



An Agricultural Law Research Article

Buying and Eating in the Dark: Can the Food and Drug Administration Require Mandatory Labeling of Genetically Engineered Foods?

by

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Originally published in TEMPLE ENVIRONMENTAL LAW & TECHNOLOGY
JOURNAL
19 TEMP. ENVTL. L. & TECH. J. 225 (2001)

**BUYING AND EATING IN
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GENETICALLY
ENGINEERED FOODS?**

*Alliance for Bio-Integrity v.
Shalala, et al.*, 116 F. Supp.2d 166
(2000)

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INTRODUCTION

The United States is presently at the leading edge of what appears to be a surge of foods modified through the use of modern recombinant DNA

technologies.¹ In recent years, biotechnology companies have introduced a number of genetically engineered² agricultural products to consumers at the grocery store.³ Between twenty-five and forty-five percent of the major crops grown in the United States are modified genetically.⁴ Additionally, an estimated thirteen to sixteen percent of the American soybean crop is currently produced from genetically engineered seeds.⁵ With approximately seventy percent of processed foods containing soy protein, the exposure of American consumers to genetically engineered foods is extensive.⁶ Because many consumers are unaware of this recent development, they lack the ability to control the extent of their exposure. Additionally, the current U.S. Food and Drug Administration (FDA)⁷ regulations do not consider recombinant DNA technologies to be fundamentally different from traditional agricultural breeding techniques, and therefore do not require any labeling of genetically engineered foods.⁸ Consumer advocates, however, disagree with the FDA's decision and question the safety of growing and consuming these foods. As a result, various consumer advocacy groups are demanding that the government mandate some form of labeling of genetically engineered foods.⁹

At the heart of the 'labeling' controversy is what is commonly referred to as

¹ "Recombinant DNA technologies" refers to the techniques (such as traditional hybridization, chemical or radiation-induced mutagenesis, cell culture, embryo rescue, and protoplast) used by scientists to transfer discrete pieces of genetic material from one kind of plant, animal, or microorganism into another, sometimes quite different, animal, plant, or microorganism. See *Strategies for Engineering Organisms* (A.T.H. Burns ed., Butterworth-Heinemann, Ltd. 1993); See also Dale E. Bauman, *Review of an Emerging Animal Technology*, 75 J. Dairy Sci. 3432, 3433 (1992).

² Genetic engineering, the "directed manipulation of genes," eliminates the limitations of traditional plant breeding. Lara Beth Winn, *Special Labeling Requirements for Genetically Engineered Food*, 54 Food Drug L.J. 667,668 (1999) [hereinafter Winn, *Special Labeling Requirements*] (citing William Bains, *BIOTECHNOLOGY FROM A TO Z* 153 (2d. ed. 1993)). Recombinant DNA (rDNA) techniques allow a biotechnologist to isolate a single gene in an organism and to transplant the gene to another organism. *Id.* The result of this genetic transfer is an intended change in one or more of the characteristics expressed by the transferee organism. *Id.*

³ See Marian Burros, *Eating Well*, N.Y. TIMES, May 21, 1997, at C3. Those genetically engineered foods already in the market include abalone, canola oil, catfish, chymosin, corn, cottonseed oil, potatoes, prawns, salmon, soybeans, and tomatoes. Those genetically engineered foods under development include alfalfa, apples, asparagus, barley, beets, broccoli, carrots, cauliflower, chestnuts, chicory, cucumbers, flaxseed, grapes, kiwi, lettuce, melons, papayas, peanuts, pepper, raspberries, rice, squash, strawberries, sugar cane, sunflowers, sweet potatoes, walnuts, watermelons, and wheat.

⁴ See Winn, *supra* note 2 at 667.

In this Note "genetically engineered" and "genetically modified" are used synonymously to indicate the introduction of DNA segments into an organism through recombinant DNA technology. These terms do not include the natural manipulation of genes through traditional methods of plant breeding.

⁵ See Burros, *supra* note 3.

⁶ See *id.*

⁷ The FDA is an agency within the Department of Health and Human Services.

⁸ See Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984 (1992) [hereinafter Statement of Policy].

⁹ See Mothers for Natural Law, *Safe Food-Campaign 2001 Petition* (visited March 2001) <http://www.safe-food.prg/-campaign/petition.html>. The petition urges mandatory labeling of all foods derived from genetically engineered organisms.

the “consumer right-to-know.” At the core of this perspective is the notion that the public has a basic right to know any fact it deems important about a food or commodity before making a purchasing decision. Since there is no mandatory federal, uniform labeling scheme for genetically engineered foods, several state legislatures have passed their own voluntary labeling laws. Vermont, however, was the only state to *require* labeling, and then only for one specific product. In 1996, Vermont passed a law mandating that milk products produced by rBST¹⁰-injected cows to be specifically labeled as such.¹¹

Bovine somatotropin (bST), a protein growth hormone that stimulates milk production, is created naturally by the cow pituitary gland.¹² The gene that codes for the production of bST has been genetically engineered into bacteria so that the hormone can be produced commercially and used as an animal drug, rBST.¹³ rBST is given to cows by intravenous injection, and although milk production is stimulated by the rBST, the milk itself and the cow are not genetically modified.¹⁴ Although the milk is stimulated by administration of rBST, it is not genetically modified but it is viewed as genetically modified because it is produced with the use of a genetically engineered hormone. As a result, milk produced with rBST raised the same concerns regarding labeling as genetically modified foods.

