Reevaluating the Food and Drug Administration’s Stand on Labeling Genetically Engineered Foods*

I. INTRODUCTION

American consumers are currently at the leading edge of what promises to be a wave of foods modified through the use of modern recombinant DNA technologies. In the years since the introduction of the “Flavr Savr” tomato, biotechnology companies continue to introduce genetically engineered agricultural products to consumers at the supermarket. There are currently eleven such agricultural products on grocer’s shelves, with an additional twenty-nine currently awaiting approval or under development. For example, an estimated thirteen to sixteen percent of the American soybean crop is currently produced from

* J.D. Candidate 2000, University of San Diego School of Law.

1. My thanks to A. Rai for her advice in preparing this Comment, and to M. De Armey for his editorial suggestions. This Comment is dedicated to Ann Whittaker and to the memory of Richard Whittaker, my parents.

2. “Recombinant DNA technologies” refers to the techniques used by scientists to transfer discrete pieces of genetic material into a recipient plant, animal or microorganism. See STRATEGIES FOR ENGINEERING ORGANISMS (A.T.H. Burns ed., Butterworth-Heinemann, Ltd. 1993).

3. Calgene’s Flavr Savr tomato was the first widely available food produced using recombinant DNA techniques. Introduced in November of 1993, first year sales were $14 million out of a total market for tomatoes of $4 billion. See Greg Beaubien, Genetic Growth Lab Work is Debated, CHATTANOOGA TIMES, Sept. 19, 1996, at F1.

4. See Marian Burros, Eating Well, N.Y. TIMES, May 21, 1997, at B8. 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. See id.
genetically engineered seeds. This figure is expected to rise to forty percent by 1998. With approximately seventy percent of processed foods containing soy protein, the exposure of American consumers to genetically engineered foods is pervasive. Given the pace of development, this exposure will probably continue to increase. Consumers, however, lack the ability to control the extent of their exposure, because current U.S. Food and Drug Administration (FDA) 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. Not surprisingly, consumer advocates disagree with the FDA's decision and question the safety of growing and consuming these novel foods. As a result, various groups are pressing for some form of labeling of genetically engineered foods.

This Comment argues that the FDA must reconsider its position on the labeling of genetically engineered foods. There is no doubt that genetic engineering of food promises a number of significant benefits to both the consumer and the farmer, and has become a permanent part of the food supply. But recent research points out that these benefits do not come without significant risks, both to the consumer and to the environment. A federal requirement that genetically engineered foods be labeled as such is a necessary step to promote confidence in the American consumer in the face of unease over these very real risks. Moreover, in the absence of a federal labeling standard, individual states have the power to impose their own labeling standards. A federal labeling standard is thus necessary to occupy the field and prevent any disruption in the national food marketplace due to a proliferation of differing state labeling standards. Finally, international initiatives for labeling genetically engineered foods are proceeding much more rapidly than are United States national labeling initiatives. A federal labeling standard is required to provide leadership to a global food marketplace that is demanding labeling and remains extremely skeptical of genetically engineered food.

This Comment will first describe the types of recombinant DNA techniques being used to modify foods, and the differences between

5. See id.
7. See Burros, supra note 4.
recombinant DNA and traditional breeding techniques. Included is a discussion of the advantages driving the rapid pace of development of genetically engineered foods, as well as the dangers to both the environment and public health posed by these foods. Second, this Comment will address the public perception of the threat presented by genetically engineered foods. This includes a discussion concerning the ability to improve consumer awareness and acceptance of such foods through product labeling, together with other appropriate educational initiatives. Third, this Comment will highlight the authority granted to the FDA regarding labeling of genetically engineered foods, and the inadequacy of the current FDA position on labeling in light of the legitimate health concerns being voiced by scientists and consumer advocacy groups. Fourth, this Comment will address the ability of individual states to require labeling of genetically engineered foods in the face of federal inaction. This requires a discussion of the potential for numerous state standards to disrupt commerce, whether states may require labeling without running afoul of the Supremacy Clause of the U.S. Constitution or First Amendment protections of commercial speech, and what interests states may take into account when determining what is a “substantial interest”. Fifth, this Comment will address the international movement towards labeling of all genetically engineered foods, the efforts by various governments to satisfy these demands, and the potential for a proliferation of standards to disrupt the international trade in food. In this context, this Comment stresses the need for the United States to provide leadership in setting a global labeling standard under the auspices of the Codex Alimentarius Commission.11 Finally, potential federal regulations will be proposed under the authority of the Federal Food, Drug and Cosmetic Act (FDCA)12 by addressing a series of questions posed by the FDA itself. These questions include 1) how should genetic engineering be defined; 2) what characteristics of foods derived from genetic engineering distinguish such foods; 3) is labeling appropriate for both fresh produce and processed foods; 4) is there a basis in science to differentiate between genetic engineering techniques and traditional breeding techniques; and 5) is it feasible to provide such

II. GENETIC ENGINEERING OF FOOD—POTENTIAL BENEFITS AND RISKS

Prior to 1900, agricultural breeding techniques had remained largely unchanged for approximately ten thousand years. At that time, the rediscovery of work by Gregor Mendel on the heritability of genetic traits began to provide geneticists with the necessary tools to selectively breed plants and animals. So while early agriculture was content with domestication of wheat, for example, the advent of modern genetics made it possible to direct the evolution of wheat, with the goal of producing a desirable new "hybrid" variety. The net results of nearly one hundred years of what are now considered traditional breeding practices are plants and animals displaying enhanced yields, disease resistance, and nutrition. Consequently, few modern agricultural products can escape being labeled "genetically modified." Hybrids created by traditional techniques are, however, typically limited to closely related species. Transferring genetic information between cow and pig, fish and tomato, or soybean and Brazil nut, is impossible using traditional breeding techniques.

