Voluntary Labeling of Bioengineered Food: Cognitive Dissonance in the Law, Science, and Public Policy

by

Frank J. Miskiel

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VOLUNTARY LABELING OF BIOENGINEERED FOOD: COGNITIVE DISSONANCE IN THE LAW, SCIENCE, AND PUBLIC POLICY

Frank J. Miskiel[*]

It has become commonplace—the norm—for government regulation to seem completely detached from common sense. So much so that regulation typically imposes enormous costs—in terms of money, time, and inconvenience—on American consumers, businesses, and employees, with very little benefit, if any.[1]

I. INTRODUCTION

"Non-GMO." This is a label that has recently begun to appear on many foods in the United States. Now the "non-GMO" segment of the food industry is vying with the "organic" food industry's growing popularity.[2] "GMO" is an acronym for "genetically modified organisms" and has been embraced as shorthand for all bioengineered foods.[3] The "non-GMO" label itself has

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[*] J.D. Candidate, August 2002, California Western School of Law; B.S. Biochemistry, Penn State University, 1985; Ph.D. Plant Physiology, Penn State University, 1990. I would like to thank the many people who helped bring this article to fruition. Special thanks go to Dr. Mike Cleary whose insights, comments, and cynicisms planted the seeds for this paper (not to mention suggesting the title!). I would also like to thank Jason Saccuzzo for his criticisms and suggestions, and Jayshree Gerken for her helpful editing and encouragement. Finally, I would like to thank Steve Leduc for his support and editing prowess throughout the entire writing process.

1. JAMES T. BENNETT & THOMAS J. DILORENZO, THE FOOD & DRINK POLICE—AMERICA'S NANNIES, BUSYBODIES & PETTY TYRANTS 17 (1999) (commenting generally on PHILIP HOWARD, THE DEATH OF COMMON SENSE: HOW LAW IS SUFFOCATING AMERICA (1994)).

2. *See Seeds of Doubt: Some Ingredients are Genetically Modified, Despite Labels*, WALL ST. J., Apr. 5, 2001, at A1, *available at* 2001 WL 2859401. The organic foods segment of the industry is currently a $7.8 billion market, and while the packaged foods segment is growing at a rate of about 2.6% per year, the organic foods segment is growing at eight times that rate. *Id.* at *3. "Organic" foods are those that are in compliance with the USDA guidelines for certified organic food, which requires that the food must be cultivated without the use of sewage sludge, synthetic chemical fertilizers, pesticides, herbicides, growth hormones, radiation, or genetically modified organisms. USDA National Organic Program, 65 Fed. Reg. 80548-01 (2000). For a good overview of the controversy defining "organic," see Cindy Hyman, *Food for Thought: Defending the Organic Foods Production Act of 1990 Against Claims of Protectionism*, 14 EMORY INT'L L. REV. 1719,1725-37 (2000).

3. These are foods that have been genetically altered through the use of recombinant deoxyribonucleic acid [rDNA] technology. Other euphemisms for such products include genetically modified foods, genetically engineered foods, and even Frankenstein foods. One problem with using the GMO acronym is that most bioengineered food contains no genetically

certain connotations. First, "non-GMO" is intended to denote that the product contains *no* genetically modified material. Yet recent studies have suggested that some foods labeled as "non-GMO" actually contain as much as forty percent genetically altered ingredients.[4] Second, the "non-GMO" label implies that something bad, unhealthy, or undesirable is not present. Scientific evidence shows that bioengineered food ingredients are not materially different from the non-engineered versions.[5] Given that no material difference has been shown between "GMO" and "non-GMO" foods, the presence of "GMO" ingredients in a food should not alter its safety. But the U.S. Food and Drug Administration (FDA)[6] is now giving serious consideration to allowing labeling of "non-GMO" food. Consider this label:

> *"This food is free from miniscule, unidentified insect fragments and rodent hair."*

Even though a food might bear this label, the food may actually contain these contaminants. Why? The government has determined that small quantities of these contaminants are not excludable in the manufacturing process and that small quantities of contamination are a "trifle,"[7] making such a label

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modified *organisms*.

4. *See Seeds of Doubt: Some Ingredients are Genetically Modified, Despite Labels*, *supra* note 2, at *1 ("A laboratory test conducted for the *Wall Street Journal* showed that about 40% of the soybean DNA detected in a sample [of Veggie bacon] came from genetically modified plants.").

5. *See* Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Availability, 66 Fed. Reg. 4839 (Jan. 18, 2001) (where the FDA suggested that *material* differences would include changes which are significantly different, which would make the common or usual name insufficient to adequately describe the new product, or if its nutritional properties are altered, or if it may contain an allergen). For comparative discourses on the subject, *see generally* K. A. Goldman, *Genetic Technologies. Bioengineered Food—Safety and Labeling*, 290 SCIENCE 457 (2000); Henry I. Miller, *A Rational Approach to Labeling Biotech-Derived Foods*, 284 SCIENCE 1471 (1999); D. A. Kessler et al., *The Safety of Foods Developed by Biotechnology*, 256 SCIENCE 1747 (1992); H. J. Atkinson *et al.*, *The Case for Genetically Modified Crops With a Poverty Focus*, 19 TRENDS BIOTECHNOL. 91 (2001); C. N. Stewart, Jr. *et al.*, *Transgenic Plants and Biosafety: Science, Misconceptions and Public Perceptions*, 29 BIOTECHNIQUES 832 (2000); *and* M. A. Martens, *Safety Evaluations of Genetically Modified Foods*, 73 (Suppl.) INT. ARCH. OCUP. ENVIRON. HEALTH S14 (2000).

6. *See* ERIC D. HIRSCH, DICTIONARY OF CULTURAL LITERACY 510 (2d ed. 1993) (explaining that the Food and Drug Administration is an agency of the federal government in the executive branch that monitors the introduction of new foods or drugs and is responsible for the safety of food and drugs in American commerce).

7. U.S. v. Capital City Foods, Inc., 345 F. Supp. 277, 279 (D.N.D. 1972). One significant problem raised in this case was that the Food and Drug Administration had set no standard for allowable foreign matter. In its "Notice of Proposed Rule Making on Natural or Unavoidable Defects in Food for Human Use that Present No Heath Hazard," published in the Federal Register Vol. 37, 3/30/1972, the FDA concluded "[f]ew foods contain no natural or unavoidable defects. Even with modern technology, all defects in foods cannot be eliminated. Foreign material cannot be wholly processed out of foods, and many contaminants introduced into foods through the environment can be reduced only by reducing their occurrence in the environment." A food manufacturer has to reduce any contamination only to the lowest level currently feasible (Action Levels for Added Poisonous or Deleterious Substances in Food, 55

unnecessary. What distinction is the government making about food that would justify a "non-GMO" label while not condoning a label on food contaminated with insect parts and rodent hair? The absence of material shown to be essentially equivalent to "normal" food *can* be labeled while the presence of contaminants can *not*? This smacks of cognitive dissonance.[8]

In January 2001, the FDA issued a "Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering" (2001 Draft Guidance).[9] The FDA is soliciting input from those concerned in an effort to formulate effective guidelines for labeling bioengineered foods. But what is the impetus behind this apparent proactive move by the FDA? Consumer interest groups want mandatory labeling of all bioengineered foods.[10] The FDA and the U.S. courts have consistently said that mandatory labeling will not be required for GMO or bioengineered foods.[11] So, the groups are using an alternate strategy to achieve essentially the result they desire. By pressuring the FDA to establish guidelines on the labeling of *non*-GMO foods, manufacturers will now have a legal way of labeling their products as "non-GMO," and will do so to achieve a marketing advantage. Foods that do contain GMOs that cannot meet the to-

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Fed. Reg. 20785, May 21, 1990). 21 C.F.R. § 109 contains regulations regarding "unavoidable contaminants in food for human consumption." Even though insect fragments are considered "filth" and therefore a violation of 21 U.S.C. § 342 (*see* Golden Grain Macaroni Co. v. U.S., 209 F.2d 166, 167-68 (9th Cir. 1953)), unless the FDA has promulgated some standard of contamination, and if there is no evidence that the contamination could have been avoided during manufacture, then it does not constitute an "adulteration" of the food.

8. Cognitive Dissonance Theory was developed in 1957 by Leon Festinger. Cognitive Dissonance is said to result when an individual holds as true two beliefs that are contradictory to each other. *See* Leon Festinger, *Cognitive Dissonance, available at* http://tip.psychology.org/festinge.html. "Dissonance can be eliminated by reducing the importance of the conflicting beliefs, acquiring new beliefs that change the balance, or removing the conflicting attitude or behavior. *Id.* For a more detailed review of this subject, *see generally Cognitive Dissonance, available at* http://www.ithaca.edu/faculty/stephens/cdback.html.

9. Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Availability, 66 Fed. Reg. 4839 (Jan. 18, 2001). Although the original comment period was set to expire after 75 days of publication in the Federal Register, requests for additional time to submit comments were allowed and the deadline was extended until May 3, 2001. *See* Premarket Notice Concerning Bioengineered Foods; Extension of Comment Period, 66 Fed. Reg. 17517 (Apr. 2, 2001).

10. These groups include the Center for Food Safety, Friends of the Earth, the Public Interest Research Groups, and Greenpeace. *See* Steve Lash, *Industry Gives Qualified Support for Voluntary Labeling (Food Industry Follows FDA's Standards for Genetically Modified Foods)*, 43(7) FOOD CHEMICAL NEWS, Apr. 2, 2001, *available at* 2001 WL 12772928, at *1. *See also, Seeds of Doubt: Some Ingredients are Genetically Modified, Despite Labels, supra* note 2, at *4. The involvement of public interest groups in the debate will be discussed in more detail in Section IIIB, *infra*.

11. *See, e.g.*, Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22984 (May 29, 1992); Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Availability, 66 Fed. Reg. 4839 (Jan. 18, 2001); International Dairy Foods Ass'n v. Amestoy, 92 F.3d 67 (2d Cir. 1996); *and* Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166 (D.D.C. 2000). This will be developed in more detail in the sections that follow below.

to-be-established guidelines will not be able to utilize the "non-GMO" label. By implication, these foods will be constructively labeled as being bioengineered. The latent problems with this approach manifest themselves when all the potentially genetically modified ingredients in a packaged food are considered. Will all ingredients need to be free from genetically altered material? What standard will be used to determine "non-GMO"? And what consequences does the "non-GMO" label have on the American food supply and on the consumer?

What is the purpose of labels on food products? And to what extent should the federal government become involved in regulating the labeling of food products anyway? For nearly a century, the federal government has carefully policed what creative entrepreneurs have attempted to place on food labels to attract consumers. Under the auspices of the Foods and Drugs Act of 1906,[12] Congress had the authority to prevent the sale of any food product that was labeled in a false or misleading manner.[13] Congress created the Food and Drug Administration (FDA) in 1931 as an executive agency dedicated to protecting the national health.[14] Thus, from its inception, the FDA has taken a keen interest in what manufacturers voluntarily place on food labels.

Until the 2001 Draft Guidance[15] was issued in January 2001, the FDA relied on the 1992 "Statement of Policy: Foods Derived from New Plant Varieties" (1992 Policy),[16] which does not require any special labeling of bioengineered foods as a class of foods.[17] Under the 2001 Draft Guidance, the FDA reaffirmed its decision not to require labeling of foods containing genetically modified material. The FDA based its decision on scientific evidence that bioengineered food ingredients are not materially different from the non-engineered versions.[18] Mandatory labeling may be "scientifically

12. 1906 Federal Food and Drugs Act, Pub. L. No. 59-384, 34 Stat. 768 (1906) (codified at 21 U.S.C. §§ 1-15 (1934) (repealed in 1938 by 21 U.S.C. § 392(a)).