The Second Circuit Court of Appeals granted an injunction against enforcement of Vermont’s labeling law in *International Dairy Foods Ass’n v. Amestoy*.¹⁵ The court concluded that consumer interest alone was not sufficient to justify requiring a product manufacturer to publish the functional equivalent of a warning about a production method (recombinant DNA engineering) that has no discernible impact on a final product.¹⁶ Vermont attempted to justify its labeling statute based solely on “consumer interest,” an interest the court “reluctantly” found inadequate.¹⁷ Following the *Amestoy* decision, Congress proposed a bill, the *Genetically Engineered Food Right To Know Act* that seeks “to require that food containing a genetically engineered material, or that is produced with a genetically engineered material, be labeled accordingly.”¹⁸ However, the question of whether a consumer has a right to know when food is altered by DNA technology remained unanswered.

In September 2000, the United States District Court for the District of Columbia granted the defendants’ motion for summary judgment in *Alliance for Bio-Integrity v. Shalala*¹⁹ ruling, *inter alia*, that the Federal Food, Drug &

¹⁰ bST is a hormone naturally produced by cows and is equivalent to the genetically engineered hormone rBST (recombinant bST).

¹¹ See Vt. Stat. Ann. tit. 6, § 2754(c) (Supp. 1996) (terminated).

¹² See Judith C. Juskevich & Greg Guyer, *Bovine Growth Hormone: Human Safety Evaluation*, 249 SCIENCE 875 (1990).

¹³ See *id.*

¹⁴ See *id.*

¹⁵ 92 F.3d 67, 68 (2d Cir. 1996).

¹⁶ *Id.* at 73.

¹⁷ *Id.*

¹⁸ H.R. 3377, 106th Cong. (1999).

¹⁹ 116 F. Supp. 2d 166 (D.D.C. 2000).

Cosmetic Act (“FDCA”)²⁰ grants the FDA limited authority to require labeling of genetically modified foods. The court reasoned that absent risks to consumer health or uniform changes to food derived through recombinant technology, the FDA is not authorized to impose food labeling.²¹

This Note examines the District Court’s decision in *Alliance for Bio-Integrity* in light of the FDCA, which has been carefully crafted to limit the amount of information that can be required to appear on the food label. This Note will focus on two contentions made by the plaintiffs: 1) the FDA’s presumption that genetically engineered foods are “generally recognized as safe” (GRAS) violates the requirements of the Federal Food, Drug, and Cosmetic Act; and 2) the FDA should have considered the widespread consumer interest in having genetically engineered foods be labeled as such. Based on the analysis, this Note will assert that the same legal impediments to labeling rBST-derived milk should not apply to labeling genetically modified foods. This Note will also take a critical look at the FDCA’s misbranding laws as they apply to production and processing methods of genetically engineered foods and conclude that the FDA could require labeling of genetically modified foods by considering them to contain “material” facts under the FDCA.

Finally, in the absence of a uniform federal labeling standard, this Note argues that mandatory labeling for genetically altered food products should be an option for states.

FACTS

Recombinant technology has enabled scientists to alter the genetic composition of organisms by mixing genes on the cellular and molecular level in order to create new breeds of plants for human and animal consumption.²² Controversy surrounds developments in biotechnology, in particular the production, sale, and trade of genetically modified organisms and foods.²³ On May 29, 1992, the FDA published a “Statement of Policy: Foods Derived From New Plant Varieties” (Statement of Policy)²⁴ In the Statement of Policy, the FDA announced that the agency would presume that foods produced through the recombinant process were ‘generally recognized as safe’ (GRAS) under the FDCA and therefore not subject to regulation as food additives. While the FDA recommended that food producers consult with it before marketing recombinant technology produced foods, the agency did not mandate such consultation. The Statement of Policy also indicated that recombinant modification was not a “material fact” under FDCA, and therefore labeling genetically modified was not necessarily required.”²⁵

Plaintiffs, a coalition of consumer groups and individuals including

²⁰ 21 U.S.C. § 321(n) (1994).

²¹ *Alliance for Bio-Integrity*, 116 F. Supp.2d at 178-179.

²² *Id.* at 169.

²³ *See id.*

²⁴ Statement of Policy, *supra* note 8.

²⁵ *Id.*

scientists and religious leaders concerned about genetically altered foods, brought suit to protest the FDA's policy on such foods in general, and in particular on various genetically modified foods that already have entered the marketplace.²⁶

THE COURT'S ANALYSIS

In *Alliance for Bio-Integrity*,²⁷ the District Court concluded that the FDA's decision to accord genetically modified foods a presumption of GRAS status is not arbitrary and capricious and does not violate the FDCA.²⁸ The FDCA provides that any substance which may "become a component or otherwise affect the characteristics of any food" shall be deemed a food additive.²⁹ The court acknowledged that in the case of foods derived from new plant varieties, it is the transferred genetic material and the intended expression product or products that could be subject to food additive regulation, if such material or products are not generally recognized as safe.³⁰ The court noted that section 321(s) of the FDCA exempts from regulation as additives substances that are generally recognized to be safe under the conditions of its intended use.³¹ The court agreed with the FDA's reasoning that the only substances added to genetically engineered foods are 'nucleic acid proteins,' generally recognized as not only safe but also necessary for survival.³² According to the FDA, "nucleic acids are present in the cells of every living organism, including every plant and animal used for food by humans or animals, and do not raise a safety concern as a component of food."³³

The court noted that the plaintiffs have not disputed the FDA's claim that nucleic acid proteins are generally recognized as safe.³⁴ However, they argue that there is a significant disagreement among scientific experts as to whether or not nucleic acid proteins are generally recognized to be safe when they are used to alter organisms genetically.³⁵ The court addressed this issue by noting that "the rationale for deference is particularly strong when the agency is evaluating scientific data within its technical expertise".³⁶ The court further observed that "in an area characterized by scientific and technological uncertainty. . .this court must proceed with particular caution, avoiding all temptation to direct the agency in a choice between rational alternatives."³⁷ Although unanimity among scientists is not required, the plaintiffs failed to

²⁶ *Id.*

²⁷ 116 F. Supp 2d. 166 (2000).