This limitation has been largely overcome in the last few years through the application of recombinant DNA technologies. These technologies, commonly referred to as "genetic engineering," allow the introduction of specific DNA sequences from any source into an agricultural product. While traditional breeding techniques allow the directed evolution of a plant or animal, the exchange of genetic material between parent strains that result in a new hybrid is relatively crude and largely uncontrollable. By comparison, genetic engineering techniques allow the insertion of a desired trait into a plant or animal with pinpoint

14. See Gregor Mendel, Versuche über Pflanzen Hybriden (Experiments in Plant Hybridization), 4 VERHANDLJNGEN DES NATURFORSCHEDEN VEREINES IN BRUNN 3 (1866). Mendel originated the study of genetics with this seminal work. The importance of this work went unrecognized until the turn of the century.
16. An example of the limits of traditional techniques would be transferring genetic material between a modern crop plant and a related wild species. See id.
17. Genetic engineering refers to any technique capable of producing a transgenic plant or animal. See generally ANIMALS WITH NOVEL GENES (Norman MacLean ed., Cambridge Univ. Press 1994). See also GENETIC IMPROVEMENTS OF AGRICULTURALLY IMPORTANT CROPS (Robert T. Fraley et al. eds., Cold Spring Harbor Lab. 1988).
accuracy. This trait could range from production of a novel protein introduced from a completely unrelated genus,\textsuperscript{18} to enhanced production of a normal constituent protein,\textsuperscript{19} or to elimination of an undesirable normal constituent protein.\textsuperscript{20} The goal of agricultural genetic engineering remains the same as in traditional breeding—improved agricultural products. But recombinant DNA technologies greatly expand the range of possible improvements. Genes may now be moved without regard to species barriers. Pigs that have better yields because they express cow genes\textsuperscript{21} or soybeans that have improved nutritional value due to the addition of a Brazil nut protein\textsuperscript{22} are now a reality.

The benefits to the farmer and to the consumer of this powerful technology are potentially enormous and should not be underemphasized.\textsuperscript{23} Transgenic plants containing natural insecticides may reduce the need for chemical pest control, benefiting the environment (which is now exposed to a barrage of harmful chemicals used in modern farming), farmers (who must now deal with an array of potentially harmful pesticides), and consumers (who ingest foods contaminated with pesticide residues). Transgenic plants with increased resistance to herbicides may make it possible to use less toxic herbicides and increase crop yields.\textsuperscript{24} Transgenic fruit that delays ripening may

\textsuperscript{18} For example, bacterial toxins may now be introduced into plants, creating a transgenic plant with enhanced insect resistance. \textit{See, e.g.}, Nicolai Štrizhov et al., \textit{A Synthetic cryIC Gene, Encoding a Bacillus thuringiensis δ-Endotoxin, Confers Spodoptera Resistance in Alfalfa and Tobacco}, 93 PROCE. NAT'L. ACAD. SCI. 15,012 (1996).

\textsuperscript{19} A typical example is the overproduction of desirable proteins in food fermenting bacteria used by the dairy industry. \textit{See, e.g.}, G.G.A. Pascalle et al., \textit{Controlled Gene Expression Systems for Lactococcus lactis with the Food-Grade Inducer Nisin}, 62 APPLIED & ENVTL. MICROBIOLOGY 3, 662 (1996).

\textsuperscript{20} Calgene's Flavr Savr tomato is an example of an agricultural product produced by this strategy. The tomato protein responsible for fruit softening during ripening was reduced in quantity through the incorporation of an "antisense" gene into the transgenic tomato. The product of the antisense gene blocks the tomato's "sense" gene product by binding to it. \textit{See} Peter R. Day, \textit{Genetic Modification of Plants: Significant Issues and Hurdles to Success}, 63 AM. J. CLINICAL NUTRITION 651S, 653S (1996).

\textsuperscript{21} \textit{See} New Type Pigs in the Future: Genetic Engineering Could Develop Porkers with Special Milk Traits, ROCKY MTN. NEWS, Apr. 14, 1996, at 32A.

\textsuperscript{22} \textit{See} Julie A. Nordlee et al., \textit{Identification of a Brazil-Nut Allergen in Transgenic Soybeans}, 334 NEW ENG. J. MED. 688 (1996).

\textsuperscript{23} \textit{See} Day, supra note 20. \textit{See also} Hoban, supra note 9.

\textsuperscript{24} \textit{See, e.g.}, George Monbiot, \textit{Watch These Beans}, THE GUARDIAN (London), Sept. 17, 1997, at 17 (outlining the development of "Roundup Ready" crops by the chemical firm Monsanto). Roundup is the trade name for the pesticide glyphosate. Roundup is a non-specific herbicide used to eliminate any plant growth on treated land.
provide improved shipping characteristics and better flavor. Transgenic soybeans and oil seeds with improved nutritional value may improve the diets of both humans and farm animals. Milk from transgenic cows may be made to more closely resemble human milk, resulting in positive effects on infant nutrition. Given such potential, genetic engineering of food will continue to be a fact of life for the consumer.

