at a reasonable cost) would have reduced the foreseeable risks of harm to the plaintiff.[220]

C. The Benefit v. Risk Analysis of GMOs

1. Benefits

GMOs have been championed in the United States as a potential solution to world famine and malnutrition.[221] It is argued that crop yields can be boosted, crops would remain fresh longer, be more resistant to insects or disease, and can tolerate herbicides to allow farmers to spray weed killers without damaging the crops.[222] Also included among the advocated advantages are that farmers can minimize their use of chemical fertilizers, pesticides, irrigation, and fuel, and therefore convert those savings into additional output.[223] A final benefit is that higher nutritional value can be achieved through bio-engineering crops.[224]

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216. *See supra* notes 186-92 and accompanying text.
217. Katharine Van Tassel, *The Introduction of Biotech Foods to the Tort System: Creating a New Duty to Identify*, 72 U. CIN. L. REV. 1645, 1688-704 (2004).
218. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2(b) (1998).
219. Van Tassel, *supra* note 217, at 1693.
220. *See id.*
221. *See* Julian Wong, Note, *Are Biotech Crops and Conventional Crops Like Products? An Analysis Under GATT*, 2003 DUKE L. & TECH. REV. 27, *3 (Oct. 2003).
222. *See id.*
223. *Id.*
224. *Id.*

2. Risks

Much of the criticism of GMOs stems from the lack of certainty experts have regarding long-term health effects.[225] Potential disadvantages include the unregulated escape of GMOs into the food supply thereby exposing humans to new allergens[226] or lead to the development of antibiotic-resistant bacteria in the human body.[227] Furthermore, critics argue that environmental risks develop by permitting unrestricted gene flow (in the form of bio-engineered traits) to fuse with wild relatives through pollination;[228] this can lead to the creation of uncontrollable "superbugs"[229] or "superweeds."[230] Another cause of concern is that large-scale cultivation of GMOs could lead to the loss of crop diversity.[231]

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225. *See* Greenpeace, *Say No to Genetic Engineering*, *at* http://www.greenpeace.org/international/campaigns/genetic-engineering (stating that there is not adequate scientific understanding of the impact of GMOs on the environment and human health) (last visited Mar. 23, 2006).

226. *See* Britt Bailey, *A Societal Role for Assessing Safety*, *in* ENGINEERING THE FARM 113, 120 (Britt Bailey & Marc Lappé eds., 2002) (stating the major hesitation to widespread acceptance of such GMOs as *Bt* crops is the potential allergic reactions that may be caused by them). For greater detail about *Bt* see *supra* note 67.

227. Sheldon Krimsky, *Ethical Issues Involving the Production, Planting, and Distribution of Genetically Modified Crops*, *in* ENGINEERING THE FARM 11, 22 (Britt Bailey & Marc Lappé eds., 2002) (asserting that antibiotic-resistant genes can be transferred to bacteria in the stomachs of humans or animals and can lead to increased populations of antibiotic resistant bacteria).

228. *Id.* at 18 (referring to the process as "genetic pollution").

229. "Superweeds" and "superbugs" are terms used often in academic criticism of GMOs to describe the effect of insects and weeds that develop immunities to the GMO resistance built into the plants and thus become resistant to pesticide and other traditional pest control mechanisms. Wong, *supra* note 221, at *5. *See also* Sean D. Murphy, *Biotechnology and International Law*, 42 HARV. INT'L L.J. 47, 59 (2001). The use of such terms is considered imprecise, or even inappropriate, by some experts because an evolving resistance to pest control mechanisms is a natural consequence that occurs even in natural breeding methods (i.e., selecting and breeding only the healthiest and most resilient specimens). *See* Stewart & Wheaton, *supra* note 179, at 531.

230. *See* Stewart & Wheaton, *supra* note 179, at 531. The theory of "superweeds" has even been dramatized in film. The movie *Corn* took the fear a step further by suggesting that pregnant women who ate meat from sheep who consumed the "superweed" were very likely to miscarry. CORN (Revere Pictures 2004) (regarding the use of GMO corn which leads to a genetically mutated weed that when eaten by sheep causes the sheep to become violent).

231. Marc Lappé, *Perspectives on Anti-Biotechnology Convictions*, *in* ENGINEERING THE FARM 135, 152 (Britt Bailey & Marc Lappé eds., 2002) (suggesting that more research should be completed to determine whether loss of biodiversity is sufficiently detrimental to justify more regulatory control of GMOs).

Another dimension of GMO criticism is the deep suspicion expressed by citizens of many European Union member countries and Japan[232] concerning genetically modified foods.[233] This concern is fueled by consumer fears that modification is an unnatural extension of traditional plant breeding, and products produced using such technology should not be presented to the population for consumption until they are proven to be safe.[234]

Regardless of the side of this debate a person empathizes with, the only certainty about GMOs is that the scientific community cannot reach a consensus on the matter.[235] Therefore, a company that desires to participate in the market of genetically modified foods would be well-served by first determining the regulations governing GMOs and evaluating potential legal risks presented by them.[236]

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232. *See* Press Release, No! GMO Campaign, Monsanto Suspends Development of Herbicide Resistant GM Wheat; Japanese Consumer Petition Stops GM Wheat (2004), *available at* http://www.no-gmo.org/new/2004/510e.htm (announcing that Japanese consumer pressure essentially forced Monsanto to abandon developing GM wheat and rice). However, Japanese rice farmers and consumers may become more accepting of GMO rice that alleviates the effects of hay fever allergies. *See* Jiji Press Ltd., *The Day When People Eat Rice to Alleviate Sneezing and Snivels Caused by Pollen-Induced Allergies May Not be Too Far Away* (Feb. 7, 2005).