²⁸ *Id.* at 177.

²⁹ *Id.* at 175 (citing 21 U.S.C. § 321 (s)).

³⁰ *Id.* at 176 (citing 21 U.S.C. § 321 (s)).

³¹ *Id.* at 176.

³² *Id.* at 176.

³³ *Id.* (citing 57 Fed. Reg. at 22,990 (1992)).

³⁴ *Alliance for Bio-integrity*, 116 F. Supp. 2d at 177.

³⁵ *Id.*

³⁶ *Id.* (quoting *International Fabricare Inst. v. United States Environmental Protection Agency*, 972 F.2d 384, 389 (D.C. Cir. 1992)).

³⁷ *Id.* (quoting *Environmental Defense Fund, Inc. v. Costle*, 578 F.2d 337, 339 (D.C. Cir. 1978)).

show "severe conflict among experts that would preclude a finding of general recognition".³⁸ The court, therefore, concluded that the plaintiffs failed to show that the GRAS presumption is inconsistent with the statutory requirements.³⁹

On the issue of labeling, the court concluded that the FDCA grants the FDA limited authority to require labeling.⁴⁰ The court determined that foods should be deemed misbranded if their labeling "fails to reveal facts . . . material with respect to consequences which may result from the use of the article to which the labeling . . . relates . . ."⁴¹ The plaintiffs not only challenged the FDA's interpretation of the term "material," but they also argued that the FDA should have considered widespread consumer interest in having genetically engineered foods labeled.⁴²

The court began its analysis by stating that this is a question of statutory interpretation and Congress has not squarely addressed whether materiality pertains only to safety concerns or whether it also includes consumer interest.⁴³ Because Congress has not spoken directly to the issue, the court determined that it must give deference to the FDA.⁴⁴ The FDA takes the position that no "material" change under section 321(n) has occurred in the genetically engineered foods.⁴⁵ Hence, absent risks to consumer health or uniform changes to food derived through recombinant technology, the FDA does not read section 321(n) to authorize an agency imposed food labeling.⁴⁶ The court agreed that the FDA's exclusion of consumer interest from the factors that determine whether a change is "material" constitutes a reasonable interpretation of the statute.⁴⁷ The court reasoned that where consumer demand is the sole justification for the requirement of labeling, "it is doubtful whether the FDA would even have the power under the FDCA to require labeling."⁴⁸

The court concluded its analysis by stating that if the product [genetically engineered food] does not differ in any significant way from what it purports to be, then it would be misbranding to label the product as different, even if consumers misperceived the product as different.⁴⁹ The court emphasized that

³⁸ *Id.* (quoting Federal Food, Drug, and Cosmetic Act, 62 Fed. Reg. 18,938, 18,939 (1997)(to be codified at 21 C.F.R. pt. 170, 184, 570)(proposed Apr. 17, 1997)).

³⁹ *Id.* *Alliance for Bio-integrity*, 116 F. Supp. 2d at 177

⁴⁰ *Id.* at 178.

⁴¹ *Id.* (citing 21 U.S.C. § 321 (1994)).

⁴² *Id.*

⁴³ *Id.*

⁴⁴ *See id.* Agency interpretations receive substantial deference, particularly where the agency is interpreting a statute that it is charged with administering. *See id.* (citing *Rust v. Sullivan*, 500 U.S. 173 (1991)).

⁴⁵ *Alliance for Bio-integrity*, 116 F. Supp. 2d at 128.

⁴⁶ *Id.* at 178-179.

⁴⁷ *Id.* at 179.

⁴⁸ *Id.* (citing *Stauber v. Shalala*, 895 F.Supp. 1178, 1193 (W.D.Wis. 1995)) ("In the absence of evidence of a material difference between rBST-derived milk and ordinary milk, the use of consumer demand as the rationale for labeling would violate [the FDCA]."). *See infra* Prior Law section of this article for a discussion of the *Stauber* case.

⁴⁹ *Id.* at 179.

the FDA has already determined that recombinant technology does not "materially" alter foods; therefore, the FDA lacks a basis to legally mandate labeling, regardless of consumer demand.⁵⁰

PRIOR LAW

I. Current FDA Regulations for Labeling Genetically Engineered Foods

THE FEDERAL FOOD, DRUG AND COSMETIC ACT (FDCA)

a) FDCA Generally

The Federal Food, Drug and Cosmetic Act ("FDCA") grants authority for food labeling to the FDA.⁵¹ Although the FDA does not require special labeling for genetically engineered foods, it has advised that labeling requirements that apply to foods in general also apply to foods produced using recombinant technologies.⁵² Hence, genetically engineered foods are currently regulated under the existing framework of the FDCA.⁵³ The requirements of the FDCA as to what must be revealed in a food label are broad and general.⁵⁴ The FDCA requires that all labeling be truthful, not misleading, and "reveal all facts that are material in light of representations made or suggested by labeling."⁵⁵ Under an FDA regulatory scheme first articulated in 1992, foods created through the use of recombinant DNA technologies are treated as though they are not essentially different from foods created through traditional breeding techniques.⁵⁶ According to the FDA, only information about the characteristics of the final product, not the method of production, constitute material information that must be disclosed under the FDCA.⁵⁷

b) The Misbranded Provision of the FDCA

The FDCA prohibits the misbranding of foods.⁵⁸ Under section 403(a)(1), a food is misbranded if its labeling is false or misleading.⁵⁹ Additionally section 403(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.⁶⁰ Thus, according to the FDA, if a bioengineered food is significantly different from its traditional counterpart such that the common or usual name no longer

⁵⁰ *Id.*

⁵¹ See 21 U.S.C. § 343 (1994). See also, *Alliance for Bio-integrity*, 116 F. Supp. 2d at 178.

⁵² Statement of Policy, *supra* note 8, at 22,991.