Along with these potential gains, however, come a number of potential risks to both humans and the environment. While crops may be engineered to contain natural insecticides, insects can adapt, becoming resistant much more quickly than expected. The intense selective pressure on insect populations from large-scale plantings of such crops may destroy the effectiveness of natural insecticides relied upon by organic farmers and those not planting transgenic crops. Farmers are attempting to mitigate this threat through resistance management plans, but the effectiveness of these plans remains uncertain. The planting of crops containing herbicide resistance genes may, ironically, result in increased herbicide use, as farmers would be free to use herbicides to control weeds without fear of harming the crop plants themselves. Further, the crop plants may transfer these resistance genes to wild plants, potentially creating herbicide-resistant...
weeds that are a threat to the environment.\footnote{\textsuperscript{30}}

Of course, these ecological and environmental risks do not impact the FDA and its position on food labeling.\footnote{\textsuperscript{31}} Rather, FDA scrutiny is limited to potential dangers arising from consuming genetically engineered foods. It is in this light that the FDA asks whether genetic engineering "would result in foods which, as a class, exhibit attributes different from foods derived by other methods of plant breeding?"\footnote{\textsuperscript{32}} A more direct concern to the FDA, then, is the possible health risk presented by foods containing unknown or unexpected proteins. Transgenic soybeans may be made more nutritious by the addition of Brazil nut protein, but to an individual allergic to Brazil nuts, consuming a food containing this protein may present a life-threatening situation.\footnote{\textsuperscript{33}} Even trace amounts of such an allergen can trigger a potentially fatal reaction.\footnote{\textsuperscript{34}} Further, antibiotic resistance proteins used for selection of transgenic plants\footnote{\textsuperscript{35}}...
have the potential to render commonly used antibiotics less effective by inhibiting their uptake, or by conferring antibiotic resistance to bacteria in the gastrointestinal tract. The consumer lacks the information necessary to determine their exposure to, and hence risk from, antibiotic resistance proteins in the diet. This limitation applies equally to the physician who is prescribing an antibiotic in order to fight infection. Finally, even though a protein added by genetic engineering might exist at safe levels in a single food, these same proteins might become a danger as more and more foods in the typical diet become genetically engineered and exposure levels become addictive.

III. CONSUMER PERCEPTIONS OF THE THREAT POSED BY GENETICALLY ENGINEERED FOODS

The ultimate success of genetically engineered foods in the marketplace will require acknowledgment of the presence of such foods by the producer and acceptance of that fact by the consumer. That acceptance will not come unless consumers gain confidence that such food is safe to grow and to eat. It has been noted that the American public has a growing skepticism of science generally, and biotechnology, in particular. Polls consistently find strong public opposition to genetic engineering, though education can significantly reduce this opposition. Current public awareness and understanding of

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36. See id. at 673-74.
37. See Distrust in Genetically Altered Foods, supra note 10. The ability of pathogenic bacteria to develop resistance to antibiotics is a major threat to our ability to fight common diseases. The presence of multiple-antibiotic-resistant bacteria in the human food chain has already been demonstrated. See Vincent Perreten et al., Antibiotic Resistance Spread in Food, 389 Nature 801 (1997). In the laboratory setting, bacteria can become transformed by DNA (antibiotic resistance genes from genetically engineered foods for example). Little is known about the ability of bacteria to become transformed within the human gastrointestinal tract, though scientists consider the prospect likely. See Julian Davies, Inactivation of Antibiotics and the Dissemination of Resistance Genes, 264 Science 375, 380 (1994). It is important to recognize that the transfer of antibiotic resistance genes to bacteria need not occur in the human gastrointestinal tract. As animal feed also becomes increasingly genetically engineered, transformation could occur just as easily in the gastrointestinal tract of food animals, such as cattle. See Perreten, supra, at 802. Bacterial contamination of consumed meat would then allow these cattle bacteria to deliver the acquired antibiotic resistance gene to bacteria within the human gastrointestinal tract. See A.P. Johnson et al., Gentamicin Resistance in Clinical Isolates of Escherichia coli Encoded by Genes of Veterinary Origin, 40 J. Med. Microbiology 221 (1994).
40. See Hoban, supra note 9, at 658S-59S.
agricultural biotechnology is dangerously deficient, leaving consumers without the tools necessary to make sound informed decisions about the risks and benefits of genetically engineered food.

It is true that food choice is a complicated matter. It is further true that simply providing information is not sufficient to change consumer behavior. But it has long been the goal of Congress and the FDA for food labeling to be used for "communication of essential information to enable consumers to choose foods more wisely." Indeed, food labels represent a significant source of information for most Americans. Labeling of genetically engineered foods is required to alert consumers to the presence of such foods in their diet. Labeling of genetically engineered foods also represents a necessary first step in the effort to educate consumers on the risks and benefits of such foods. This does not mean that a larger educational effort beyond labeling should not be undertaken. Recent research regarding how to best present food and nutrition information to consumers can provide guidance for this educational effort. If the food industry wishes to profit from genetically engineered foods, it is incumbent upon them to lead this educational effort.

41. See id. at 660S.
44. See, e.g., Food Labels Impact Shopping Choices, REUTERS NEWS SERV., Sept. 5, 1997 (discussing the results of the latest American Dietetics Association poll on the impact of food labels on shopping choice, in which two-thirds of Americans say they make changes in food purchases based upon labels). Recognizing the importance of food labeling in the context of food allergies, a number of commentators have stressed the need for accurate content labeling of foods. See, e.g., Hugh A. Sampson, Managing Peanut Allergy: Demands Aggressive Intervention in Preventional and Treatment, 312 BRIT. MED. J. 1050 (1996) ("Finally, the medical community should put pressure on governmental agencies responsible for product labeling. . . ."); Shank, supra note 34, at E1 ("[Individuals with food allergies] need to be avid label readers."); J.J. Hanley, Allergy Attack; Minimizing the Risk of Food Allergies, 58 FOOD PROCESSING 79 (1997) ("[O]ne of the most important things a company can do to reduce the number of food allergy incidences is to communicate with the consumer through its package label.").
45. See Food Labels Impact Shopping Choices, supra note 44 (discussing strategies for public health professionals to provide food and nutrition education). See also Communicating Emerging Scientific Information, 54 NUTRITION REV. 153 (1996) (reviewing the need for effective information transfer from scientists to the public); Hoban, supra note 9 (applying social science research techniques to education of the public about bioengineered foods); Lester H. Myers, Food Consumption Data Needs for Food and Agricultural Policy, 124 J. NUTRITION 1853S (1994) (outlining data collection strategies for public policy purposes).
effort.