233. *See generally* Thomas J. Hoban, *International Acceptance of Agricultural Biotechnology*, *in* AGRICULTURAL BIOTECHNOLOGY AND ENVIRONMENTAL QUALITY: GENE ESCAPE AND PEST RESISTANCE 59 (Ralph W.F. Hardy & Jane Baker Segelken eds., 1998). Hoban conducted a study in the United States, Canada, and several other European countries. The survey provided participants with several different statements and asked the participant to answer whether they thought the statement was "True," "False," or that they didn't know. One statement was that "[o]rdinary tomatoes do not contain genes, while genetically modified ones do." *Id.* at 68. Fifty-two percent of Canadian participants and 46% of United States participants responded "False"—the correct answer. *Id.* By comparison, European participants who responded False were as follows: Austria, 34%; France, 32%; Germany, 36%; Ireland, 20%; Italy, 35%; Spain, 28%; United Kingdom, 40%. *Id.*

234. *See, e.g.*, Stewart & Wheaton, *supra* note 179, at 533 (discussing the popular opinion that GMOs are the byproducts of an unnatural science).

235. *See generally* notes 221-234 and accompanying text.

236. *See* Kershen, *supra* note 117, at 1 (stating that those who produce or use agricultural biotechnology need to know about the legal standards to which they will be held accountable); *see also* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 7 (1998) (stating that one who sells or distributes a food product that is defective is subject to liability for harm caused by the defect).

3. GMOS And Liability For Failing To Warn Of Common Allergens

It is estimated that approximately 11,000,000 people in the United States suffer from food allergies.[237] In general, allergies (including allergies to non-food products) are the sixth leading cause of chronic diseases in the United States and cost the health system approximately $18 billion annually.[238] A food allergy is an immunological response to a food which the body mistakes as being harmful.[239] When that happens, the body creates a specific antibody, immunoglobulin E (IgE), to protect the body from that food product in the future.[240] The next time the individual eats that food, the food interacts with the IgE antibody and triggers the release of chemicals like histamines to protect the body from that food.[241] This process results in a series of allergic symptoms that affect the skin, respiratory system, cardiovascular system, or gastrointestinal tract.[242] An allergic reaction to food can happen within a few minutes or until an hour after eating the food.[243]

Ninety percent of all food allergies involve milk, eggs, peanuts, tree nuts (walnuts and cashews), fish, shellfish, soy, and wheat.[244] The most common symptoms of food allergies are skin irritation (rashes, hives, and eczema) and gastrointestinal symptoms (nausea, diarrhea, and vomiting).[245] The respiratory system is also affected sometimes with such symptoms as sneezing, runny nose, and short-

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237. The Food Allergy & Anaphylaxis Network (FAAN), *Answers to Frequently Asked Questions*, *at* http://www.foodallergy.org/questions.html (last visited Mar. 23, 2006) [hereinafter FAAN FAQs]. Food allergies should not be confused with food intolerances. A food intolerance is a reaction to a food product that does not involve the body's immune system. *See id.* For example, a person who is lactose intolerant has a food intolerance which means he or she lacks an enzyme needed to digest milk sugar. *Id.*

238. National Institute of Allergy and Infectious Diseases (NIAID), *Allergy Statistics*, *available at* http://www.niaid.nih.gov/publications/pdf/foodallergy.pdf [NIAID Statistics].

239. FAAN, *Common Food Allergens*, *at* http://www.foodallergy.org/allergens.html (last visited Mar. 23, 2006) [hereinafter FAAN Common Allergens].

240. NIAID, *Food Allergy: An Overview*, at 3 (July 2004), *available at* http://www.niaid.nih.gov/publications/pdf/foodallergy.pdf [hereinafter NIAID Overview].

241. *Id.*

242. *Id.* at 4.