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ See Statement of Policy, *supra* note 8, at 22,991 (citing FDCA § 403(i)(1994), 21 U.S.C. §343(i) (1994)).

⁵⁶ See *id.* at 984.

⁵⁷ See *id.* at 991.

⁵⁸ See *id.*

⁵⁹ See *id.*

⁶⁰ See 21 U.S.C.S. § 403(i)(1994).

adequately describes the new food, the name must be changed to describe the difference.⁶¹ Furthermore, if a bioengineered food has a significantly different nutritional property, its label must reflect the difference.⁶²

II. The Nutrition Labeling And Education Act

The passage of the Nutrition Labeling and Education Act of 1990 (NLEA) added another requirement to the food label: complete nutrition labeling.⁶³ The NLEA imposes additional requirements on a manufacturer who wants to make nutrition-related claims about its product.⁶⁴ Reduced to simplest terms, the NLEA reveals a strong congressional desire that the food label convey meaningful nutrition information about foods in a simple and clear format.⁶⁵ In passing and implementing the NLEA, Congress recognized that educational potential of the food label is limited and, as a result, the label should contain the essential information about the identity and nutritional quality of food.⁶⁶

While the NLEA specifies the nutrients for which information must be provided in nutrition labeling, section 403(q)(2)(B) gives the agency authority to exclude any nutrient from the declaration requirement, despite its presumptive public health importance, when the agency finds that the information “is not necessary to assist consumers in maintaining health dietary practices.”⁶⁷ When it adopted final rules excluding numerous declarations, the FDA emphasized “[n]ot all information related to maintaining healthy dietary practices can be included on the food label Not only would space constraints not allow for this, but the large amount of information would interfere with consumers’ abilities to use the information of the greatest public health significance”⁶⁸

III. The Debate Over Milk From Cows Treated With Recombinant Bovine Somatotropin (rBST)

The FDA’s “Interim Guidance” on labeling milk produced with the use of rBST

Recombinant Bovine Somatotropin (“rBST”), a synthetic growth hormone, is produced in laboratories through recombinant DNA technology.⁶⁹ rBST is

⁶¹ See Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering [hereinafter Guidance for Industry]. (Visited January 15, 2001) <<http://vm.cfsan.fda.gov/~dms/biolabgu.html>>.

⁶² See *id.*

⁶³ Pub. L. No. 101-535, § 2, 104 Stat. 2353 (1994)(codified at 21 U.S.C. § 343 (q) (1) (1994)).

⁶⁴ *Id.* § 3, 104 Stat. at 2357.

⁶⁵ *Id.*

⁶⁶ *Id.*

⁶⁷ H. REP. NO. 101-538, at 17, 101st Cong., 2d Sess. 18 (1990).

⁶⁸ Food Labeling, 58 Fed. Reg. 2079, 2107 (Jan.6, 1993)(to be codified at 21 C.F.R. pt. 1 and 101).

⁶⁹ See *supra*, note 12. See also *International Dairy Foods Ass’n v. Amestoy*, 898 F. Supp. 246, 248 (D. Vt. 1995).

injected into the bloodstream of a cow to increase its milk production.⁷⁰ Although the milk production is stimulated by the administration of rBST, the milk is not genetically modified.⁷¹ Nonetheless, milk produced with the use of rBST has raised the same kinds of issues and consumer concerns as genetically modified foods. Consequently, the FDA's approach to rBST and genetically engineered foods is the same.⁷² Although rBST is a drug, it is developed by a recombinant (DNA) technology and is also regulated by the FDCA.⁷³

In February of 1994, the FDA published its "interim" guidelines on rBST product labeling.⁷⁴ The guidelines did not pertain to products that come from rBST-treated cows, but sought to regulate, albeit "voluntarily," the labeling of products that did not come from treated cows.⁷⁵ Because rBST use carries no explicit or implicit changes in milk quality or composition, the FDA decided that labels on rBST-derived products would not be required.⁷⁶ Nothing in the nutritional quality of the milk changed with rBST use and no evidence of other health risk appeared; thus the FDA had no reason to require any type of product labeling.⁷⁷ The FDA recognized, however, that genuine consumer interests might necessitate some product information about whether the milk comes from rBST-treated cows.⁷⁸ Therefore, the FDA did not prohibit labeling of milk products from untreated cows, as long as any such label information was not misleading.⁷⁹

The Interim Guidance follows the FDCA's prescriptions by stating that a misleading label may fail to disclose either facts material to representations made about the product, or facts material to the consequences of using the product.⁸⁰ As rBST appears in all milk, a label claim that milk is "bBST-free" would be false.⁸¹ The addition of a notation that the milk is "rBST-free" could be misleading if it implies a nutritional or compositional difference between non-rBST milk and rBST-produced milk.⁸² Instead, labels should only convey the fact that there is a difference in the production method between non-rBST-produced milk and rBST-produced milk.⁸³ Yet, even an accurate label statement about the different production methods could imply that non-rBST milk is healthier or safer than rBST milk, resulting in a false and misleading

⁷⁰ See *International Dairy Foods Ass'n*, 898 F.Supp. at 248.

⁷¹ See *supra*, note 12.

⁷² See FDCA, 21 U.S.C. §301-343 (1994).

⁷³ See *id.*

⁷⁴ Interim Guidance on the Voluntary Labeling of Milk and Milk Products From Cows That Have Not Been Treated With Recombinant Bovine Somatotropin, 59 Fed. Reg. 6279 (1994) [hereinafter Interim Guidance].

⁷⁵ Interim Guidance, 59 Fed. Reg. at 6280.

⁷⁶ See *id.* at 6279-80.