The failure to inform consumers of the presence of genetically engineered foods in their diets through proper labeling, together with the failure of the food industry to educate consumers about the risks and benefits involved, presents a potentially volatile situation. The average consumer is inept at measuring and understanding relative risks. As an example, the risks of air travel are often believed to be far greater than the risks of automobile travel, when, in fact, that is quite to the contrary. To an insufficiently educated public, the sudden, frightening disclosure of even small risks can result in disastrous losses of both money and consumer confidence for food producers. One example of such a disastrous outcome in the context of a perceived threat to food safety was seen in response to a 1989 story on the CBS television news magazine “60 Minutes” concerning residues of the chemical Alar on apples.\textsuperscript{46} Alar\textsuperscript{47} was used by growers to boost crop yields and promote fruit color development. Alar is also classified as a probable human carcinoogen.\textsuperscript{48} Sales of apples plummeted as frightened consumers and food processors stopped purchasing apples, even though only four percent of the nation’s apple crop was being treated with Alar, and Alar residues in fresh market apples were far below Environmental Protection Agency (EPA) standards.\textsuperscript{49} As a result of consumers’ loss of confidence in the safety of apples, “apple growers and others dependent upon apple production lost millions of dollars. Many of the growers lost their homes and livelihoods.”\textsuperscript{50} Alar was subsequently removed from use on food in November 1989.\textsuperscript{51} Given the unease with which consumers view agricultural biotechnology, one can reasonably assume the response to a story concerning the safety of genetically engineered foods would be at least equal to that seen concerning Alar. Only “[o]pen communication and prudent education will help to establish confidence in bio-engineered products.”\textsuperscript{52} For the typical consumer, communication and education begins with labeling.

\begin{thebibliography}{52}
\bibitem{47}Alar is the brand name for daminozide (chemical name butanedioic acid mono (2,2-dimethylhydrazide)), produced by the Uniroyal Chemical Company.
\bibitem{50}Auvil, 67 F.3d at 819.
\bibitem{52}Kurt Danner, \textit{Acceptability of Bio-Engineered Vaccines}, 20 COMP. IMMUNOLOGY, MICROBIOLOGY & INFECTIOUS DISEASES 3, 11 (1997).
\end{thebibliography}
IV. CURRENT FDA REGULATIONS FOR LABELING GENETICALLY ENGINEERED FOODS

Regulatory authority for food labeling is granted to the FDA by the Federal Food, Drug and Cosmetic Act.\textsuperscript{53} Under an FDA regulatory scheme first articulated in 1992,\textsuperscript{54} foods created through the use of recombinant DNA technologies are treated as though they are not fundamentally different from foods created through traditional breeding techniques. Producers are required to describe a food product by a common name, or otherwise use appropriately descriptive terms.\textsuperscript{55} This applies equally to all foods, regardless of whether they originate from either recombinant DNA or traditional breeding techniques. All facts that are material with respect to customary use of the food, including issues of food safety and usage, must be disclosed.\textsuperscript{56}

The FDA’s regulatory approach does not consider the fact that recombinant DNA technologies were used to produce a food to be a material fact \textit{per se},\textsuperscript{57} just as the traditional breeding techniques used are not considered material facts. Nor is the addition of DNA itself viewed as use of a food additive. FDA policy notes that typically, DNA is not infused directly into food. Rather, the source DNA is first copied in a laboratory, then inserted into the recipient agricultural product such that the DNA becomes an integral part of the recipient’s genetic information. This new DNA is then indistinguishable from all other DNA in the recipient.\textsuperscript{58} As DNA is a normal constituent of any living thing, DNA as a component of food is presumed to be “generally regarded as safe” (“GRAS”).\textsuperscript{59}

Of course, the utility of DNA in genetic engineering does not lie in the DNA itself, but instead in the expression of that DNA once it is inserted into the recipient plant or animal. Rather than the addition of DNA then, it is the products of DNA expression that come under FDA scrutiny.

\textsuperscript{53} See 21 U.S.C § 343 (1994).
\textsuperscript{55} See 21 U.S.C. § 343(i).
Labeling is required to alert the consumer only if the genetically engineered food differs from the original food to such an extent that either the common name no longer applies, or a safety issue is apparent. Addition of a foreign gene, without anything more, would not be sufficient to trigger the labeling requirement. Pointedly, the FDA states "a tomato does not become 'fish-like' following the addition of a copy of a fish gene." Insufficient knowledge of the introduced protein's potential to cause allergic reactions in a susceptible population, however, would trigger a labeling requirement, as would introduction of a protein with known allergic potential.

A significant limitation to the FDA's regulatory approach lies in its determination of the allergenicity or toxicity of genetically engineered foods. While it is certainly true that a tomato containing a fish gene does not begin to swim around, it certainly does become in some sense fish-like. This is particularly true for the individual who is allergic to the product of that fish gene. Determining if a population exists that is allergic to a novel food will largely be left to prior experience with the added protein. Thus, a genetically engineered soybean with a Brazil nut protein will be judged safe (or unsafe) based on experience with consumption of Brazil nuts. Food producers are permitted by the FDA to make their own determination that the added protein is GRAS. So, with the exception of the few known food allergens and toxins, food producers are allowed "to determine independently the safety of the resulting food" without any automatic "[a]gency review of a manufacturer's food safety data." The FDA's approach will likely be successful for the majority of people and the majority of foods. No evidence exists that proteins added by recombinant DNA techniques will be more allergenic than normal proteins. Nor is there evidence such proteins will be less allergenic, however. There are currently no methods to determine the allergenic potential of recombinant proteins beyond the very few that are previously known to be allergens.