13. *Id.* at 772.

14. *See* NEW YORK TIMES ALMANAC 2000 147 (John W. Wright, ed. 2000). The Food and Drug Administration was formed when the Agriculture Appropriation Act of 1931 became law, and was reorganized in November 1995 as part of the Health and Human Services Department. *Id.*

15. Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Availability, 66 Fed. Reg. 4839 (Jan. 18, 2001).

16. Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22984 (May 29, 1992).

17. *Id.*

18. *See* Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Availability, 66 Fed. Reg. 4839 (Jan. 18, 2001) (where the FDA suggested that *material* differences would only include those changes that make the food so significantly different that the common or usual name no longer adequately describes the new product, or alters its nutritional properties, or introduces an unexpected allergen). For more detailed insight into the rationale used by the FDA, and comments made by Jane E. Henney, M.D., an FDA Commissioner, *see generally*, Larry Thompson, *Are Bioengineered Foods Safe?*, 34 FDA CONSUMER 1 (2000).

unwarranted" and face "significant legal impediments."[19] Specifically, mandatory labeling of bioengineered foods may constitute a violation of the manufacturer's First Amendment right not to speak.[20] Strong consumer concern alone is not sufficient to justify mandatory labeling.[21] The FDA is without authority to mandate labeling without first determining that bioengineered food as a class poses inherent risks to consumers.[22] Moreover, the courts have affirmed the FDA's decisions to accord bioengineered foods a presumption of "generally recognized as safe" (GRAS) status[23] and to not mandate labeling of genetically engineered foods.[24]

The FDA's policy is in stark contrast to the situation in Europe. Since 1998, the European Union (EU) has required labeling of all foods that contain genetically modified organisms.[25] In January 2000, the Commission of the European Communities (CEC) issued labeling directives for bioengineered foods, and established a tolerance level for adventitious "contamination" of non-bioengineered food by rDNA or recombinant protein.[26]

Although the debate on the issue of mandatory labeling for bioengineered foods continues in the United States,[27] there may be legitimate rea-

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19. Karen A. Goldman, *Labeling of Genetically Modified Foods: Legal and Scientific Issues*, 12 GEO. INT'L ENVTL. L. REV. 717, 718 (2000).

20. International Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 72 (2d Cir. 1996).

21. *Id.* at 73-74.

22. Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 179 n.8 (D.D.C. 2000).

23. *Id.* at 178.

24. *Id.* at 179.

25. *See generally* Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms, Document 390L0220, *Official Journal L 117, 08/05/1990,* at 15-27 (1990), *available at* http://europa.eu.int/eur-lex/en/lif/dat/1990/en_390L0220.html; *and* Council Regulation (EC) No. 1139/98 concerning the compulsory indication on the labeling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC, *Official Journal L 244, 03/09/1998,* at 20 (1998).

26. Commission Regulation (EC) No. 49/2000 of 10 January 2000 amending Council Regulation (EC) No. 1139/98 concerning the compulsory indication on the labeling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC, Document 300R0049, *Official Journal L 006, 11/01/2000* pp. 13-14.

27. Depending on who is conducting the survey, Americans either want or do not want labeling of all bioengineered food. *Compare* Joan Murphy, *IFIC Survey Shows Support for Labeling All Bioengineered Foods,* 43 Food Chemical News, *1 (2001) *available at* 2001 WL 12772710 (where various polls revealed contrasting results regarding whether Americans wanted to know about the presence of bioengineered foods), *with Seeds of Doubt: Some Ingredients are Genetically Modified, Despite Labels*, supra note 2, at *4 (where a January 2001 survey found that "75% of respondents wanted to know about the presence of genetically modified ingredients in food and 58% opposed such ingredients."). In a May 2000 poll, 52% of Americans favored the FDA position that labeling bioengineered foods was unnecessary. Murphy, *supra,* at *4. However, after the discovery of StarLink™ corn in taco shells, that stance shifted with 58% of Americans polled in favor of labeling all bioengineered food. *Id.* But in a different survey, when asked what information is missing from food labels, 74% responded "nothing" and only 2% said "genetically altered" ingredients. *Id.* Further, 64% "voiced continued support for the use of genetically engineered foods." *Id.* For some insight

sons for allowing voluntary labeling of bioengineered food products.[28] For instance, manufacturers may be under pressure from the global market to identify whether their products contain any bioengineered material.[29] Other groups see the "non-GMO" label as a way of capturing a certain (and growing) segment of consumers.[30] In issuing the 2001 Draft Guidance, the FDA is proactively assisting manufacturers with guidelines to ensure that they do not make any false or misleading statements on their voluntary labels.

Most of the world's existing regulations deal with only popular genetically modified plants, such as corn and soybeans.[31] Labeling bioengineered products themselves, like the Flavr Savr™ tomato or products predominately corn- or soy-based, makes intuitive sense. What these regulations do not address is how labeling laws should be applied to certain *food ingredients*, such as flavors or thickeners,[32] or to process ingredients such as yeast or enzymes,[33] present in very small quantities in many prepared foods.[34] The FDA's 1992 policy only addresses genetically engineered plants, while microorganisms (that may or may not have been genetically modified) produce

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as to why some Americans want labeling, see, e.g., *Politics & Policy—Genetically Modified Food: Consumers Want Labels*, Am. Pol. Network, 6 Am. Health Line, *1 (2001), *available at* Westlaw, APN-HE 10, *and* Bill Radford, *Allergies Prompt Fears of Bioengineering*, Newark, N.J. Star-Ledger, Apr. 25, 2001, *available at* 2001 WL 19749740.

28. *See* Lash, supra note 10, at *1. Although continuing to oppose mandatory labeling of bioengineered food, the food industry groups told the FDA that they would tentatively support voluntary labeling, but even voluntary labeling "could needlessly alarm consumers or lead them to think erroneously that they should beware of genetically modified foods." *Id.* For an economic approach to food labeling, see generally Elise Golan, *Economics of Food Labeling*, Economic Research Service, U.S. Department of Agriculture, Agricultural Economic Report No. 793 (2000), *available at* http://www.ers.usda.gov/publications/aer793.

29. *See generally* Michael A. Whittaker, *Reevaluating the Food and Drug Administration's Stand on Labeling Genetically Engineered Foods*, 35 SAN DIEGO L. REV. 1215, 1231-35 (1998).

30. *See Seeds of Doubt: Some Ingredients are Genetically Modified, Despite Labels*, *supra* note 2.

31. *See* Kathryn Brown, *Seeds of Concern*, SCIENTIFIC AMERICAN, Vol. 284, No. 4, April 2001, at 56. The dominant bioengineered food crops for 2000 were soybeans, corn, and canola. Additionally, bioengineered versions of potatoes, squash, papayas, melons, and tomatoes have also been introduced into the marketplace, but are dwarfed in comparison to the dominant three.

32. LARRY SYNDER & WENDY CHAMPNESS, MOLECULAR GENETICS OF BACTERIA 449 (1997). For example, xanthan gum, which is ubiquitous in prepared foods, is a polysaccharide produced commercially by fermentation of *Xanthomonas campestris*. *Id.*

33. P. C. WINTER ET AL., INSTANT NOTES IN GENETICS 322, Table 2 (Andrea Bosher, ed., 1998). For example, recombinant enzymes have been utilized for cheese manufacture (rennin and lipase), beer production (α-amylase), alcohol and glucose production (cellulase), meat tenderizing (bromelain), and as antioxidants in food (catalase). *Id.*

34. *See* Elizabeth A. Yetley, *Energy for a New Millennium—Regulatory Perspectives*, 59(1) Nutrition Reviews (2001), *available at* 2001 WL 18219216. "Historically, food additives were used in small amounts to achieve technical effects such as color and low-calorie sweetness. A multifold margin between estimated consumption levels associated with the technical effect and possible adverse effects was used to establish safety." *Id.* at *3.

some of these food additives.[35] And even where genetically modified organisms were not employed to manufacture the ingredients, genetically engineered products such as corn or soybeans may have been utilized in their production.[36] This article addresses whether the use of these food additives should subject the food products containing them to bioengineered food labeling requirements, and argues for *not requiring* labeling of these ingredients or the foods that contain them. The low use levels of these food additives result in a miniscule contribution of genetically modified material, and regulations for "organic" foods already exist which would address the bioengineered food labeling issue.

Section II of this article will address the existing regulations and policies that deal with foods produced using biotechnology, as well as the authority under which the FDA acts to regulate food labeling. Section III assesses the rationale for labeling bioengineered food, with a focus on the consumer, evaluating the fears and concerns expressed regarding this technology. Section IV considers the ramifications of labeling with respect to food additives, such as flavor or texture modifiers, that have not been addressed in the Draft Guidance. Finally, Section V explores how the voluntary labeling of bioengineered foods may potentially create mischief and confusion. Without appropriate guidance and constraint, these labels may confound any education of the consumer or protection of the safety of the food supply.

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35. Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22984 (May 29, 1992). The specific scope of the policy was delineated as follows:

> This notice discusses scientific and regulatory considerations for foods derived from new plant varieties. This notice does not address foods and food ingredients regulated by FDA that have been derived from algae, microorganisms, and other non-plant organisms, including: (1) foods produced by fermentation, where microorganisms are essential components of the food (e.g., yogurt and single cell protein); (2) food ingredients produced by fermentation, such as many enzymes, flavors, amino acids, sweeteners, thickeners, antioxidants, preservatives, colors, and other substances; (3) substances produced by new plant varieties whose purpose is to color food; and (4) foods derived from animals that are subject to FDA's authority, including seafood.

Id.

36. For example, the bacteria *Xanthomonas campestris* is employed to produce xanthan gum by growing in a fermentation medium that may contain cornstarch or corn syrup as a carbon source and soybean hydrolysates as a nitrogen source. *See* U. S. Patent 4,696,900 (issued September 29, 1987), Ellwood et al., Production of Bacterial Polysaccharides, col. 1, lines 13-25; *also see generally* Letisse et al., *Kinetic analysis of growth and xanthan gum production with Xanthomanas campestris on sucrose, using sequentially consumed nitrogen sources,* 55 Applied Microbiology and Biotechnology 417 (2001).

II. FOOD LABELING REGULATIONS

A. Statutory Authority

Originally, the FDA regulated manufacturers' voluntary claims on food labels to protect consumers.[37] Eventually, the FDA imposed mandatory labeling requirements on food products. Currently the FDA requires a number of elements on food labels to avoid misbranding: (1) the name and address of the manufacturer, packer, or distributor; (2) the precise name of the food; (3) a list of the ingredients used to manufacture the article, including artificial flavoring, coloring, or preservatives, if used; (4) a declaration of the net weight of the contents of the food; and (5) complete nutritional labeling.[38] Section 403 of the Federal Food, Drug, and Cosmetic Act (FFDCA) authorizes the FDA to regulate food labels.[39] Under Section 343(a), a food is misbranded if its label is false or misleading.[40] The FDA defines *misleading* in the Act.[41] It states that labeling is misleading if it fails to reveal material facts in light of the representations made or suggested in the labeling. In addition, it must reveal facts that are material with respect to consequences resulting from customary or usual conditions of use. Section 343(i) of the Act requires that each food bear a common or usual name or, in the absence of such a name, an appropriately descriptive term.[42] If the food is manufactured by the combination of two or more ingredients, the common or usual name of each ingredient must appear on the label.[43]

Some voluntary labeling of foods is already subject to regulation. Regulations currently exist for foods that make health claims. Foods subject to these regulations include foods that claim the ability to lower cholesterol using soluble fiber[44] or plant sterols or stanol esters,[45] or foods, which allow the

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37. 1906 Federal Food and Drugs Act, Pub. L. No. 59-384, 34 Stat. 768 (1906) (codified at 21 U.S.C. §§ 1-15 (1934) (repealed in 1938 by 21 U.S.C. § 392(a)).