243. *Id.*

244. FAAN Common Allergens, *supra* note 239.

245. International Food Informational Council Foundation, *Understanding Food Allergy*, at 2, *available at* http://www.ific.org/publications/brochures/upload/Understanding-Food-Allergy-Brochure.pdf.

ness of breath.[246] Although rare, some persons may suffer from anaphylaxis, which is a potentially fatal condition when allergic reactions occur in multiple parts of the body at the same time such as itching, hives, swelling of the throat, difficulty breathing, lower blood pressure, and unconsciousness.[247] Tree nuts and peanuts are the primary causes of anaphylaxis.[248]

James A. Henderson, Jr. has described the paradigm products liability cases involving allergic reactions as follows:

> A widely distributed [product] containing an allergen causes the user or consumer to suffer [an] allergic [reaction] . . . . The onset of symptoms is abrupt, with little or no forewarning . . . . The producer cannot remove the allergen from the product without significantly reducing its effectiveness. The product unit that causes injury is harmless to the large majority of users and consumers who are not allergic to it, and thus including the allergen is a reasonable design choice. Typical of a majority of users and consumers, the victim does not and cannot know ahead of time that he will suffer an allergic reaction to the product or any of its ingredients. The producer knows ahead of time that a small percentage of persons will suffer such allergic reactions . . . and warns of this possibility in its marketing. But neither the producer nor users/consumers can identify those specific individuals who will suffer unexpected adverse reactions until those reactions actually occur.[249]

In general, a warning is required when a substantial number of people are allergic to a harm-causing ingredient of the food product.[250] The ingredient that causes the allergic reaction must be something that consumers do not generally know is present in the product or do not know is dangerous.[251] However, the plaintiff must

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246. *Id.*

247. *Id.*

248. *See* NIAID Overview, *supra* note 240, at 6. About 150 Americans die annually from anaphylaxis caused by food. *See* NIAID Statistics, *supra* note 238.

249. James A. Henderson, Jr., *Process Norms in Products Litigation: Liability for Allergic Reactions*, 51 U. PITT. L. REV. 761, 777-78 (1990).

250. *See* Santarelli v. BP Am., 913 F. Supp. 324, 332 (M.D. Penn. 1996) (regarding ingestion of salmon contaminated with ciguatera toxin); Allen v. Delchamps, Inc., 624 So. 2d 1065, 1069 (Ala. 1993) (regarding a consumer alleging injuries from ingestion of celery hearts treated with sodium bisulfite); Livingston v. Marie Callender's Inc., 72 Cal. App. 4th 830, 840 (1999) (holding that a plaintiff who ate a bowl of soup containing monosodium glutamate after having been told the soup did not contain it should be allowed to bring a claim for failure to warn of an ingredient to which a substantial number people are allergic); Brown v. McDonald's Corp., 655 N.E.2d 440, 444 (Ohio Ct. App. 1995) (involving a customer who suffered severe reaction to carrageenan, a seaweed-derived ingredient in hamburger product). *See also* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmt. k (1998).

251. *See, e.g.*, Pelman v. McDonald's Corp., 237 F. Supp. 2d 512, 536 (S.D.N.Y. 2003) (dismissing plaintiff's allegations that cholesterol, fat, salt, and sugar are al-

show "the allergic predisposition is not unique to the plaintiff."[252] Furthermore, a manufacturer generally is not required to provide warnings about allergic reactions that are not reasonably foreseeable at the time of sale.[253]

When genetic material from a common food allergen is transferred into another food product, people who eat the resulting food product may have an allergic reaction.[254] The plaintiff in that case will have a strong argument that the manufacturer should have warned the consumer that the food product contained allergen substances similar to those in Brazil nuts because Brazil nuts are a commonly known allergen and it is reasonably foreseeable that a consumer would have an allergic reaction after consuming the food product.[255] This is the area of the law of food products liability that may be affected most by the requirements of the Allergen Labeling Act.[256]

VIII. CONCLUSION: CAVEAT VENDITOR

Assuming that a biotechnology company can find its way through the labyrinthine regulations of several different federal agencies, it will be faced with another difficult obstacle in the risk analysis of entering the GMO market. First, if the company must defend a food products liability case, the company will encounter great difficulty in overcoming the challenges regarding either the foreign-natural or consumer expectations tests. Furthermore, if the company faces an allergic reaction case, it is not guaranteed protection from failure to warn if it should have been aware that a substantial portion of persons would have an allergic reaction to its prod-

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lergens for lack of evidence and failing to demonstrate that the existence of such ingredients are unknown to the public); Daley v. McNeil Consumer Prod. Co., 164 F. Supp. 2d 367, 373 (S.D.N.Y. 2001). *See also* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmt. k (1998).

252. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmt. k (1998).

253. *See, e.g.*, RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmts. k, m (1998).

254. Lori B. Andrews, *Patents, Plants, and People: The Need for a New Ethical Paradigm, in* ENGINEERING THE FARM 67, 77 (Britt Bailey & Marc Lappé eds., 2002) (referring to Pioneer Hi-Bred's project in which proteins from Brazil nuts were transferred to soybeans and persons allergic to nuts suffered allergic reactions when the soy products were consumed). *See also* T.J. Higgins & Maarten J. Chrispeels, *Plants in Human Nutrition and Animal Feed, in* PLANTS, GENES, AND CROP BIOTECHNOLOGY 152, 178 (Maarten J. Chrispeels & David E. Sadava eds., 2d ed. 2003).

255. *See supra* notes 251-54 and accompanying text.

256. *See* discussion *supra* Section V.B.2 and accompanying notes.

uct—particularly in light of the requirements of the Allergen Labeling Act. Therefore, a company desiring to enter the GMO market does so at the risk of uncertainty as to what legal standard it will be held if its GMO product causes harm. Let the merchant beware.