⁷⁷ See *id.*

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ *Id.*

⁸² *Id.*

⁸³ *Id.*

label claim under the FDCA.⁸⁴

To respond to these circumstances and avoid false and misleading label claims, rBST use must be put in proper context through additional descriptive information. The Interim Guidance suggests that whenever a dairy product carries a label that reads "From Cows Not Treated with rBST," the label should also include the disclaimer that "no significant difference has been shown between milk derived from rBST-treated and non-rBST-treated cows."⁸⁵ In this manner, the FDA reasoned, consumers would not be misled by a rBST-label claim.

IV. Cases Challenging the FDA's Decision Not To Require Mandatory Labeling of rBST-Derived Milk

Stauber v. Shalala

In *Stauber v. Shalala*⁸⁶ milk consumers and two food cooperatives challenged the FDA's decision not to require labeling of products from cows treated with rBST. The most significant of the Stauber's court's pronouncements was its review of the Interim Guidance with respect to labeling rBST-derived products.⁸⁷ The plaintiffs argued for mandatory labeling based on their interpretation of the FDCA provisions.⁸⁸ Given the broad spectrum of information that may be considered material under the misbranding provisions, the plaintiffs felt that the absence of required labeling was false or misleading.⁸⁹ The plaintiffs contended that rBST-derived milk differs in sufficiently significant ways from milk produced without rBST to constitute material facts warranting a label.⁹⁰ According to the plaintiffs, the initial distinction between rBST- and non-rBST-derived milk was certain organoleptic differences.⁹¹ On this basis, the plaintiffs argued that the different taste, smell, or appearance of rBST-derived milk should be considered as a material fact that should necessitate labels.⁹² The court acknowledged that organoleptic differences in a food product could require

⁸⁴ See Interim Guidance, 59 Fed. Reg. at 6280; See also *United States v. An Article of Food*, 482 F.2d 581 (8th Cir. 1973). In *An Article of Food*, the government brought a misbranding action under the FDCA. See *id.* at 582. The court of appeals noted that although the label was technically accurate, it needed to also comply with the FDCA misbranding requirement that it not be misleading. See *id.* at 584. An ambiguity was created by listing several ingredients that were of no nutritional value or in quantities so minute as to not enhance the nutritional value of the product. See *id.* at 582, 586. Due to the possibility that the label "could persuade a purchaser that the product possessed greater nutritional value than it actually did," the ambiguity caused the label to be false and misleading.

⁸⁵ Interim Guidance at 6280.

⁸⁶ 895 F. Supp. 1178 (W.D. Wis. 1995).

⁸⁷ See *id.* at 1192-93.

⁸⁸ See *id.* at 1193.

⁸⁹ *Id.*

⁹⁰ *Id.*

⁹¹ See *id.* (defining an organoleptic difference as "one capable of being detected by a human sense organ" citing Webster's Collegiate Dictionary 953 (1991)).

⁹² See *Stauber*, 895 F.Supp. at 1193.

labeling,⁹³ but also stated that the plaintiffs were unable to show any discernable organoleptic differences between rBST-and non-rBST-derived milk exist.⁹⁴ Because no information supported a physical difference between the milk from the two production methods, no material fact requiring labels was found.⁹⁵

The *Stauber* plaintiffs also argued that widespread consumer interest in mandatory labeling for rBST-derived milk constitutes a material fact sufficient to require labeling.⁹⁶ The court noted that the FDA considers consumer interest and consumer perceptions whenever “a product differs materially from the type of product it purports to be.”⁹⁷ For rBST-derived milk, however, the court could not find any significant difference in the composition or quality of the milk as compared to non-rBST-derived milk.⁹⁸ Thus, there was no difference that warranted labeling.⁹⁹ Moreover, the court stated that distinguishing rBST-produced milk would constitute misbranding under the FDCA.¹⁰⁰ Even if consumers perceived rBST-derived products as different, the absence of a difference means that they cannot be labeled to distinguish them from non-rBST-derived products.¹⁰¹

International Dairy Foods Ass'n v. Amestoy

On April 13, 1994, Vermont enacted a statute requiring that “if rBST has been used in the production of milk or a milk product for retail sale in this state, the retail milk or milk product shall be labeled as such.”¹⁰² Vermont does not claim that health or safety concerns prompted the passage of the Labeling Law.¹⁰³ Instead, it bases its justification for mandatory labeling not otherwise required by the FDA on strong consumer interest and the public’s “right to know” whether a particular dairy product contains milk produced by cows given rBST.¹⁰⁴ The Labeling Law allows for shelf labeling of milk derived from rBST-treated cows through the use of blue shelf labels, blue stickers, or explanatory signs placed in retail establishments.¹⁰⁵ Thus, while tracking some of the FDA’s suggested language, the Vermont label is the converse of the labeling suggested by the FDA in its Interim Guidelines.¹⁰⁶

Dairy manufacturers challenged the Vermont law arguing that the law

⁹³ *See id.*

⁹⁴ *See id.*

⁹⁵ *See id.*

⁹⁶ *See id.* (arguing that the sufficiently high consumer interest levels would thereby trigger mandatory labels on rBST-produced milk products).

⁹⁷ *Id.*

⁹⁸ *See Stauber*, 895 F.Supp. at 1193.

⁹⁹ *See id.*

¹⁰⁰ *See id.* The court did not elaborate on how it arrived at this conclusion.

¹⁰¹ *See id.*

¹⁰² *See International Dairy Foods*, 898 F. Supp at 249.