38. *See* Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 343(e), (g), (i), (k), and (m) (2001); and *see generally* Nutrition Labeling and Education Act of 1990 (NLEA), Pub. L. No. 101-535, 104 Stat. 2353 (codified at 21 U.S.C. §§ 301 et seq. (2001).

39. *See* Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301 et seq. (2001).

40. *See* 21 U.S.C. § 343(a) (2001).

41. 21 U.S.C. § 321 (n) (2001).

42. *See* 21 U.S.C. § 343(i)(1) (2001).

43. *See* 21 U.S.C. § 343(i)(2) (2001).

44. *See* Food Labeling: Health Claims; Soluble Fiber From Certain Foods and Coronary Heart Disease, 21 C.F.R. pt. 101, 63 Fed. Reg. 8103-01 (1998) *and* Food Labeling: Health Claims and Label Statements; Dietary Fiber and Cardiovascular Disease, 58 Fed. Reg. 2552-01 (1993).

45. *See* Food Labeling: Health Claims; Plant Sterol/Stanol Esters and Coronary Heart Disease, 65 Fed. Reg. 54686-01 (2000). These compounds have been claimed to reduce cholesterol in the body when they are consumed on a regular basis. Plant sterols interfere with the uptake of dietary and biliary cholesterol from the intestinal tract. *See* Heineman et al., *Mechanisms of Action of Plant Sterols on Inhibition of Cholesterol Absorption. Comparison of Sitosterol and Sitostanol*, 40 (supp. 1) EUR. J. CLINICAL PHARMACOL. S59 (1991). Inclusion of

consumer to effectuate diet modification, such as reduced fat[46] or sodium.[47] Regulations also make it possible for consumers to choose foods manufactured in a certain way, such as organic foods.[48] In addition, manufacturers are required to warn consumers about adverse health risks of any ingredient in the food.[49] Moreover, the "Delaney Clause," enacted in 1958, mandates that a food additive "shall be deemed unsafe [for food use] . . . if it is found . . . to induce cancer in man or animal."[50] Hence, most compounds that are found to cause cancer in laboratory animals are prohibited for use in foods. The FDA has attempted to create certain exceptions for *de minimis* risks using a risk-utility analysis, but the courts' reactions have been mixed.[51] Foods that contain allegedly carcinogenic ingredients must carry warning labels. An example of an approved warning label that states the carcinogenic potential of a food ingredient is the label that (until very recently) has been required on foods containing saccharin.[52]

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these compounds in the diet has been shown to have a hypocholesterolemic effect. *See generally* Tu T. Nguyen, *The Cholesterol-Lowering Action of Plant Stanol Esters*, 129 J. NUTR. 2109 (1999) *and* Maarit A. Hallikainen et al., *Plant Stanol Esters Affect Serum Cholesterol Concentrations of Hypercholesterolemic Men and Women in a Dose-Dependent Manner*, 130 J. NUTR. 767 (2000). These compounds have been incorporated into margarine sold under the brand name Benacol™ or Take Control™, and studies suggest that ingesting two grams of the sterol or stanol esters on a daily basis can lower serum cholesterol. *See* Maarit A. Hallikainen et al., *Comparison of the Effects of Plant Sterol Ester and Plant Stanol Ester-Enriched Margarines in Lowering Serum Cholesterol Concentrations in Hyper-Cholesterolemic Subjects on a Low-Fat Diet*, 54 EUR. J. CLINICAL NUTR. 715 (2000).

46. *See* Food Labeling: Nutrient Content Claims Pertaining to the Available Fat Content of Food, 61 Fed. Reg. 67243-01 (Dec. 20, 1996).

47. *See* Food Labeling: Declaration of Sodium Content of Foods and Label Claims for Foods on the Basis of Sodium Content, 49 Fed. Reg. 15510 (Apr. 18, 1984).

48. The Federal Organic Foods Production Act of 1990, Pub. L. No. 101-624, 104 Stat. 3935 (codified at 7 U.S.C. § 6501 (1999) (the federal statutes that govern *organic* claims). *See also* Program to Assess Organic Certifying Agencies, 64 Fed. Reg. 30,861, 30,862 (1999). The USDA adopted national standards for organic foods on 12/21/2000 (USDA National Organic Program, 65 Fed .Reg. 80548-01 (2000)).

49. 21 U.S.C. § 321(n). Examples of such warning labels are those found on products that contain aspartame (due to the phenylalanine component and the potential risk to phenylketonurics) or products that contain peanuts or other nut products (due to the severe allergic reaction a small segment of society has to certain nut proteins).

50. 21 U.S.C. § 376(b)(5)(B) (1982).

51. *See, e.g.*, Public Citizen v. Young, 831 F.2d 1108 (D.C. Cir. 1987) (overturning the FDA's approval of Orange Dye No. 17 where the risk of cancer was determined to be less than one in 19 billion); Simpson v. Young, 854 F.2d 1429 (D.C. Cir 1988) (affirming the FDA's approval of Blue Dye No. 2, deferring to the FDA's interpretation of carcinogenic testing data); *and* Monsanto Co. v. Kennedy, 613 F.2d 947 (D.C. Cir. 1979) (allowing the presence of acrylonitrile, a carcinogenic material found in plastic food containers believed to migrate into food).

52. *See* Consolidated Appropriations – FY 2001, Pub. L. 106-554, § 1(a)(1) [Title V, § 517], 114 Stat. 2763, 2763A-73 (Dec. 21, 2000). In December 2000, Congress passed legislation, known as the SWEETEST Act, which stands for Saccharin Warning Elimination via Environmental Testing Employing Science and Technology (*see* Introduction of H.R. 5668, Saccharin Warning Elimination via Environmental Testing Employing Science and Technology, 146 Cong. Rec. E2237-01, *available at* 2000 WL 1847450 (Cong.Rec.)) that stated that the

B. Misbranding: Misleading or Material?

The food label may be presented in creative shapes adorned with attractive colors or artwork, and is often the product of much marketing and advertising research.[53] From the manufacturer's perspective, the label is used more to attract consumers and promote a sale than to inform the consumer.[54] It is probably the regulatory scheme, evolved over the last century, which has led to a careful balance between the hype and hubris of marketing and the public policy requirements of consumer information and education. One way in which the federal government has crafted this balance is to monitor labels to ensure that they do not misbrand the product. To determine whether a food is misbranded, the FDA reviews statements and claims on food labels. The FDA may declare the food misbranded if the label is false or misleading in any way.[55] Both the presence and the absence of information are relevant to whether the label is misleading.[56] Generally, *misleading* refers to the failure to reveal material facts that the consumer needs to know about the food.[57] Although it would be easy to determine whether the container's actual weight comports with the stated weight, or that it contains the ingredients claimed on the label, some claims may require further substantiation in order to be considered truthful. An example is the purported ability of oatmeal consumption to remove cholesterol.[58] Many scientific studies have been con-

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warning label is no longer required. The warning label on a package of Sweet 'N Low™, which is a product of Cumberland Packaging Company, formerly read, "Use of this product may be hazardous to your health. This product contains saccharin, which has been determined to cause cancer in laboratory animals." Although most companies would deplete their existing inventory of packaging materials before making labeling changes, these warning labels quickly disappeared due to the resulting positive marketing impact of the removal of this warning.

53. Fred H. Degnan, *Biotechnology and the Food Label: A Legal Perspective*, 55 Food & Drug L.J. 301, 301 (2000) (contending that "the food label inspires and provides the critical stimulus for a food purchase" and that the label "is the front line of product marketing and, thus, subject to fundamental yet idiosyncratic decisions as to what information, art work, form, and level of taste will attract consumer attention and induce a purchase.").

54. *Id.* at 310. Manufacturers generally include information on the label to promote the product, but may voluntarily include information to respond to consumer demand or desire for additional information.

55. 21 U.S.C § 343(a) (2001).

56. 21 U.S.C. § 321(n) (2001).

57. American Frozen Food Inst. v. Mathews, 413 F. Supp. 548, 554 (DCDC 1976) *affirmed* 555 F.2d 1059, 181 U.S.App.D.C. 122 (1977). *See also* 21 CFR 102.5(b) (2001). An example would be whether the food contains any peanuts, either as an intended ingredient or adventitiously introduced during manufacture. Individuals allergic to peanuts face life-threatening allergic responses if subjected to even minute quantities of the peanut protein responsible for their allergic reaction. Failure to warn of potential peanut protein components in the food would be a *misleading* label, since it falsely leads a consumer to believe that the food contains no peanut products.

58. On a recently purchased 42-ounce package of Quaker Oats, manufactured by the Quaker Oats Company, the claim "Oatmeal Helps Reduce Cholesterol" appears twice on the package in large, bold type, accompanied by an even larger red heart. Further, the following

ducted which suggest that including soluble fiber in a diet low in saturated fat and cholesterol may reduce the risk of heart disease.[59] Without this evidence to support these claims, this labeling would be false, not just misleading.

Information on the label does not have to be false to be misleading. One example is the use of the words *low fat* or *reduced fat* on some food labels. The foods may be lower in total fat content, but that does not always mean that they have fewer calories.[60] The caloric content of many of these products is the same (or sometimes higher) than the full fat alternative.[61] Another example is the claim that a particular juice product contains 100% juice.[62] In actuality, the product is 100% juice, but the consumer purchasing cranberry juice with such a label expects to get 100% *cranberry* juice, not a blend of cranberry and apple juices.[63] In terms of regulations, however, "misleading"

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appears on the back of the package: "You know that oatmeal helps reduce cholesterol. But do you know how? Eating a good-sized bowl of Quaker Oatmeal for 30 days will actually **remove** cholesterol from your body. Think of oats simply as tiny sponges that soak up cholesterol and carry it away. And this simple lifestyle change can make a big difference in the health of your heart." (A literal reading of this advertisement begs the question, Why would one want to eat a single good-sized bowl of oatmeal over the course of thirty days?) Further in the ad, in the cooking directions for 1, 2, and 3 servings, the number 2 is replaced by a red heart with an arrow indicating that this serving size provides 3 grams of soluble fiber, suggesting that this is the "good-sized" bowl they recommend.

59. *See generally* Michael H. Davidson et al., *The Hypocholesterolemic Effects of Beta-Glucan in Oatmeal and Oat Bran. A Dose-Controlled Study*, 266 JAMA 1079 (1991) (sponsored by Quaker Oats Company); R. W. Kirby et al., *Oat Bran Intake Selectively Lowers Serum Low-Density Lipoprotein in Cholesterol Concentrations of Hypercholesterolemic Men*, 34 AM. J. CLINICAL NUTR. 824 (1981); L. Van Horn et al., *Serum Lipid Response to Oat Product Intake with a Fat-Modified Diet*, 86 J. AM. DIET ASS'N 759 (1986); J. F. Swain et al., *Comparison of the Effects of Oat Bran and Low-Fiber Wheat on Serum Lipoprotein Levels and Blood Pressure*, 322 NEW ENG. J. MED. 147 (1990); P. A. Judd & A. S. Truswell, *The Effect of Robed Oats on Blood Lipids and Fecal Steroid Excretion in Man*, 34 AM. J. CLINICAL NUTR. 2061 (1981); *and* L. Van Horn et al., *Effects of Serum Lipids of Adding Instant Oats to a Usual American Diet*, 81 AM. J. PUB. HEALTH 183 (1991).

60. *See* CHI. TRIB., Jan. 11, 2001, Evening Health, at 7, *available at* 2001 WL 4029404, which states that these terms have become a "marketing gimmick" to sell the product, and the fat is often replaced with other high-calorie ingredients.