60. See id. at 22,991.
65. See Bohrer, supra note 35, at 662.
66. Id.
68. See id. at 560-61.
Predicting whether recombinant proteins not known to be allergens are "expressed in such a fashion that they have substantial allergenic activity" is problematic, and the results of exposure to such proteins in a susceptible population can be quite severe. "Avoidance may be the only means of preventing the adverse reaction." It is likely, in the absence of required labeling, educational efforts, or effective testing, adverse reactions to genetically engineered food will occur, resulting in the potential to erode public confidence in the safety of genetically engineered agricultural products.

V. THE POTENTIAL FOR INDIVIDUAL STATE REGULATION OF LABELING GENETICALLY ENGINEERED FOODS

The regulatory vacuum created by the FDA's position on labeling genetically engineered foods should cause enough concern that each of the fifty states might try to fill that vacuum by individually mandating labeling. It is clear, however, that a proliferation of up to fifty differing labeling statutes would cause disruption in the commercial market. A recent settlement between the state of Illinois and several dairy product producers who wished to label their products "rBGH-free" emphasizes that, with a need to maintain consistent packaging and minimize costs, it is not feasible for national companies to label products differently for individual markets. Nonetheless, in an effort to protect consumers, individual states will likely step into the breach created by the FDA's failure to propose a national labeling standard. These efforts may vary from voluntary labeling initiatives aimed at satisfying consumer

69. Id. at 560.
70. See David Kitts et al., Adverse Reactions to Food Constituents: Allergy, Intolerance, and Autoimmunity, 75 CAN. J. PHYSIOLOGY & PHARMACOLOGY 241 (1997).
71. Id. at 251.
72. Bovine growth hormone (BGH), or bovine somatotropin (BST), is a hormone produced normally in the pituitary gland of cattle. Produced through recombinant DNA technology, rBGH can be injected into dairy cattle, with a resulting increase in milk production of as much as 20%. rBST was approved in the U.S. in 1993. Consumer advocates continue to question the effect on humans of residual rBST in dairy products and meat from treated cattle. See Bohrer, supra note 35, at 674-78; see also Beth Berselli, Settlement Reached in Hormone Labeling Case; Ben and Jerry's, States Agree Food Makers Can Indicate Absence of Added Product, WASH. POST, Aug. 15, 1997, at A22.
73. See Berselli, supra note 72.
74. A bill requiring labeling of genetically engineered foods has been proposed in at least one state. See H.B. 790, 118th Leg., 1st Reg. Sess. (Me. 1997).
curiosity to allowing for “free from genetic engineering” labeling,\textsuperscript{75} or to comprehensive initiatives along the lines of California’s Proposition 65.\textsuperscript{76} Clearly, as pointed out by a Maine commission on biotechnology, a national standard for labeling genetically engineered foods established by the FDA would be preferable to action at the state level.\textsuperscript{77}

In asking whether individual states may mandate labeling of genetically engineered foods, one must first address the possibility that the FDCA effectively preempts any state regulation of the food label.\textsuperscript{78} Because there is no specific preemption language in the FDCA itself,\textsuperscript{79} the notion of preemption of state legislation is implied, under the Supremacy Clause of the U.S. Constitution.\textsuperscript{80} Interpretation of the Supremacy Clause by the U.S. Supreme Court indicates that compliance with federal standards does not immunize against compliance with a more stringent state standard.\textsuperscript{81} Rather, preemption will only be implied when the state regulation stands as an obstacle to the objectives of Congress. Specifically, there must be “such actual conflict between the two schemes of regulation that both cannot stand in the same area, [or] evidence of a congressional design to preempt the field.”\textsuperscript{82}

It is against this standard, then, that state legislation regulating food labels has been measured. Courts have found state legislation regarding food labels to not be automatically preempted under the FDCA (or under its predecessor, the Pure Food and Drugs Act).\textsuperscript{83} Instead, such legislation is only preempted when compliance with both the state and

\begin{footnotes}
\item \textsuperscript{75} International Dairy Foods Ass’n v. Amestoy, 92 F.3d 67, 74 (2d Cir. 1996).
\item \textsuperscript{76} See Safe Drinking Water and Toxic Enforcement Act of 1986, CAL. HEALTH & SAFETY CODE §§ 25249.5-13 (West Supp. 1998) (mandating widespread warning labels for any chemical known to the state of California to cause cancer or reproductive harm).
\item \textsuperscript{77} See Labeling; Mandatory Premarket Review Recommended by Maine Commission on Biotechnology, 38 FOOD CHEMICAL NEWS 1 (1996).
\item \textsuperscript{78} For a thorough review of this issue, see Diane M. Allen, Annotation, Federal Pre-Emption of State Food Labeling Legislation or Regulation, 79 A.L.R. FED. 181 (1996).
\item \textsuperscript{79} See id. at 182. The mere fact that federal regulation exists in a given field does not indicate that federal law occupies the field to the exclusion of state regulatory power. See id.
\item \textsuperscript{80} See U.S. CONST. art. VI, cl. 2.
\item This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.
\item Id.
\item \textsuperscript{82} Id.
\item \textsuperscript{83} See 34 Stat. 768 (1906).
\item \textsuperscript{84} See Grocery Mfrs. of America, Inc. v. Gerace, 755 F.2d 993 (1985).
\end{footnotes}
federal statutes is impossible. For example, state regulations dealing with labeling of egg weights, milk fat content in ice cream or requiring more detailed ingredient lists were held not preempted. Conversely, regulations which provided a definition of "imitation," or which prohibited the use of the word "butter," in direct conflict with the FDCA, were held preempted. Accordingly, while any state statute regulating labeling of genetically engineered food must be drafted carefully so as not to actually conflict with the FDCA, such statutes are not preempted under the Supremacy Clause per se. The fact that a state standard is more stringent concerning labeling of genetically engineered foods than the FDA standard is not sufficient to create a direct conflict between state and federal regulations.