¹⁰³ *Id.*

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*

¹⁰⁶ *Id.* at 250.

infringed upon their constitutional right not to speak and acts as a warning by raising consumer concerns about the safety and wholesomeness of milk.¹⁰⁷ In response, Vermont asserted a state interest: its citizens' right to know such information.¹⁰⁸ State surveys show that a majority of Vermonters do not want to purchase milk products derived from rBST-treated cows because: (1) they consider the use of a genetically-engineered hormone in the production unnatural; (2) they believe that use of the hormone will result in increased milk production and lower milk prices, thereby hurting small dairy farmer; (3) they believe that use of rBST is harmful to cows and potentially harmful to humans; and, (4) they feel that there is a lack of knowledge regarding the long-term effects of rBST.¹⁰⁹

A divided Second Circuit Court of Appeals concluded that consumer interest alone was not sufficient to justify requiring a product's manufacturer to publish the functional equivalent of a warning about a production method [recombinant DNA engineering] that has no discernible impact on a final product.¹¹⁰ The Court concluded that by forcing appellants to make an involuntary statement contrary to their views when they sold their products, Vermont's statute implicated their First Amendment freedom to speak, causing them irreparable harm.¹¹¹

The majority noted that it has no doubt that Vermont asserted interest, [the demand of its citizenry for such information], is genuine.¹¹² However, the majority denied that Vermont adopted the consumer concerns enumerated by the district court, and "reluctantly" concluded that the simple consumer interest for information or consumer curiosity did not constitute sufficient justification for imposing the mandatory labeling law.¹¹³

These two cases, *Stauber* and *International Dairy Foods*, suggest that there are substantial legal obstacles to states' imposition of mandatory labeling for genetically engineered foods. The courts in both cases reached the same conclusion as the FDA: the FDCA provides no basis for requiring mandatory labeling of these foods. These cases deal with rBST-derived milk and milk products, which, according to the FDA, are not genetically modified.

This Note contends that the same legal impediments to labeling rBST-derived milk should not apply to labeling genetically modified foods; therefore, *Alliance For Bio-Integrity* was wrongfully dismissed by the District Court.

PERSONAL ANALYSIS

Consumers are worried about a variety of problems associated with genetically engineered foods; specifically, consumers have voiced concerns

¹⁰⁷ *Id.*

¹⁰⁸ See *International Dairy Foods*, 898 F. Supp at 250.

¹⁰⁹ *Id.*

¹¹⁰ *International Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67, 73 (2d Cir. 1996).

¹¹¹ *Id.* at 70-71.

¹¹² *Id.* at 73.

¹¹³ *Id.*

about potential health side effects, appropriate testing methods, and adequate labeling.¹¹⁴ Consumers want to be able to choose whether or not to purchase food products that were genetically modified. However, the current federal regulatory framework does not mandate that biotech producers provide consumers with the information they need to make informed decisions about the foods they buy and eat.

Examination of the *Alliance* decision in light of the FDCA

In *Alliance For Bio-Integrity*, one of the plaintiffs claims centered around the FDA's presumption that genetically engineered foods are "generally recognized as safe" (GRAS) because the genetic material added to the food is not an "additive." The district court, however, incorrectly ruled that the nucleic acid (DNA), generally recognized as safe, is not an additive and hence is not regulated under the FDCA. According to the court, the FDA does not view the addition of the genetic material itself as a food additive.¹¹⁵ Because DNA is a normal constituent of any living thing, DNA as a component of food is presumed to be GRAS. Once the DNA is inserted into the recipient plant or animal, it is the product of the DNA expression that the FDA chooses to scrutinize, not the addition itself. According to the court, addition of a foreign gene, without anything more, is insufficient to trigger the labeling.¹¹⁶

The *Alliance* court deferred to the FDA's traditional definition of "additive" which has posed the largest obstacle to testing and labeling of genetically engineered foods. The court conceded, however, that "a protein, carbohydrate, fat or oil, or other substances that differs significantly in structure, function, or composition from substances currently found in food" will be considered not to be GRAS and may require regulation as a food additive.¹¹⁷ In the case of a genetically engineered soybean, the genes that are added can come from any source (i.e. another plant, animal, or microbe). With approximately seventy percent of processed foods containing soy protein¹¹⁸, this soybean becomes a food "additive" when it is used to make cereal, potato chips, bread, baby food, etc. Whole foods, such as this soybean, may indeed be additives when used as components of prepared foods. The FDA, however, has been silent on the GRAS status of whole foods when used as a component of the final product.

If for example a final product, such as cereal, is found in the market to be "poisonous or deleterious," it can be excluded from commerce, but only if the FDA can show that the additive 'may render' the food injurious because it caused an allergic or other forms of reaction in a consumer.¹¹⁹ The problem then becomes the inability of the consumer to identify the source of the reaction/allergy if the cereal did not contain a label identifying the genetically

¹¹⁴ See 58 Fed. Reg. 25,837-38 (1993).

¹¹⁵ See *Alliance*, 116 F. Supp. 2d. at 176-78.

¹¹⁶ See *id.*

¹¹⁷ *Id.* at 176 (citing Statement of Policy, *supra* note 8 at 22,990).

¹¹⁸ Burros, *supra* note 3.

¹¹⁹ See FDCA of 1938 § 403(a)(1)(1994).

engineered soybean as an ingredient. Although reasonable people would believe that an animal gene introduced into soybean would qualify as a 'novel substance,' and therefore and "additive," it is still not required to be labeled by the FDA. Disturbingly, it is the food manufacturers that are permitted by the FDA to make their own determination that the added gene protein is GRAS without any automatic review of safety data.¹²⁰

The *Alliance* court neglected to consider that the FDA is responsible for assuring the safety of genetically engineered foods, not the food manufacturers. The FDA's deference to these biotech companies creates loopholes through which genetically engineered foods can slip into the marketplace untested. The court could have issued an alternative ruling that include as "additives" under the FDCA, whole foods that are genetically engineered. It follows that genetically engineered components that are used to make whole foods should be regulated as "additives" under the FDCA. If the FDA found that genetically engineered foods contain "additives," the court in *Alliance* would have no choice but to require mandatory labeling of those foods. In refusing to acknowledge that genetically engineered foods contain additives, the FDA has continued to make no distinction between genetically engineered foods and the drug rBST, whose products contains no "additives."