61. *See* Lawrence Lindner, *Eating Right: The Truth About Food "Facts"—Common Nutrition Notions Aren't Always Based on Reality*, WASH. POST, Jan. 18, 2000, Health Section (providing a few interesting comparisons of *fat free* or *reduced fat* food products to their full fat versions. As examples, Smucker's fat-free butterscotch topping has the same caloric content as the full fat version, as does the reduced-fat version of Jif peanut butter. Similarly, the reduced-fat version of Drake's chocolate Yodels has more calories than the full-fat version.).

62. *See* Marian Burros, *Chugging Juice Can Mean Guzzling Sugar*, MILWAUKEE JOURNAL SENTINEL, Aug. 30, 2000, Food Section (suggesting that many fruit juice products are no more nutritious than soft drinks, and that the type of juice used is just as important as the amount it contains. "All juices are not created equal. If the first ingredient is apple, grape, or pear juice, there is no nutritional bang for the buck.").

63. *See Mott's To Change Some Juice Labels*, THE FOOD INST. REP., Aug. 7, 2000, at *2, *available at* 2000 WL 24466199. After complaints from and an investigation by the NY Attorney General, Mott's, a leading producer of fruit juices, agreed to change its labeling practices which the Attorney General suggested was misleading although technically in compliance with FDA labeling requirements. *Id.* The labels on Mott's juice products say "100%

generally is confined to failing to reveal material facts about the food product. According to the 2001 Draft Guidance:

> Historically, the agency has generally interpreted that scope of the materiality concept to mean information about the attributes of the food itself. FDA has required special labeling on the basis of it being "material" information in cases where the absence of such information may: 1) pose special health or environmental risks (e.g., warning statement on protein products used in very low calorie diets); 2) mislead the consumer in light of other statements made on the label (e.g., requirement for quantitative nutrient information when certain nutrient content claims are made about a product); or 3) in cases where a consumer may assume that a food, because of its similarity to another food, has nutritional, organoleptic, or functional characteristics of the food it resembles when in fact it does not (e.g., reduced fat margarine not suitable for frying).[64]

Following the above guidelines, there would be insufficient evidence to support mandatory labeling of bioengineered foods. In general, products produced by rDNA technology have been screened to ensure that they pose no special health risks (although this is a hotly debated issue among proponents of mandatory labeling). In the 2001 Draft Guidance, the FDA suggested circumstances under which bioengineered foods would require labeling to conform to the dictates of Section 201(n) with regard to revelation of the material facts about a food. These included:

> 1) if a bioengineered food is significantly different from its traditional counterpart such that the common or usual name no longer adequately describes the new food, the name must be changed to describe the difference; 2) if an issue exists for the food or a constituent of the food regarding how the food is used or consequences of its use, a statement must be made on the label to describe the issue; 3) if a bioengineered food has a significantly different nutritional property, its label must reflect the difference; and 4) if a new food includes an allergen that consumers would not expect to be present based on the name of the food, the presence of that allergen must be disclosed on the label.[65]

The FDA has indicated that no information has been supplied to it which would allow it to "form the basis for concluding that . . . bioengineering [a food or food ingredient] is a material fact that must be disclosed under sections 403(a) and 201(n)."[66]

Juice" with a picture of grapes or cherries and the fruits' names in large letters directly below, even though the juice may be primarily apple juice blended with only portions of grape or cherry juice to provide the designated flavor. It was asserted that this labeling could lead consumers to falsely assume the product is 100% grape or cherry juice. *Id.*

64. Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Availability, 66 Fed. Reg. 4839 (Jan. 18, 2001).

65. *Id.*

66. Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Availability, 66 Fed. Reg. 4839, 4840 (2001).

C. Case Law Regarding Labeling Genetically Modified Foods

This decision by the FDA not to require mandatory labeling for bioengineered foods has some support in recent case law. One of the earliest cases dealing with the issue of labeling bioengineered food was *International Dairy Foods Association v. Amestoy*,[67] which dealt with a Vermont regulation requiring labeling of milk obtained from cows treated with recombinant bovine somatotropin (bST).[68] The FDA had determined that dairy products that came from treated cows were indistinguishable from products from untreated cows, and therefore declined to require any special labeling.[69] The State of Vermont enacted a statute requiring milk produced by cows treated with recombinant bST to be labeled as such[70] and imposed civil[71] and criminal[72] penalties for failure to comply with the state law. The Second Circuit determined that the law was unconstitutional in that it violated the manufacturers' First Amendment right not to speak.[73]

In the recent case *Alliance for Bio-Integrity v. Shalala*,[74] the lack of mandatory labeling of bioengineered food was again at issue. In *Alliance*, a coalition of consumer interest groups and consumers protested the FDA's policy on bioengineered foods. They attacked the policy on a number of grounds. They alleged the FDA's policy violated the Administrative Procedure Act by not having a notice-and-comment period and that the FDA did not provide an Environmental Assessment or Environmental Impact Statement. They also contended that the FDA's policy statement was arbitrary and capricious under the "generally regarded as safe" (GRAS) requirements of FFDCA, and that the FDA's failure to require labeling for bioengineered food was arbitrary and capricious.[75] In a Memorandum Opinion, the District Court for the DC Circuit granted the defendant's—and denied the plaintiffs'—motion for summary judgment.

At issue was the 1992 "Statement of Policy: Foods Derived from New Plant Varieties," in which the FDA announced that it would presume foods produced using rDNA technology were GRAS under 21 U.S.C. § 321(s)

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67. 92 F.3d 67 (2d Cir. 1996). For a thorough exploration of this case, see Goldman, *supra* note 19, at 728-34.

68. Bovine somatotropin is a cow growth hormone naturally produced by cows. The recombinant version was produced by Genentech and licensed to Monsanto. Cows given supplemental growth hormone produced more milk, and milk produced by cows so treated is indistinguishable from that produced by untreated cows, which is why the FDA declined to require any labeling of products from cows treated with the supplemental hormone.

69. International Dairy Foods Ass'n v. Amestoy, 92 F.3d at 69.

70. VT. STAT. ANN. tit. 6, § 2754(c) (1994).

71. *See* Consumer Fraud Act, VT. STAT. ANN. tit. 9, ch. 63, §§ 2451 *et seq.* [Add. to Blue Br. 12-13].

72. *See* Vt. Stat. Ann. tit. 6, ch. 151 (Supervision, Inspection and Licensing of Dairy Operations), § 2671 *et seq.*.

73. International Dairy Foods Ass'n v. Amestoy, 92 F.3d at 72.

74. 116 F. Supp. 2d 166 (D.D.C. 2000).

75. *Id.* at 170.

and, therefore, not subject to regulation as a food additive.[76] The 1992 Policy also indicated that bioengineering of food by rDNA modification was not a "material fact" under 21 U.S.C. § 321(n), and that bioengineered foods did not require special labeling.[77] The district court held the 1992 Policy was a policy statement and not a substantial rule; therefore, the 1992 Policy did not come under the auspices of the Administrative Procedure Act, and the FDA was not required to have a notice-and-comment period for this policy statement.[78] The district court also affirmed the position taken by the FDA in the 1992 Policy Statement itself that the Statement was not a major federal action, and, therefore, the FDA was not required to provide an Environmental Assessment or Environmental Impact Statement.[79]

The plaintiffs challenged the FDA's decision not to require labeling of bioengineered food. They asserted that bioengineered food should not be presumed to be GRAS. They also argued that bioengineered food without a label would be misbranded under 21 U.S.C. § 321(n). The court concluded that the FDA's decision to accord bioengineered food a presumption of GRAS status was neither arbitrary nor capricious.[80] According to the court, the FDA's decision was based on scientific data that recombinant proteins are no different from proteins required for nutrition, and thus it was proper to defer to the FDA's expertise in evaluating such scientific data.[81]

The court then addressed the issue of misbranding. The plaintiffs alleged that the products containing bioengineered foods were misbranded because they failed to present "facts . . . *material* with respect to consequences which may result from the use of the article to which the labeling . . . relates under the conditions of use prescribed in the labeling . . . or under such conditions of use as are customary or usual."[82] The statutory meaning of *material* became the focal point, as the plaintiffs contended that whether the foods contained bioengineered material was material to a wide section of the consuming public, some religious groups, and to many people with food allergies.[83] The court opined that an executive agency's interpretation of a statute that it is charged with administering is afforded substantial deference,[84] and that as long as the interpretation is reasonable, courts are reluctant to impose judicial interpretation.[85]

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76. *See* Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22984 (1992).

77. *Id.* at 22991 (1992).

78. Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 172-73 (D.D.C. 2000).

79. *Id.* at 174-75.

80. *Id.* at 177.

81. *Id.* (citing International Fabricare Institute v. U.S.E.P.A., 972 F.2d 384, 389 (D.C.Cir. 1992), which stated, "The rationale for deference is particularly strong when the [agency] is evaluating scientific data within its technical expertise.").

82. 21 U.S.C. § 321(n).

83. Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d at 178.

84. *See* Rust v. Sullivan, 500 U.S. 173, 184 (1991).

85. *See* Pauley v. Beth Energy Mines, Inc., 501 U.S. 680, 702 (1991) (concluding that

The FDA concluded that foods produced using rDNA technology were not materially different from other foods and therefore warranted no additional labeling. The court found that consumer interest alone was insufficient to deem the use of rDNA technology in food production material for the purposes of mandatory labeling.[86] In addition, the court noted that the 1992 Policy already contained provisions requiring special warning statements on labels where the FDA has identified an increased safety risk or a material change in bioengineered foods.[87] The court concluded, "without a determination that, as a class, rDNA-derived foods pose inherent risks or safety consequences to consumers, or differ in some material way from their traditional counterparts, the FDA is without authority to mandate labeling."[88]

III. THE RATIONALE BEHIND THE LABELING PROPOSAL

A. Informed Consumer Choice

Although the courts have held that the FDA lacks authority to mandate labeling of bioengineered foods, manufacturers are able to include information on the label as long as it does not deceive the consumer and thus result in misbranding. Manufacturers may wish to provide this information by including whether or not their product utilized bioengineering technology. Some consumers have expressed concern over bioengineered foods, citing fears for both food safety and the environment.[89] These consumers would be the targeted market for labeled foods. In addition, legislation entitled The Genetically Engineered Food Right-to-Know Act was introduced in Congress in May 2000 to require labeling of bioengineered foods, and if enacted, failure to label bioengineered food would result in the products being misbranded under the Federal Food, Drug, and Cosmetic Act.[90] To address these issues, the FDA issued its Draft Guidance as a proactive step toward a coherent and workable voluntary labeling scheme.

But when one takes a close look at the rationale behind addressing consumer concerns, it becomes evident that labeling may not create informed consumers. The very purpose of the voluntary label needs to be addressed in order to ascertain the public good that would be derived. Since some consumers have stated that they choose to avoid bioengineered food altogether,

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the interpretation does not have to be "the best or most natural by grammatical or other standards," but merely reasonable).

86. *See* Stauber v. Shalala, 895 F. Supp. 1178, 1193 (W.D. Wis. 1995) (holding that "in absence of evidence of a material difference, the use of consumer demand as the rationale for labeling would violate the Food, Drug, and Cosmetic Act").

87. Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d at 179 n.8.

88. *Id.*

89. *See* Matthew Franken, *Fear of Frankenfoods: A Better Labeling Standard for Genetically Modified Foods*, 1 MINN. INTELL. PROP. REV. 153, 158-59 (2000).