In addition to the potential to run afoul of the Supremacy Clause of the U.S. Constitution, a recent U.S. Court of Appeals decision suggests that state labeling mandates may also run afoul of First Amendment protections of commercial speech. A Vermont statute, which required the labeling of dairy products produced from cattle treated with recombinant bovine somatotropin (rBST), was found to be an unacceptable restriction on commercial speech. Noting that the Vermont statute was not aimed at suppressing speech, but rather at compelling the disclosure of methods used by dairy producers in production of dairy products, the court recognized that First Amendment protections include both the right to speak, as well as the right to refrain from speaking. Further, the court found, although purely commercial speech is accorded a lesser protection under the First Amendment than the strict scrutiny standard accorded to other constitutionally protected speech, the Vermont statute failed to meet even the less stringent

85. This statement is not limited to food labeling under FDCA, but also extends to state legislation impacting the Federal Meat Inspection Act, 21 U.S.C. §§ 601-695 (1994), and the Poultry Products Inspection Act, 21 U.S.C. §§ 451-470 (1994). See also Allen, supra note 78, for a detailed discussion.

89. See Gerace, 755 F. 2d at 993.
91. VT. STAT. ANN. tit. 6, § 2754 (1996).
92. See supra note 72, for an explanation of rBST.
94. See id. at 71.
constitutional protections for commercial speech.  

While it is certainly true that state governments may restrict, or compel, commercial speech in the public interest, the Supreme Court has set out a four-part test to determine whether such regulations pass constitutional muster.  

In the case of a food labeling law compelling speech, the test is: (1) whether the compelled speech concerns lawful activity and is not misleading; (2) whether the government interest is substantial; (3) whether the labeling law serves that interest; and (4) whether the law is no more extensive than necessary.  

In the case of the Vermont labeling statute, the court held that Vermont failed to identify a substantial interest. Vermont attempted to justify its labeling statute based solely on "the existence of consumer concern," an interest the court "reluctantly" found inadequate.  

It is worth noting the dissent believed Vermont had demonstrated a substantial interest based upon concerns for bovine health, for effects on dairy industry well-being, and for safety of recombinant gene technology, in general, and rBST, in particular.  

The majority did not disagree that these concerns present a substantial interest. Rather, the majority found Vermont did not base its labeling statute upon these concerns.  

It seems clear from the appeals court's discussion in *International Dairy Foods Ass'n. v. Amestoy* that a state could certainly draft a statute mandating labeling of genetically engineered foods that successfully passes constitutional muster with regard to First Amendment issues. Note that the required substantial government interest is not limited to issues of food safety alone. Just as Vermont may consider the effect on bovine health, philosophic objections to biotechnology and the economic effect on the dairy industry when drafting a labeling law regarding use of rBST, states are free to consider philosophic opposition to the use of genetic engineering in food crops and animals, possible environmental threats posed by genetic engineering and food safety when determining if a substantial interest to require labeling exists. Crafting a labeling statute which is not

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95. See id. at 72.
97. See id.
100. See id. at 75.
101. See id. at 73 n.1.
102. 92 F.3d 67 (2d Cir. 1996).
103. See id. at 78.
104. See supra part II.
misleading, which addresses this substantial interest and which does so with the minimum restriction on commercial speech, is certainly 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. Further, these court challenges will occur on a state-by-state basis. A single federal standard would serve to both preempt state efforts at labeling, and to settle the issue in a timely fashion with a minimum amount of litigation.

VI. LABELING GENETICALLY ENGINEERED FOODS FOR THE WORLD MARKET

While U.S. consumers can be characterized as wary of accepting genetically engineered food, consumers outside the United States can best be characterized as deeply distrustful of any use of recombinant DNA technology to modify foods. In Britain, retailers are facing demands from consumers to trace the origins of food products in the wake of the BSE crisis. As a result, members of the British Retail Consortium recently began a boycott of American soy-based products because of the failure to label lots containing genetically engineered soybeans. Chefs in Britain have demanded labeling laws that would enable them to keep genetically engineered foods off their menus. In France, the government has threatened to ban imports of genetically engineered corn from the United States due to a disagreement with the European Parliament over labeling rules. In Switzerland, opponents of genetic engineering have introduced an initiative to Parliament to forbid many types of genetic engineering and restrict most others. Much of this distrust has been described as stemming from the high environmental

105. Bovine Spongiform Encephalopathy, or “mad cow” disease, caused a panic amongst the beef eating public in Britain in 1996, and resulted in the collapse of the British beef industry. The consumption of infected beef appears to be the cause of a number of cases of fatal human disease (known as Creutzfeld-Jakob disease). The panic stems from three sources. These are the 1) unusual nature of the infectious particle, known as a “prion”, 2) the nature of the disease, a degenerative and ultimately fatal damage to the brain, and 3) a loss of confidence in government ability to protect consumers. See Ehsan Masood, ‘Mad Cow’ Scare Threatens Political Link Between Food and Agriculture, 380 Nature 273 (1996).


price paid for agricultural overuse of chemical fertilizers and insecticides, and from aggressive agribusiness tactics.\(^\text{109}\)