The *Alliance* court erroneously relied on *Stauber and International Dairy Foods* and therefore applied the same legal impediments to genetically modified foods as it did to the rBST-generated milk. These cases involve the administration to cows of a milk-producing hormone developed through recombinant DNA technology. The milk, the end product, was not itself genetically engineered. The milk and the cow are not genetically altered. However, in cases involving genetically engineered foods, it is certainly debatable whether a tomato cross-bred with a fish gene or a potato injected with a soil bacterium responsible for producing an organic insecticide, have no material change in their characteristics. More than the milk cases, genetically engineered foods raise legitimate health, ethical, and environmental concerns that the courts should begin to give greater weight. The FDA may have made the right decision when it chose not to require mandatory labeling of milk. However, the FDA is simply wrong when it concludes that labeling is not necessary for genetically engineered foods in general.

The FDA can require labeling of genetically engineered foods under the "misbranded" provision of the FDCA

A food is considered misbranded if a label is false or misleading or fails to provide the common or usual name of a food or its ingredients.¹²¹ Section 201(n) of the FDCA provides additional guidance on how a food label may be misleading. It states that labeling is misleading if it fails to reveal facts that are

¹²⁰ See Robert A. Bohrer, *Food Products Affected by Biotechnology*, 55 U. PITT. L. REV. 653, 662 (1994). See also *Alliance*, 116 F. Supp 2d. at 170.

¹²¹ See 21 U.S.C § 343(a)(1994).

“material” in light of representations made or suggested in the labeling.¹²² This is referred to as the “materiality test.” The FDA contends that genetically engineered food labels, in the absence of this information, are not misleading because they do not exclude material information.¹²³

Historically, the FDA has interpreted the scope of the materiality concept to mean information about attributes of the food itself. The 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; 2) mislead the consumer in light of other statements made on the label; 3) in cases where a consumer may assume that a food, because of its similarity to another food, has nutritional, or functional characteristics of the food it resembles when in fact it does not.¹²⁴

Based on the above factors, the FDA formulated a “materiality test.” The FDA explained that whether information is material depends on whether consumers think the information is important, and whether the omission of that information from the label may mislead a consumer.¹²⁵ The FDA used this materiality test when it required mandatory special labeling of irradiated food.¹²⁶ Although the FDA has traditionally required labeling in response to scientific health and safety data, not in response to consumer fears or ethical beliefs, it has however promulgated food-labeling regulations in an effort to better inform consumers. In the case of irradiated food products, the FDA required labeling of foods processed using irradiation techniques even though it has declared such techniques safe.¹²⁷ The FDA required labeling because irradiation is a material fact that the consumers viewed as important and should be included on the food label.¹²⁸ The FDA mandated that retail packages of irradiated food contain a special logo and the statement “treated with radiation” or “treated by irradiation.”¹²⁹ The FDA acknowledged that in the case of irradiated foods, the materiality of the information “depends not on the abstract worth of the information” but on whether consumers view such information as important and whether the omission of the information will be misleading.¹³⁰ The FDA required labeling of irradiated food in part because of reduced nutrition value, flavor, or texture of the food.¹³¹ The FDA noted that because irradiation was a new technology, “manufacturers may want to use additional labeling statements as part of a consumer education effort.”¹³² The FDA therefore was carefully acting in the consumer interest

¹²² 21 U.S.C. § 321(n)(1994).

¹²³ See Guidance for Industry, *supra* note 56.

¹²⁴ See 21 U.S.C. § 201(n)(1994).

¹²⁵ See 51 Fed. Reg. at 13,376, 13,388.

¹²⁶ See Final Rule, Irradiation in the Production, Processing, and Handling of Food, 51 Fed. Reg. 13,376 (1986); 21 C.F.R. § 179.26 (c) (1994).

¹²⁷ 21 C.F.R. § 179.26 (c) (1994).

¹²⁸ 51 Fed. Reg. at 13,388.

¹²⁹ 21 C.F.R. § 179.26(c)(1994).

¹³⁰ 51 Fed. Reg. at 13,388.

¹³¹ *Id.*

¹³² *Id.*

when it required labeling of irradiated food.

In the case of genetically engineered foods, the FDA should use the same "materiality test" to determine whether consumers think the information is important, and whether the omission of that information is misleading. There is sufficient evidence to suggest that consumers think information about genetic engineering is important.¹³³ It follows that if the FDA used the same materiality standard and policy considerations for genetically engineered foods that it used in the irradiated food context, it would likely conclude that genetic engineering information is material.

However, in a recent press release,¹³⁴ the FDA reaffirmed its decision not to require special labeling of genetically engineered food or ingredients. The FDA stated that it does not have data regarding adverse health effects to consumers from eating genetically engineered foods.¹³⁵ According to the FDA, there is no information to form a basis for concluding that the fact that a food or its ingredients was produced using bioengineering is a material fact that must be disclosed.¹³⁶ The FDA justifies this position by claiming that genetic engineering is merely an extension of traditional plant breeding techniques. Contrary to this position, however, the ability to overcome genetic barriers and produce novel foods, genetic engineering presents a significant leap over traditional breeding techniques.

Genetic engineering allows breeders to produce a plant that expresses a desirable trait in virtually no time, compared to other breeding techniques.¹³⁷ Genetic engineering allows the immediate transfer of a desirable gene into the target plant, and the immediate expression of the new gene by that plant.¹³⁸ Genetic engineering also permits substantive modifications that are impossible to make using traditional methods of plant breeding.¹³⁹ Traditional breeding limits the number of potential trait variations, because it involves a limited gene pool, given that plants can breed only with other plants.¹⁴⁰ Genetic engineering breaks through this natural barrier, because genes can be taken from plants, or animals, or microbes and introduced into food crops.¹⁴¹ For example, if the goal is to develop a pepper that is able to withstand the cold, genetic engineering allows the gene responsible for temperature adaptation in fish to be inserted into pepper.¹⁴² This never could happen with traditional methods, as peppers cannot breed with fish. With genetic engineering the possibilities are endless because it allows a look at thousands of organisms for

¹³³ See Petition to Government, *supra* note 9. As of January 2001, over 300,000 consumers have signed the petition.