90. *See* S. 2080, 106th Cong. (2000) (introduced in the House as H.R. 3377, 106th Cong. (1999)).

it has been proposed that a general label such as "contains bioengineered ingredients" would be a cost-effective method of satisfying consumer interest. But what such a label connotes is that there is some materially different attribute between bioengineered ingredients and traditional ingredients, for which there is scant supporting scientific evidence. In addition, such labeling would suggest that traditional food is somehow superior to bioengineered food, which would be disallowed.[91] A further problem arises in determining what quantity of bioengineered product in a food would make such a label accurate. In the EU, the presence of any amount of genetically modified material *intentionally* introduced into the food results in mandatory labeling,[92] while *adventitious* introduction of less than one percent of genetically modified material would not require labeling.[93] Further, it is not entirely clear exactly what aspect of the food is to be quantified to determine whether it should be regarded as a bioengineered food. When the dietary exposure of a consumer to a novel protein produced using rDNA technology is calculated for bioengineered canola oil compared to traditional canola oil, the total exposure in one year is 0.0000094 grams or 9.4 micrograms.[94] In addition, the technology[95] that allows detection of rDNA in products is not ubiquitous and requires some sophistication for its application. In fact, the process for rDNA detection needs a copy of the very same DNA sequence that is under

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91. *See* Natalie Pargas, *Next Generation Biotech Products Will Face Traditional Labeling Issues in U.S.*, Maryanski Notes, 40 FOODS CHEMICAL NEWS (Information Access Co.) No. 21 (July 13, 1998), *available in* Westlaw, 1998 WL 10981464; *and* Cliff D. Weston, *Chilling of the Corn: Agricultural Biotechnology in the Face of U.S. Patent Law*, J. SMALL & EMERGING BUS. L. 377, *38 (2000) where the author contends that the opponents to mandatory labeling present at the meeting "argued that singling out GM products would mark them as *different* and, in the eyes of consumers bombarded with activist messages, paint them as tainted and dangerous."

92. *See generally* Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms, Document 390L0220, *Official Jounral L 117, 08/05/1990,* pp. 15-27 (1990) *available at* http://europa.eu.int/eur-lex/en/lif/dat/1990/en_390L0220.html.

93. *See generally* Commission Regulation (EC) No. 49/2000 of 10 January 2000 amending Council Regulation (EC) No. 1139/98 concerning the compulsory indication on the labeling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC, Document 300R0049, *Official Journal L 006, 11/01/2000* pp. 13-14.

94. ALAN MCHUGHEN, PANDORA'S PICNIC BASKET—THE POTENTIAL AND HAZARDS OF GENETICALLY MODIFIED FOODS 97 (2000). This calculation is based on the annual consumption of canola oil in the UK, the amount of protein present in the oil, and the percentage of modified protein attributable to bioengineering. *Id.* Providing an example with which to compare these exposures, the author states, "The amount of arsenic that most people ordinarily ingest in food or water . . . is about 18.25 milligrams per year, [which] is not considered to be of health concern." *Id.*

95. The method currently employed for detecting minute amounts of modified genetic material is the polymerase chain reaction, or PCR. For a concise explanation of the basic principles, *see* Lori A. Kolmodin & J. Fenton Williams, *PCR—Basic Principles and Routine Practice in PCR Cloning Protocols*, 67 METHODS IN MOLECULAR BIOLOGY 3 (Bruce A. White, ed. 1997).

investigation in order to work.[96] Policing whether or not rDNA may be present in the food then becomes troublesome, because requiring a copy of the very rDNA in question for its detection may intrude on a manufacturer's right to maintain processing and manufacturing details as trade secrets.[97]

The bioengineering process itself has come under attack as an alternative to attacking the food produced using the technology.[98] The Federal Food, Drug, and Cosmetic Act does not require disclosure of the method of manufacture, and the Act considers the method of manufacture immaterial.[99] How food is produced may be a factor in determining the safety or nutrition of the finished food, but the key factors in determining food safety should be the characteristics of the food itself, rather than the methods used to produce it.[100] Precautionists warn that not everything is known about the potential consequences of biotechnology and that the very process of genetic manipulation may be unsafe and therefore material.[101] Most are staunch supporters of the precautionary principle, one rendition of which states that "[a]ctivities which are likely to pose a significant risk to nature shall be preceded by an exhaustive examination; their proponents shall demonstrate that expected benefits outweigh potential damage to nature, and where potential adverse effects are not fully understood, the activities should not proceed."[102] The potential costs and benefits of bioengineered foods have recently been addressed,[103] and although some consumer concerns may be understandable,[104]

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96. *Id.* at 3. *See also* R. D. Pridmore et al., *Genomics, Molecular Genetics and the Food Industry*, 78 J. BIOTECHNOL. 251 (2000); B. E. Erickson, *Detecting Genetically Modified Products in Food*, 72 ANAL. CHEM. 454A (2000); M. Vaitilingom et al., *Real-Time Quantitative PCR Detection of Genetically Modified Maximizer Maize and Roundup Ready Soybean in Some Representative Foods*, 47 J. AGRIC. FOOD CHEM. 5261 (1999); *and* S. Vollenhofer et al., *Genetically Modified Organisms in Food—Screening and Specific Detection by Polymerase Chain Reaction*, 47 J. AGRIC. FOOD CHEM. 5038 (1999).

97. Trade secret and confidential commercial information, as well as manufacturing methods or processes, including quality control procedures, are considered information protected from disclosure by the Food, Drug, and Cosmetic Act regulations 21 C.F.R. § 312.130 and 21 C.F.R. § 314.430.

98. *See* Julie Teel, *Regulating Genetically Modified Products and Processes: An Overview of Approaches*, 8 N.Y.U. ENVTL. L.J. 649, 655-58 (2000) *and* J. Howard Beales III, *Modification and Consumer Information: Modern Biotechnology and the Regulation of Information*, 55 FOOD & DRUG L.J. 105, 108-11 (2001).

99. *See* Karen A. Goldman, *Labeling of Genetically Modified Foods: Legal and Scientific Issues*, 12 GEO. INT'L ENVTL. L. REV. 717, 723 (2000) (citing United States v. Ninety-five Barrels (More or Less) Alleged Apple Cider Vinegar, 265 U.S. 438, 445 (1924)).

100. *See* Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22984, 22984-85 (May 29, 1992).

101. *See* Teel, *supra* note 96, at 655-58.

102. World Charter for Nature, Oct. 28, 1982, para. 11(b), 22 I.L.M. 455, 458.

103. Jeffrey K. Francer, *Frankenstein Foods or Flavor Savers?: Regulating Biotechnology in the United States and European Union*, 7 VA. J. SOC. POL'Y & L. 257, 263-65 (2000).

104. *See* A. Bryan Endres, *"GMO:" Genetically Modified Organism or Gigantic Monetary Obligation? The Liability Schemes for GMO Damage in the United States and the European Union*, 22 LOY. L.A. INT'L & COMP. L. REV. 453, 456 (2000) (suggesting that at least in Europe, many consumers fear the potential future problems of bioengineered foods because

most of the stated concerns have been regarded as *misdirected* from a scientific perspective.[105]

Regardless of one's perspective, the precautionary principle played a part in the development of the Cartagena Protocol on Biosafety, which will allow countries to regulate bioengineered food, either by labeling requirements or by precluding access to the nation's consumer market.[106] The Cartagena Protocol's rendition of the precautionary principle stated that "lack of scientific certainty due to insufficient relevant scientific information and knowledge . . . shall not prevent [a member nation] from making a decision" regarding the importation of bioengineered foods.[107] This smacks of a Luddite approach to technology, demanding absolutes when none are available.[108]

When confronted with uncertainties, the scientific method suggests that testing be repeated and confirmed and then repeated and confirmed independently.[109] It is only then that a result is accepted as reproducible, although not necessarily as true. No scientific evidence exists which suggests that there is any basis for concern over the safety of bioengineered food as a class.[110] Existing regulations address areas of concern such as the introduction of potential food allergens, toxic substances, or breakdown products.[111] Introduction of new products or new technologies all have some inherent risks, and it is not the total elimination of the risk, but a careful assessment of the risk that is required. An alternate line of thought states that there is no risk/benefit analysis for food.[112] However, if the risk is manageable and pre-

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they relate these products to "recent food scares involving Mad Cow Disease, bacterially contaminated meat, and dioxin in poultry, pork, and beef products . . . [where the] affected country's government either suppressed *inconvenient scientific data* or directly lied about the food's safety.").

105. *See* John Stephen Fredland, *Unlabel Their Frankenstein Foods!: Evaluating a U.S. Challenge to the European Commission's Labeling Requirements for Food Products Containing Genetically Modified Organisms*, 33 VAND. J. TRANSNAT'L L. 183, 187-90 (2000).

106. Convention on Biological Diversity, Cartagena Protocol on Biosafety, *at* http://www.biodiv.org/biosafety/iccp.asp (last visited Apr. 5, 2001).

107. *Id.* at art. 10, § 6.

108. *See* ERIC D. HIRSCH, DICTIONARY OF CULTURAL LITERACY 225 (2d ed. 1993). In the early 1800s, a Luddite protested the use of laborsaving machinery by destroying it. In modern usage, the term refers to any opponent of technological change. *Id.*

109. The scientific method is generally defined as an orderly technique of investigation. "The method consists of the following steps: 1. Careful observation of nature. 2. Deduction of natural laws. 3. Formation of a hypothesis [to explain the observations]. 4. Experimental or observational testing of the validity of the predictions thus made." *Id.* at 487.

110. Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Availability, 66 Fed. Reg. 4839 (Jan. 18, 2001).

111. Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22984, 22986-22988 (May 29, 1992).

112. Elizabeth A Yetley, *Energy for a new millennium—Regulatory perspectives*, NUTRITION REVIEWS, January 1, 2001 ("For food, safety means reasonable certainty of no harm: there is no risk–benefit assessment for food.").

sents little danger of harm, then the risk is *acceptable*. Although statistics are often useful for comparative risk assessment, taken out of context the same assessment could be interpreted to suggest that the amount of risk is unacceptable.[113]

B. Consumer Interest vs. Consumer Interest Groups

Regardless of the magnitude of the potential risks, some consumers demand the right to know what is in their food, or how it got there.[114] An interesting statistical analysis would be to determine how much of the labeling demand comes from consumers, versus how much of the demand could be attributed to consumer interest groups.[115] Public interest groups are becoming more vocal and more litigious. The Center for Science in the Public Interest (CSPI)[116] is one such group that has indirectly taken on the FDA on a number of labeling issues. Some examples of these include attacks made on the official serving size standards established by the FDA,[117] the fat content of meals served at Chinese, Mexican, and Italian restaurants,[118] and Olestra, the fat substitute created by Proctor and Gamble.[119] In addition to an increased participation by consumer interest groups, there appears to be a steady increase in "the use of *junk science* to promote certain political agendas while ignor-

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113. *See* MCHUGHEN, *supra* note 94, at 129-35. This author provides a comprehensive overview of risk assessment relative to genetically modified organisms in food. An interesting corollary he interjects is that while the opponents of bioengineered food demand assurances that bioengineered food is risk free, similar demands are not made for conventional versions of the same product, even though the risks may be higher. "Failure to consider all of the relevant comparisons [between the two products] leads to erroneous conclusions." *Id.*

114. For example, in Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166 (D.D.C. 2000), the plaintiffs "expressed fears that bioengineered food would contain unexpected toxins or allergens, while others believed that their religion prohibited consumption of foods produced through rDNA technology." 116 F. Supp. 2d at 175.