In the face of this deep distrust, a commission of the European Union (E.U.) recently enacted labeling requirements offering consumers "comprehensive information on the use of biotechnology in food products."\(^\text{110}\) This labeling requirement is comprehensive and follows genetically engineered foods "from farm to table."\(^\text{111}\) Foods that have been genetically modified will be labeled as such, including the percentage that has been modified.\(^\text{112}\) This labeling standard, farsighted in its protection of consumers (particularly in comparison to the FDA’s position), represents a reasonable compromise over much more stringent proposals to completely segregate genetically engineered foods from those without any genetically engineered content.\(^\text{113}\)

The distrust of genetically engineered foods is by no means restricted to Europe. Recent draft standards in Australia and New Zealand require labeling of any fresh fruits, vegetables or meat that have been genetically engineered. Further, any processed food containing more than five percent of a genetically engineered plant or animal would require labeling.\(^\text{114}\) This labeling standard, based on proposed E.U. regulations, would be a far stronger protection of consumer interests than is provided by current FDA regulations. Still, this draft guideline has been roundly criticized by both agribusiness and Australian consumer groups as being an "unacceptable compromise."\(^\text{115}\) Whatever the final outcome of this battle for labeling standards, it is apparent that the FDA is lagging behind the international trend toward labeling genetically engineered foods.

Just as a proliferation of individual state labeling standards for genetically engineered foods would create problems for producers attempting to ship foods on a national level, so too would a proliferation of differing national standards create problems for U.S. food exporters in the global food market. These problems reach beyond relatively simple economic arguments such as increased packaging costs stemming from

109. See Distrust in Genetically Altered Foods, supra note 10, at 559.
113. See id.
115. Id.
different labeling mandates. Rather, the existence of differing national standards presents the possibility of using such standards as trade barriers designed to protect a local food industry, so-called technical barriers to trade. It is difficult to doubt that a proliferation of standards presents a potential risk to the $50 billion United States agricultural export market. An example of the risk posed by differing national standards can be seen in the current controversy over exports from the United States to the E.U. of meat and dairy products from cattle treated with rBST. By blocking any decision on an international standard for rBST residues in meat and dairy products for the next two years, the E.U. has effectively blocked the export of these products from the United States to E.U. countries. Unrelated to genetic engineering, but still emphasizing the ability of differing national standards to disrupt trade in food, the E.U. has also banned imports of beef products from the United States based on consumer fears of BSE contamination of United States herds. The position of the United States is that any such ban has "no scientific basis" and will disrupt "billions of dollars in trade."

Recognizing that harmonization of international food regulations is a desirable goal, the United States, together with 150 other countries, is a member of the Codex Alimentarius Commission, created under the auspices of the United Nations with the purpose of developing and promoting an international set of food standards, including labeling standards. It should be noted that while member countries are not obligated to adopt Codex standards, under the Uruguay Round of the

116. See Berselli, supra note 72, at A22.
117. For a detailed discussion of this issue, see John S. Eldred & Shirley A. Coffield, What Every Food Manufacturer Needs to Know: Realizing the Impact of Globalization on National Food Regulation, 52 FOOD DRUG COSM. L.J. 31 (1997). U.S. Agriculture Secretary Dan Glickman has expressed concern that European labeling requirements may be the equivalent of a non-tariff trade barrier. See U.S. Opposes EC Labeling Proposal – Glickman, REUTERS NEWS SERV., Dec. 4, 1997.
119. See supra note 71.
120. See Codex Delays for Two Years Standards on rBST-Produced Milk and Beef Products, 39 FOOD CHEMICAL NEWS 27 (1997).
122. Id.
123. See Eldred & Coffield, supra note 117, at 31-32.
124. See Degnan, supra note 43, at 57.
125. See Eldred & Coffield, supra note 117, at 33.
General Agreements on Tariffs and Trade (commonly referred to as GATT), Codex standards may be relied upon when challenging foreign standards before the World Trade Organization. For its part, the United States has the stated goals of enhancing Codex credibility with regulatory authorities and consumers, and routinely evaluating Codex standards to serve as the basis for U.S. standards. In the United States, the agencies with responsibility for Codex initiatives on food labeling are the FDA and the Food Safety and Inspection Service, an arm of the Department of Agriculture.

The Codex standards for labeling of foods obtained through biotechnology are currently in an early stage of development. The FDA, in position papers concerning Codex labeling standards, argues that the consumer’s right to know should not influence international standards. Rather, all standards should be based upon sound scientific and technical information. Certainly this is a laudable goal, but one must realize “scientific certainty” is a rare commodity, and this includes questions of the safety of genetically engineered foods. Rather than certainty, science provides hypotheses based upon a limited set of data. Acknowledging the uncertainty inherent in science’s understanding of the safety of genetically engineered foods “does not diminish the scientific nature of the inquiry.” It does, however, provide a rational basis for governments to err on the side of precaution when developing standards intended to protect public health. In particular, a case can certainly be made for labeling of genetically engineered foods based upon the safety and ecological issues discussed herein. Moreover, given the levels of distrust in biotechnology present in many countries, some form of labeling of genetically engineered foods is inevitable. An

127. See Eldred & Coffield, supra note 117, at 34.
130. See id. at 28,432 (noting that draft recommendations for labeling such foods are currently at step three of an eight-step adoption process). See also id. at 28,439-40 (describing the adoption process).
134. See id. at 838.
135. See supra Part II.
international labeling standard, instituted under the Codex, would be preferable to standards instituted on a nation-by-nation basis. Such an international labeling standard would go a great distance towards avoiding the potential trade barriers presented by a proliferation of differing national standards.