¹³⁴ *Draft Guidance for Industry*, *supra* note 56.

¹³⁵ *See id.*

¹³⁶ *See id.*

¹³⁷ Winn, *supra* note 2 at 671.

¹³⁸ *Id.*

¹³⁹ *Id.*

¹⁴⁰ *Id.*

¹⁴¹ *Id.* (citing Statement of Policy, *supra*, note 8 at 22,886).

¹⁴² Winn, *supra*, note 2 at 671.

traits desirable for food crops.¹⁴³

Through genetic engineering a new and different gene can be introduced into plants. When the genes are mixed during traditional breeding, the “new” gene stays in its ancestral home, the spot evolved for only that gene.¹⁴⁴ With genetic engineering, however, the truly new gene, after insertion, can land almost anywhere, without predictability.¹⁴⁵ There is no natural place for this gene, there is some uncertainty in its expression through its new host organism, and there is some uncertainty in its interaction with other genes.¹⁴⁶ Therefore, crops produced through traditional breeding and crops produced through genetic engineering are not identical, despite the fact that they may look the same in the grocery store.¹⁴⁷ Consequently, there is current research that points out potential risks inherent to these genetically engineered foods.¹⁴⁸

The potential health effects of consuming genetically engineered foods, the inability to effectively test for allergenic and toxicological potential of such foods, the potential for a decrease in nutritional value, the inability of consumers to identify such foods in the supermarket so that they may avoid certain ingredients, and the inability to trace problems back to their source in the absence of biotech food labeling give the FDA adequate reasons to find the use of genetic engineering techniques to be a material fact under the FDCA. Thus, the FDA has statutory authority to mandate labeling of genetically engineered foods. It follows that under these circumstances, consumers must be notified through proper labeling if a genetically engineered food differs from its traditional counterpart such that the common or usual name no longer applies to the new food, or if a safety or usage issue exists to which consumers must be alerted.

Individual states have the power to impose their own labeling standards

Given the present trend of the law, any state-compelled genetically engineered labeling scheme must overcome challenges of violating the FDCA. However, as seen in the *Alliance* decision, the FDCA offers little guidance for evaluating genetically modified foods issues. As evidenced in *Alliance*, *International Dairy Foods* and *Stauber*, the court will ultimately defer to the FDA absent any statutory command.¹⁴⁹ However, until the FDA guidance with respect to genetically modified food products is developed, courts will continue to neglect consumer demand for information.

Vermont's labeling law was designed to compensate for the lack of federal guidance in this area. Since states have a substantial interest in regulating health and safety initiatives within their borders, states should have the power

¹⁴³ *Id.*

¹⁴⁴ *Id.*

¹⁴⁵ *Id.*

¹⁴⁶ *Id.*

¹⁴⁷ *Id.*

¹⁴⁸ See Thomas R. Mikkelsen et al., *The Risk of Crop Transgene Spread*, 380 *Nature* 31 (1996).

¹⁴⁹ See *Stauber*, 895 F. Supp. at 1193. See also *Amestoy*, 92 F.3d at 67.

to impose their own labeling standards. Critics, while conceding that this may be a viable alternative, predict that state regulation offers problems to interstate commerce. Vermont's labeling law, however, did not violate the Commerce Clause because it was narrowly tailored to provide information in a way that did not disproportionately impact out-of-staters. To avoid interstate commerce issues and consumer confusion, the FDA could revisit the FDCA and "Guidance for Industry" proposal and decide that a mandatory (as opposed to voluntary) federal labeling standard is needed.

CONCLUSION

Since existing FDA regulations prove inadequate to protect human health, labeling regulations which mandate that consumers be informed when foods have been genetically engineered, would at least provide consumers with a choice whether or not to be exposed to such products in the first place. Given the conflicting evidence as to the risk presented by these novel foods, a labeling requirement for genetically engineered foods is certainly scientifically justifiable. The potential health risks of genetically engineered foods and widespread consumer concerns provide the FDA with the necessary statutory authority to mandate labeling under the FDCA.

The FDA, with the support of biotech food producers, decided that there is no data supporting the view that genetically engineered foods are unsafe, therefore, consumer concerns about these foods are not a sufficient reason to label them. This argument promulgated by the FDA, and supported by the *Alliance* court, is problematic.

First, the FDA does not know if all genetically engineered products are indeed safe. For example, no evidence exists that proteins added by recombinant DNA techniques will be more allergenic than normal proteins but there is also no evidence that such proteins will be less allergenic. Second, to determine whether such information is material as required under the FDCA, the FDA should have used the same 'materiality test' used to require mandatory labeling of irradiated foods. Under this test, the FDA would probably find that consumers think genetic engineering information is important and the omission of such information from a label is misleading.

Given the present confusion by the FDA and courts when applying or refusing to apply certain provisions of the FDCA to genetically engineered foods, it seems clear that a state could certainly draft a statute mandating labeling of genetically engineered foods. Drafting a labeling statute that is not misleading, which addresses the state's substantial interest concerning the health welfare of its citizens and which does so with the minimum restriction on commercial speech, is within the ability of every state legislature. It is likely that such state-mandated labeling of genetically engineered foods will be challenged in the courts. A single federal standard would serve to both preempt state efforts at labeling, and to settle the issue in a timely manner with minimum amount of litigation.