115. For example, Greenpeace began launching their campaign against bioengineered food in the U.S. in 1999. *See Seeds of Doubt: Some Ingredients are Genetically Modified, Despite Labels*, *supra* note 2, at *4. Meanwhile, the Genetically Engineered Food Alert, a coalition which includes members of the Center for Food Safety, Friends of the Earth, and the Public Interest Research Groups leads in the demand for mandatory labeling of all bioengineered food. *See* Steve Lash, *Industry Gives Qualified Support for Voluntary Labeling (Food Industry Follows FDA's Standards for Genetically Modified Foods)*, 43 FOOD CHEMICAL NEWS, *1 (Apr. 2, 2001), *available at* 2001 WL 12772928.

116. Michael Jacobson, the leader of CSPI, has been described as a non-compromising zealot or idealist likened to the Ayatollah Khomeini. BENNETT & DILORENZO, *supra* note 1, at 6 (quoting Jeff Nedelman, Grocery Manufacturers of America, from Stephen Glass, *Hazardous to Your Mental Health*, NEW REPUBLIC, Dec. 30, 1996 p. 18), while Bernadine Healy, former director of the National Institutes of Health, said that the Center for Science in the Public Interest is "really a misnomer. It's not always science, and these mini-scares are not in the public interest." *Id.*

117. JAMES T. BENNETT & THOMAS J. DILORENZO, THE FOOD & DRINK POLICE—AMERICA'S NANNIES, BUSYBODIES & PETTY TYRANTS 10 (1999).

118. *Id.* at 22-24.

119. *Id.* at 93-100.

ing genuine science that may be critical of that agenda."[120] The combination of these forces may result in a less-informed consumer. "It is one thing to simply provide citizens with information about healthy lifestyles; it is quite another thing to provide citizens with dubious or false information that promotes a prohibitionist agenda."[121]

C. Consumer Right to Know

The FDA is the administrative agency that makes sure that such dubious or false information never makes it on to the food label. Still, a consumer may demand that a "right to know" exists.

A "right to know" could be invoked to justify labeling about any detail of the production process, from use of chemical fertilizers, to the wage rate and national origin of the workers who planted and harvested the crop, to the labor practices of the manufacturer, to the soil conservation practices of the farmer. It is impossible to list all the things that might matter to everyone . . . the "right to know" is limitless.[122]

However, consumers may not want to know *everything* about the food they purchase.[123] The FDA regulates the manufacture of food and prohibits the sale of any adulterated product.[124] A manufactured food product is considered adulterated if it contains *excessive* amounts of poisons, pesticide residues, additives, filth, or decomposed matter.[125] The FDA has established threshold limits for acceptable levels of these contaminants. Trace amounts of these materials are allowed because of technical or economic prohibitions on removing them.[126] Preservatives, flavors, and colorants in very small concentrations are safe for food use, but potentially dangerous at high concentrations.[127] The presence of even trace amounts of rat hair or insect fragments may be material to some consumers. But in terms of food quality or public health, as long as the levels are below those set by the FDA, the manufacturing process is acceptable and the resulting food is not adulterated.[128] Addi-

120. *Id.* at 15.

121. *Id.*

122. *See* J. Howard Beales III, *Modification and Consumer Information: Modern Biotechnology and the Regulation of Information*, 55 FOOD & DRUG L.J. 105, 109 (2001).

123. NEIL POSTMAN, TECHNOPOLY 74 (1992) (suggesting that too much information is a bad thing, because providing an overwhelming amount of information makes society uncertain and unable to ascertain the truth).

124. 21 U.S.C. § 301 (2001).

125. 21 U.S.C. § 342 (2001).

126. *See generally* Michael Merrill, *Regulating Carcinogens in Food: A Legislator's Guide to the Food Safety Provisions of the Federal Food, Drug, and Cosmetic Act*, 77 MICH. L. REV. 171 (1978).

127. *Id.*

128. *See* 21 U.S.C. § 342 (2001); *see also* Defect Action Levels for the Adulteration of Wheat Flour and Macaroni Products by Insects, 53 Fed. Reg. 1520 (January 20, 1988) (where the FDA has established the "defect action level" of insect fragments present in flour to be 75 fragments per 50 grams of flour, while that for macaroni and noodle products is 225 insect

tionally, there are no labeling requirements for the "amount or type of fungal spores or bacterial toxins"[129] in foods. As long as these components fall within the FDA guidelines, the foods are safe and no labeling is required. Further, some foods may contain natural substances that are toxic to humans; nevertheless, under the FDA guidelines, the food is not adulterated "if the quantity of such substance in the food does not ordinarily render it injurious to health."[130] It is of interest to note that many of these natural toxins are prevalent in organic foods.[131]

IV. FOOD ADDITIVES

A. Definition and Regulation

The FDA has established similar guidelines for food additives.[132] Food additives are defined in Section 201 of the Federal Food, Drug, and Cosmetic Act as

> any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in production, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food).[133]

Food additives include processing enzymes that may or may not be present in the final food, food colors and flavors, preservatives, sweetening agents, and thickening agents.[134] Many food additives are substances that are "generally recognized as safe" (GRAS) based on appropriate scientific evaluation.[135] The GRAS exemption will continue to apply as long as a

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fragments per 225 grams of macaroni).

129. *See* MCHUGHEN, *supra* note 94, at 211.

130. 21 U.S.C. § 342(a)(1). A common example would be aflatoxin, produced by the fungus *Aspergillus flavus,* that attacks diverse food crops including peanuts, corn, and cottonseed (*see* Charles W. Henderson, *Researchers Work to Combat Dangerous Fungal Compounds*, CANCER WEEKLY, September 26, 2000, *available at* 2000 WL 19896262). Another example is the mycotoxin, patulin, produced by a mold that grows on bruised apples; it has been found in 20% of all apple juice samples tested. *See* Hazard Analysis and Critical Control Point (HAACP); Procedures for the Safe and Sanitary Processing and Importation of Juice, 66 Fed. Reg. 6138, 6142 (January 19, 2001).

131. *See* Dennis T. Avery, *The Hidden Dangers in Organic Food* (1998), *available at* http://www.americanoutlook.org/articles_fa98/avery.htm (last visited November 21, 2001).

132. *See* 21 U.S.C. § 321(s)(4) (2000).

133. *Id.* at § 321(s).

134. *See Evaluation of Certain Food Additives. Fifty-first Report of the Joint FAO/WHO Expert Committee on Food Additives,* World Health Organ. Tech. Rep. Ser. 891, 1 (2000).

135. 21 U.S.C. § 321(s) (2000). A substance can be granted GRAS status if trained and experienced scientific experts agree that adequate safety has been shown through scientific procedures. 21 C.F.R. § 170.30(b) (2000). However, substances that were used in foods prior to Jan. 1, 1958, may be granted GRAS status based on a substantial history of human consumption in the United States, under 21 C.F.R. § 170.30(c).

manufacturer uses that substance in the quantity and manner generally regarded as safe.[136] Any new food additive is presumed unsafe unless a qualified person either establishes that it is GRAS[137] or establishes the safety of the substance in food under the conditions for its intended use.[138] A similar approval process must be followed when a manufacturer wishes to use an approved food additive in a new way.[139] The procedures used to obtain FDA approval of a new compound as a food additive are rigorous, and petitions for approval must contain:

> information on the chemical identity and composition of the food additive; the conditions of proposed use of the additive, including directions for use; data concerning the effects of the additive, including quantities required to produce such effects; methods for detecting the presence of the additive and any metabolites; and disclosure of reports of investigations concerning the safety for use.[140]

Once the substance is approved, the FDA will issue a regulation "prescribing . . . the conditions under which such additive may be safely used."[141] There is a significant difference between food additives that are GRAS and those that have been approved through FDA petition. The only limitation on the use of GRAS food additives is that they be used in accordance with good manufacturing practices (GMP).[142] Food additives approved by petition to the FDA may be subject to regulations imposing conditions on their use including "the category of food, the technical effect or functional use, and the level of use."[143]

B. Bioengineered Foods and Food Additives—Guidance Required

As mentioned in Section IID above, the FDA has afforded bioengineered food ingredients GRAS status. Under this designation, their use in foods would normally be regulated under the GMP standard.[144] And although the 1992 Guidance dealt only with food derived from genetically modified plants, the 2001 Labeling Guidance covers foods that are bioengineered or contain bioengineered ingredients.[145] The purpose of the guidance is "to as-

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136. 21 C.F.R. § 188.22 (2000) (the GRAS exemption will apply if the additive is of good commercial food grade and used in accordance with good manufacturing practices).

137. 21 U.S.C. § 348(a) (2000).

138. *Id.* at § 348(b).

139. *Id.*

140. *See* 21 U.S.C. § 348(b)(2).

141. *See* 21 U.S.C. § 348(c)(1)(A).

142. 21 C.F.R. § 182.1(b) (2000).

143. 21 C.F.R. § 184.1(b)(1) (2000).

144. 21 C.F.R. § 182.1(b) (2000).

145. Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Availability, 66 Fed. Reg. 4839 (Jan. 18, 2001).

sist manufacturers who wish to label their foods voluntarily as being made with or without the use of bioengineered ingredients."[146] The proactive approach of the FDA should be applauded. Specifically, the agency is requesting comments on the use of the terms "GMO free," "biotech free," and "no genetically engineered materials" and whether such statements could be made without being false or misleading.[147] The agency demonstrated the difficulty in using this terminology on labels since such wording implies a "zero content" claim, which it concluded would be "very hard to substantiate."[148] In terms of food additives, the difficulty comes in determining where to draw the line demarcating bioengineered food from traditional food.

Although a reasonable consumer may suspect that tortillas could contain bioengineered corn or that tofu may contain bioengineered soybeans, it may not be as obvious to most consumers that even chocolate cake might be subject to a bioengineered food label. The ingredient list for a commercial chocolate cake mix[149] included partially hydrogenated soybean oil, riboflavin, artificial flavors, and xanthan gum. The soybean oil would be an obvious potential product of bioengineering. What is not as obvious is that the riboflavin may have been produced using bioengineered microorganisms, or that corn syrup or protein derived from bioengineered plants was used in the fermentation media for the bacteria used to manufacture the artificial flavors[150] or the xanthan gum. The label itself declares that the dry cake mix contains less than two percent artificial flavors or xanthan gum.[151] If the "zero content" standard were adopted, then any use of bioengineered material anywhere in the manufacturing process would potentially make the final food subject to labeling. Such a standard has been adopted in Europe[152] and results in an interesting phenomenon. Any intentional introduction of a bioengineered material into a food results in automatic mandatory labeling.[153] If, however, the amount of material is less than the *de minimis* threshold (set at one percent) and the material was introduced adventitiously, then no labeling is required.[154] Tracing the origin of all raw materials has introduced a new

146. *Id.* at 4840.

147. *Id.*

148. *Id.*

149. Duncan Hines' Moist Deluxe® Devil's Food Cake Mix.

150. *See* U. Krings & R. G. Berger, *Biotechnological Production of Flavors and Fragrances*, 49 APPL. MICROBIOL. BIOTECHNOL. 1 (1998).

151. Xanthan gum is regulated under 21 C.F.R. § 172.695. According to the Product Data Sheet for CP Kelco's KELTROL® xanthan gum, the typical use level is 0.05–0.5%. *Available online at* http://www.cpkelco.com.

152. Council Regulation (EC) No. 1139/98 concerning the compulsory indication on the labeling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC, *Official Journal L 244, 03/09/1998* p. 20 (1998) (which states that the intentional introduction of bioengineered material into a food results in the compulsory labeling of that food as being produced from genetically modified organisms).

153. *Id.*

154. Commission Regulation (EC) No. 49/2000 of 10 January 2000 amending Council

phraseology in the ingredient-manufacturing vernacular: *identity preservation*.[155] In order to ensure that a *zero bioengineering material* claim can be made in the EU, a few U.S. companies have already started to track the origin of raw ingredients.[156] The FDA anticipated in its 2001 Draft Guidance that absent a validated testing protocol to ensure that a product does not contain bioengineered ingredients, such a document handling system would need to be established.[157] This could impose a bureaucratic and logistical nightmare on many manufacturers. The FDA estimates that a one-time burden for voluntarily labeling bioengineered food would be close to $2 million.[158] But the FDA does not address how far back in the chain one needs to venture in order to assure that no genetic modifications ever occurred in any ingredient which may eventually end up in that chocolate cake.

An alternative to the "zero content" standard would be a *de minimis* standard, similar to that adopted by the EU for adventitious contamination.[159] The FDA has not promulgated any *de minimis* levels below which an ingredient could be exempt from labeling, and this author argues that many food additives (most of which are used at levels less than the EU *de minimis* standard of one percent) should be exempt from labeling. It has yet to be addressed whether aggregation of all the ingredients would be appropriate to determine the *de minimis* content of the food. To ensure uniformity, it is recommended that the FDA address this issue rather than allow market discretion to establish independent criteria. Recommendations by the National Food Producers Association (NFPA) are a good start; these include establishing a "quantitative threshold for what is GMO-free, [requiring] compa-

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Regulation (EC) No. 1139/98 concerning the compulsory indication on the labeling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC, Document 300R0049, *Official Journal L 006, 11/01/2000* pp. 13-14 (introducing the *de minimis* threshold of one percent for adventitiously introduced genetically modified material into food).

155. *Compare* John Stephen Fredland, *Unlabel Their Frankenstein Foods!: Evaluating a U.S. Challenge to the European Commission's Labeling Requirements for Food Products Containing Genetically Modified Organisms*, 33 VAND. J. TRANSNAT'L L. 183, 192 (2000) *with* Lara Beth Winn, *Special Labeling Requirements for Genetically Engineered Food: How Sound are the Analytical Frameworks Used by FDA and Food Producers*, 54 FOOD & DRUG L.J. 667, 688 (1999).

156. Pillsbury, for example. *See* Winn, *supra* note 155, at 685 n.106.

157. *See* Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Availability, 66 Fed. Reg. 4839 (Jan. 18, 2001) (suggesting that manufacturers that wish to label a food using a *free* claim would need to document the source of the food, "demonstrat[ing] handling practices and procedures about how the food was processed . . . [including] affidavits from farmers, processors, and others in the food production and distribution chain."

158. *See id.* at 4841.

159. *See* Commission Regulation (EC) No. 49/2000 of 10 January 2000 amending Council Regulation (EC) No. 1139/98 concerning the compulsory indication on the labeling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC, Document 300R0049, *Official Journal L 006, 11/01/2000* pp. 13-14.

nies to keep substantiating information to back their claims, and [adding] accompanying statements to put the claims in context."[160]

V. POTENTIAL FOR MISCHIEF AND CONFUSION

Although the 2001 Draft Guidance on labeling is intended for manufacturers who voluntarily wish to label their foods regarding the presence or absence of bioengineered products, it does introduce the potential for mischief and confusion throughout the food industry. The number of products potentially affected is high. "In the U.S., an estimated 60 percent of processed foods—from breakfast cereals to soft drinks—contain a [bioengineered] ingredient, especially soy, corn, or canola; some fresh vegetables are genetically altered as well."[161] The introduction of labeling changes can have positive as well as negative effects.[162] An example of an effective labeling change imposed by the FDA was the 1994 introduction of regulations for uniform nutritional labeling.[163] Within a year, "56 percent of consumers used the labels *often* to check nutrients and compare brands."[164] However, only four years later, "sophisticated shoppers, irritated with what many considered misleading information," checked the labels less frequently.[165]

The consumer is bombarded with contradictory messages of what is *good* for you and what is *bad* for you.[166] These contradictory messages breed

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160. *NFPA Calls on FDA to Define "Biotech Free" in Product Testing Standards*, Food Labeling News. Apr. 26, 2000, *available at* 2000 WL 11948741, *1.

161. Karen Hopkin, *The Risks on the Table*, 284 SCIENTIFIC AMERICAN 60 (2001).

162. *See* Hollie Weaver Beason, *Nutrition: Learn How to Interpret Labels on Food Products*, GANNETT NEWS SERVICE, May 9, 2000, *available at* 2000 WL 4399166. As an example, the labeling of milk is undergoing a labeling change, in an effort to make the descriptive terms used to describe the fat content more comparable to other reduced fat foods. Milk labeled "2 percent" will now be labeled "reduced fat"; "1 percent" milk will be labeled "low fat" or "light"; and "0 percent" milk can be labeled "fat free," "skim," or "nonfat." It is this author's opinion that the numerical designation of butterfat content was more informative and easier to understand.

163. *See* Guy Gugliotta, *Nutrition Labels Both a Success and Failure*, PORTLAND OREGONIAN, May 30, 2000, *available at* 2000 WL 5407122 (opining that the regulations "were designed to set government standards for the labeling of processed foods, [and] impose[d] accuracy and uniformity on conflicting and often misleading information provided by food companies").

164. *Id.*

165. *Id.*

166. For example, eggs were condemned as causing high cholesterol which resulted in an almost 50 percent reduction in per capita consumption, although few studies showed any correlation to high cholesterol, while nutritionists viewed eggs as high in protein and iron yet low in fat and calories. BENNETT & DILORENZO, *supra* note 1, at 21. Coffee was maligned as causing heart disease and pancreatic cancer, but five years after the study supposedly supporting the claims, the authors could not verify the causal link. *Id.* at 27. Butter was taboo because of its high cholesterol content, and many Americans switched to margarine, only to be told later that the *trans* fatty acids in margarine may cause heart disease. *Id.* at 28. Finally, a "startling" *good* surprise from the National Center for Health Statistics in 1996 when it:

mistrust. In addition, too much information might result in "information overload" where an overwhelming amount of information causes consumers to completely ignore most or all of the information presented.[167] What appears on a label may also influence the confidence of the consumer. An example would be the warning label on products containing Olestra™ fat substitute. Olestra was "the first no-fat, no-calorie, fat substitute."[168] The problem with Olestra is that because of the chemistry of the molecule, it is not absorbed by the body and passes through the intestinal tract intact.[169] Proctor & Gamble supplied the FDA with more than 150,000 pages of data, making it "the most thoroughly tested new food ingredient ever considered by the FDA."[170] Because Olestra was not absorbed and it could dissolve fat-soluble vitamins, Proctor & Gamble agreed to add the fat-soluble vitamins directly to Olestra.[171] However,

> [t]here was one other FDA string attached. . . . Products made from Olestra must bear this label: 'The product contains Olestra. Olestra may cause abdominal cramping and loose stools. Olestra inhibits absorption of some vitamins and other nutrients. Vitamins A, D, E, and K have been added.' This warning label was required even though Olestra 'is less of a problem than baked beans, dietary fiber, or prunes.'[172]

The Center for Science in the Public Interest (CSPI) was determined to keep Olestra off the market and generated national publicity campaign to stop "greasy feces" from overtaking America.[173] And their campaign seems to have been successful, as evidenced by the lack of Max chips (the first product launched containing Olestra) on grocery shelves in San Diego.

> hypothesized that the reason for the falling rate of heart disease is not only exercise but the artificial flavorings used in junk food. . . . The heart-friendly element in many artificial flavors appears to be salicylates, which are related to aspirin, which helps to prevent blood clots. . . . [T]hose flavors . . . are strawberry, grape, butter, vanilla, cinnamon, mint, caramel, and walnut.

Id. at 28-29.

167. Jacob Jacoby et al., *Corrective Advertising and Affirmative Disclosure Statements: Their Potential for Confusing and Misleading the Consumer*, J. MARKETING, Winter 1982, at 61. For a review of overload theory, see Jason R. Penzer, *Grading the Report Card: Lessons from Cognitive Psychology, Marketing, and the Law of Information Disclosure for Quality Assessment in Health Care Reform*, 12 YALE J. ON REG. 207, 238-39 (1995).

168. *See* BENNETT & DILORENZO, *supra* note 1, at 93.

169. *Id.*

170. *Id.* at 95 (citing *Keith C. Triebwasser,* Speaker Notes Used at FAC [Food Advisory Committee of the FDA] Meeting, Nov. 1995, p. 12).

171. *Id. See also* Food Additives for Direct Addition to Food for Human Consumption; Olestra, 61 Fed. Reg. 3118-01 (Jan. 30, 1996).

172. *See* BENNETT & DILORENZO, *supra* note 1, at 97 (quoting Michael Parize, director of the Food Research Institute at the University of Wisconsin-Madison, from *CSPI Throws Consumer Choice Down the Toilet, Says Consumer Alert*, press release (Washington, DC: Consumer Alert, 1 July 1996)).

173. *See* BENNETT & DILORENZO, *supra* note 1, at 98.

Charles Grossman stated in the *Journal of the American Medical Association* that "it is both inappropriate and wrong for special-interest groups to play on the health and safety fears of the public to further their own ends."[174]

VI. CONCLUSION

Regardless of one's stance on the issue, the GMO labeling issue is now "the genie escaped from the bottle [and] is not easily cabined."[175] It is now up to the FDA to ensure that these labels are used for the benefit and not detriment of the American consumer. The FDA's proactive approach to provide guidance to the food industry on voluntary labeling of bioengineered food is laudable. In seeking feedback from the industry, a win-win situation for all involved can be accomplished with little uncertainty as to potential misbranding of products.[176] In order to attain this goal, the issue of bioengineered food ingredients needs to be addressed. Additional data need to be collected to ascertain the effects, on both manufacturers and consumers, of the voluntary labeling of foods as "GMO" in which the only bioengineered ingredient is a food additive that constitutes only a small fraction of the total composition of the food. In addition, it must be determined whether consumers and manufacturers who advocate the "non-GMO" label desire to have products completely devoid of bioengineered products.

The prevalence of the "non-GMO" label on certain grocery shelves suggests that these labels will not be easily regulated away, regardless of the scientific data that may be presented. While the debate continues on foods that are entirely or predominately composed of a bioengineered food crop, little time has been devoted to the issue of food additives that either utilize bioengineered crops during manufacture or utilize biotechnology techniques for production of the food ingredient. Two alternative strategies are presented for consideration for the regulation of labeling food where the only potential bioengineered component is a food additive—prohibition of "non-GMO" labels or regulation under the National Organics Act. Both of these strategies have their own advantages and disadvantages, as discussed below.

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174. *Id.* at 110 (citing Charles J. Grossman, *Genetic Engineering and the Use of Bovine Somatotropin*, 22 JAMA, 1003 (1990) (speaking about a similar scare raised concerning the use of recombinant bovine somatotropin (bST) and the potential hazardous effects to people drinking milk from cows treated with recombinant bST)).

175. *See* Welch v. Cadre Capital, 735 F. Supp. 467, 478 (U.S. Dist., 1990); *available at* 1990 U.S. Dist. LEXIS 4357, *7.

176. *See* Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Availability, 66 Fed. Reg. 4839, 4840 (2001) (requesting comments on the nomenclature to be used on the labeling, and information regarding the collection of information that would constitute *identity preservation*).

A. Prohibition of the "non-GMO" label

When the food product is predominately free of any bioengineered food component, it is recommended that all "non-GMO" labeling be prohibited as unnecessary. Current regulations governing food ingredients, including those manufactured using biotechnology, address any potential safety and health issues.[177] These food ingredients are generally used at very low levels in food, and, even if added together, would generally constitute less than ten percent of a final food product.[178]

The issue to be addressed is how to define "predominately free" of bioengineered food components in a final food product. The ten percent figure could be considered arbitrary. Is it too high? Would five percent or less be more appropriate? As discussed in this article, the bulk of the scientific evidence suggests that bioengineered food *per se* is no different than traditional foods, and that labeling them is unnecessary. But due to consumer demand and marketing pressure, although this may be the best logical alternative, it may no longer be a viable one. Consumer perception and belief may not be assuaged by scientific evidence. Some consumers believe that "organic" foods are safer than other foods. But the question is

> whether those beliefs are accurate. The record overwhelmingly demonstrates, through the testimony of soil scientists, nutritionists, fertilizer experts, pesticide experts, and others, that there is absolutely no difference between "organic" foods and "non-organic" foods in terms of either nutrient content or safety. Indeed, much of the resistance to the use of the term stems from the fact that there is no difference between "organic" and "non-organic" food, thus leading to the conclusion that the distinction drawn is spurious from a scientific standpoint.[179]

If one would substitute "bioengineered" for "organic" in the above quote, the conclusion would be the same. We are therefore faced with the reality that some standard will need to be established for determining how much of a bioengineered food ingredient should make a final food product ineligible for a non-GMO label. It is recommended that the FDA establish a *de minimis* standard for food ingredients, below which GMO-labeling would be prohibited.

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177. 21 U.S.C. § 348(a) and (b) (2000).

178. For instance, consider our cake mix from Section IV above. The ingredients are listed in descending order by weight. The ingredients constituting the bulk of the cake mix are sugar and flour. In chocolate cakes, processed cocoa is the next predominant ingredient. Partially hydrogenated oils are next, followed by leavening agents, mono- and diglycerides, salt, xanthan gum, flavors, and colors. Even assuming that the xanthan gum was used at 0.5%, and that hydrogenated soybean oil was used at 5%, adding in the flavors and colors would not reach the 10% level.

179. *See* Nat'l Nutritional Foods Ass'n v. Whelan, 492 F. Supp. 374, 381 (U.S. Dist., 1980) (quoted from Staff Report and Recommendations, Federal Trade Commission, September 25, 1978, p. 238).

1. De Minimis *Standard*

If consumers and manufacturers who advocate non-GMO labeling are willing to accept bioengineered food additives in the final product at some small levels, then the FDA must promulgate what threshold would be acceptable, and by what methods that level can be ascertained. This threshold would then be established as the *de minimis* standard, and food containing less than the *de minimis* level of a bioengineered food ingredient would not require a "non-GMO" label.

I propose that the EU *de minimis* standard of one-percent or less of a food additive should be adopted under this standard. Lynne Jensen, chairperson of the Board of the National Corn Growers Association, has stated that existing limitations on how U.S. commodity grain is processed will make a zero tolerance of bioengineered products almost impossible, and suggests that the FDA will "have to search for a number that's both palatable and doable."[180] A problem that would need to be addressed is the effect on the *de minimis* level when more than one food additive is present in a food product. I recommend that an arithmetic aggregate of each individual ingredient's contribution to the final product would be an appropriate approach in multi-ingredient products. But first, it must be determined how a "bioengineered product" is defined in a *de minimis* scenario, since this may have an effect on whether to subject the final product to the voluntary label.

As an illustrative example, suppose that the manufacturer of our chocolate cake mix from Section IV is struggling with the labeling issue. They have replaced the soybean oil with sunflower oil that is not bioengineered. The artificial flavors and the riboflavin that they use are also produced using traditional technology. The only question remaining is whether the cake mix could be labeled *GMO free* if the xanthan gum (suppose that it is used at 0.4% based on dry weight of the mix) was made using bioengineered soy protein during fermentation. Since the xanthan gum itself was made using non-genetically engineered bacteria, would the inquiry stop there? If the residual amount of protein in the xanthan gum were five percent, would the resulting 0.02 gram protein per 100 grams cake mix potentially from bioengineered soy make the cake mix bioengineered? But of the total protein content, if we assume that only one picogram [0.000 000 000 001 gram] is DNA,[181] then 100 grams of cake mix contains five billionths of one percent DNA; furthermore, only a portion of *that* DNA has been modified. If this were insect fragments, the courts would consider this a "trifle, not a matter of concern to the law."[182]

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180. *See* Kathleen Hart, *USDA, FDA grappling with identity preservation issues,* 43 Food Chemical News *3, July 2, 2001, *available at* 42001 WL 12773479.

181. *See* MCHUGHEN, *supra* note 94, at 96. If linseed typically contains about one half a picogram of the protein as DNA, then one picogram is a reasonable estimate for soybean. *Id.*

182. U.S. v. Capital City Foods, Inc., 345 F. Supp. 277, 279 (1972).

In addition, the FDA would need to promulgate rules addressing the issue of liability. If testing done in good faith and using state of the art technology fails to accurately detect a bioengineered food ingredient, and that results in the final food product containing more than the *de minimis* quantity of bioengineered material, should the non-GMO food product be removed from the shelves because of misbranding? Who should assume the risk of liability? Should such an event even result in misbranding and product recall?

Taken together, the many unanswered questions suggest that even adopting a *de minimis* standard to establish when a food product could be subject to voluntary labeling would not be adequate to provide sufficient guidance to the industry. Since it is unlikely that a complete ban on voluntary labeling of bioengineered foods would accomplish the FDA's goals of protecting the consumer and providing consumer information, another approach should be considered.

2. *Adopting the National Organic Standards for "non-GMO" Labeling*

A different yet workable approach would be to eliminate the need for a separate label identifying bioengineered food. This can be accomplished by using the *organic food* label.[183] Allowing a "non-GMO" or "GMO-free" label only on organic foods would address the most vocal segment of consumers demanding such labeling, without adversely impacting the entire food industry. Since the regulatory mechanism is already in place for organic foods, adding the "GMO-free" claim should not introduce confusion into the stream of commerce with respect to the presence of bioengineered food.

It is this author's opinion that the best approach for addressing the bioengineered food-labeling conundrum is to allow only organic foods to be labeled as "non-GMO." By definition, an organic food cannot contain genetically modified material, so "non-GMO" is an accurate label for such foods. That segment of the industry already has established an identity preservation system, and has initiated a manufacturing tracking system to ensure that the products adhere to the government regulations. No additional burdens for record-keeping or product tracking would be encountered. Companies wishing to expand into the "non-GMO" food segment would need to meet all the regulations that exist for organic foods, as outlined in the National Organic Program.[184] Implementing this approach would require adopting the *zero content* standard.

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183. *See* Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Availability, 66 FR 4839, 4842 (2001) ("according to a proposal in the Federal Register of March 13, 2000 [65 FR 13512] a food labeled as *organic* would not be permitted to contain bioengineered materials."). *See also,* Eric F. Greenberg, *Biotech and Organic Rules Related*, 38 PACKAGING DIGEST, *1, Feb. 1, 2001, *available at* 2001 WL 15622399.

184. USDA National Organic Program, 65 Fed. Reg. 80548-01 (2000) (requiring that certified organic food must not only be free of genetically modified organisms, but must also

3. Zero Content Standard

In order to comply with the National Organics Program, products will need to be completely devoid of bioengineered products. The *zero content* standard would need to be implemented, and the presence of *any* bioengineered ingredient would render the final product subject to the voluntary labeling scheme. The *zero content* standard would preclude a "non-GMO" label on any food shown to contain even trace amounts of recombinant DNA. Although the *zero content* standard establishes a bright line approach to this issue, it brings with it its own consequences. One consequence would be the requirement for an identity preservation system, which is expected to inject huge costs into the food industry.[185] Even an ideal identity preservation system may be unable to meet a *zero content* standard. But because this mechanism is already in place for the organic food segment, it makes sense that GMO-labeling should utilize the existing system, instead of creating a new one. By allowing voluntary labeling only on organic foods, the need for an independent identity preservation system for the entire food industry can be avoided.

Another disadvantage that only complete prohibition of the "non-GMO" label avoids is the requirement that a uniform analysis system be developed. The detection of the bioengineering modification presents both scientific and legal burdens. As discussed earlier, the existing PCR technology requires a primer segment in order to ascertain what modifications have been made. If a manufacturer needs to provide such a primer sequence in order to develop and utilize a PCR detection system, trade secret issues would need to be addressed. Further, once a detection system is established, it will need to be determined whether all manufacturers in a product chain must do their own testing.

Again, as an illustrative example, let us consider the manufacturer of our chocolate cake mix from Section IV. The mix is to be labeled "non-GMO." In order to ensure that the ingredients used during manufacture of the cake mix contain no bioengineered ingredients, they purchase raw materials only from manufacturers that maintain an identity preservation system and certify that their ingredients are "GMO free." Unless they produce only GMO-free food products in their manufacturing facility, there is the potential of cross-contamination with even trace amounts of bioengineered products that could show up in the final product. Because even trace amounts of

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be cultivated without the use of sewage sludge, synthetic chemical fertilizers, pesticides, herbicide, growth hormones, or treated using radiation).

185. *See* Rick Weiss, *Next Food Fight Brewing is Over Listing Genes on Labels*, WASH. POST, Aug. 15, 1999, at A17 ("expensive separate transportation and processing streams for engineered and nonengineered foods" will be required to maintain the identity preservation system); *see also*, Henry I. Miller, *A Rational Approach to Labeling Biotech-Derived Foods*, 284 SCIENCE 1471 (1999) ("both traditional and bioengineered food would have to be segregated throughout all phases of production, including planting, harvesting, processing, and retail distribution").

bioengineered products under the *zero content* standard would preclude using a "non-GMO" label, further testing of the final cake mix would be required to ensure that it is indeed free of *any* bioengineered product. But the cake mix may comprise more than a single "potentially bioengineered" ingredient, and each separate ingredient would require a unique PCR identification test. Multi-food product producers, such as Kraft and Nabisco, for example, would need to establish facilities dedicated solely to the production of non-bioengineered food products to eliminate potential cross-contamination. They would also need personnel to do nothing but run identification testing.

The testing regime itself will inject additional costs at every step of the manufacturing chain, resulting in a large cumulative cost that will need to be captured in the form of higher retail prices. By allowing a "non-GMO" label only on organic foods, the costs associated with testing can be avoided by all food manufacturers not wishing to produce foods that could be labeled as "non-GMO." Because organic food consumers are already willing to pay the higher prices associated with organic foods, it seems likely that any additional costs that would result from allowing a "non-GMO" label to be placed on organic foods would be acceptable to that segment of the food consumer market.

An additional issue that will need to be addressed is the methods for detecting bioengineered products in food. The government will need to determine how detection testing will be conducted, and who should bear the costs of developing such testing. By limiting the use of voluntary labeling of bioengineered foods to those that comply with the National Organic Program, the playing field has been narrowed, and this issue may be more manageable. In addition, the legal issues surrounding divulging trade secrets of food product manufacture would potentially be minimized because those manufacturers not wishing to divulge such information may avoid doing so by not participating in the organic food market.

In conclusion, bioengineered food and bioengineered food ingredients are not materially different from those produced by traditional methods. Since voluntary labeling would seem to cause more confusion than provide relevant information to the consumer, I recommend that voluntary labeling of bioengineered food be restricted. Allowing only certified organic food to be voluntarily labeled as "non-GMO" would placate the most vocal proponents of such labeling while having a minimal adverse impact on the overall food industry. Manufacturers wishing to exploit the emerging "non-GMO" market trend could do so by complying with the standards set for certified organic foods. By restricting such labeling to the organic food segment, the potential problem of constructive labeling as being bioengineered by implication can be avoided; all organic foods are by definition free of bioengineered material. Manufacturers wishing to continue using bioengineered food ingredients could do so without fear of negative marketing. And consumers desiring foods free of bioengineered material could purchase certified organic food with the voluntary "non-GMO" label. This approach would be a win-win situation for both advocates and opponents of bioengineered food.