The FDA recognizes three paths to development of an international standard. These are

(1) The U.S. voluntary standards community or an agency, such as FDA, develops a U.S. standard and takes it to an international forum so it can be made an international standard; (2) a standard already developed in an international forum (or by another country or a regional standards body) is adopted as a U.S. voluntary or regulatory standard; or (3) a new international standard is developed “from scratch” in an international forum.

As previously noted, standards for labeling of genetically engineered foods are already being instituted in a number of countries, together with an E.U.-wide standard. For this reason, the time for developing a standard de novo has likely passed. Further, given the level of distrust of biotechnology outside the United States, the current FDA position regarding labeling (that no per se labeling of genetically engineered food is necessary) will likely not serve as the basis for an international standard. By stepping forward with a proposal that provides for labeling of genetically engineered foods, the FDA can take a position of leadership in development of an international labeling standard. By arguing against labeling, the FDA will permit others, particularly the E.U., to take the lead in development of an international labeling standard. Any delay in the adoption of international standards can only harm a major food exporting country like the United States.

VII. TOWARDS A REASONABLE STANDARD FOR LABELING OF GENETICALLY ENGINEERED FOODS

As discussed above, the FDA is granted authority to regulate the

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137. See EU Gene Label Decision Seen in Need of Follow-Up, supra note 108; see also Australia-New Zealand Transgenic Draft Labeling Standard Sets Labeling Threshold for Processed Food, supra note 114.
138. See supra Part IV.
139. See Codex Delays for Two Years Standards on rBST-Produced Milk and Beef Products, supra note 120; U.S. Decries EU Plan to Ban Imports of its Tallow, supra note 121.
140. See supra Part IV.
food label under the FDCA.\textsuperscript{141} The FDCA provides a number of potential avenues for a labeling requirement to be imposed upon genetically engineered foods through its regulation of misbranded food\textsuperscript{142} and information deemed material to the food label.\textsuperscript{143} A food is deemed misbranded if the label does not bear "the common or usual name of the food" or, if fabricated from two or more ingredients, "the common or usual name of each."\textsuperscript{144} Further, an article is deemed misbranded if the label "fails to reveal facts material... with respect to consequences which may result from the use of the articles to which the labeling or advertising relates... under such conditions of use as are customary or usual."\textsuperscript{145} FDA guidelines indicate that, under these standards, consumers must be notified through appropriate 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."\textsuperscript{146} Currently the FDA applies these standards narrowly, with the goal of not over-labeling products and thereby reducing the overall effectiveness of such labels.\textsuperscript{147}

The goal of not over-labeling products is certainly an important one. Information contained on the food label must be limited in volume and complexity so as not to overwhelm the consumer and diminish the impact of information critical to an informed choice. In its 1992 policy statement, the FDA said it "was not aware of any information to suggest that the application of recombinant DNA techniques... to the development of new plant varieties would result in foods which, as a class, exhibit attributes different from foods derived from other methods of plant breeding."\textsuperscript{148} If such a statement were true, the FDA goal of limiting the information present in food labels would indeed call for no labeling of genetically engineered foods. But, due to the ability to overcome genetic barriers and produce novel foods, recombinant DNA techniques present a quantum leap over traditional plant breeding techniques. Current research\textsuperscript{149} points out the potential risks inherent to these novel foods. The potential health effects of consuming genetically

\textsuperscript{142} See id. § 343(i).
\textsuperscript{143} See id. § 321(n).
\textsuperscript{144} Id. § 343(i).
\textsuperscript{145} Id. § 321(n).
\textsuperscript{147} See Degnan, supra note 43, at 52.
\textsuperscript{149} See supra Part II.
engineered foods, the inability to effectively test for allergenic and toxicological potential of such foods, and the inability of consumers to identify such foods in the marketplace so that they might avoid certain ingredients, give the FDA sufficient reasons to find the use of genetic engineering techniques to be a material fact under the FDCA,\(^\text{150}\) and thus give the FDA statutory authority to mandate labeling of genetically engineered foods.

In a request for information from all parties interested in the FDA’s stand on labeling genetically engineered foods, the FDA posed a number of questions which indicate the direction such a labeling standard might take.\(^\text{151}\) It is appropriate to answer several of these questions here. First, “[h]ow should ‘genetic engineering’ be defined?”\(^\text{152}\) Genetic engineering should be defined broadly as this will likely be the initial step in determining whether a food should be labeled. So, in addition to recombinant DNA techniques, genetic engineering should include any technique that allows the production of a transgenic plant or animal.\(^\text{153}\) Under this broad definition, genetic engineering would include cell or protoplast fusion techniques,\(^\text{154}\) for example.

Next, the FDA asked what is perhaps the key question for any labeling standard—that is, “[w]hat specific characteristics of foods derived from ‘genetically engineered’ plants distinguish such foods from other foods, and thus, such foods might warrant special labeling? Are there foods derived from genetically engineered plants without such characteristics and, thus, would not warrant labeling disclosing the method of production on the food?”\(^\text{155}\) The FDA describes six possible modifications that might distinguish genetically engineered foods, such that labeling might be appropriate. These are: (1) foods modified to contain proteins not previously found in food, even if present in minute


\(^{152}\) Id. at 25,839.

\(^{153}\) See Animals With Novel Genes, supra note 17; Genetic Improvements of Agriculturally Important Crops, supra note 17.

\(^{154}\) In cell fusion techniques, two cells are induced to merge, forming a new cell containing the genetic material of both donor cells. Protoplast fusion involves removing the cell wall of a plant cell, forming what is known as a “protoplast”, prior to cell fusion. See James F. Shepard et al., Genetic Transfer in Plants Through Interspecific Protoplast Fusion, 219 Science 683 (1983).

quantities; (2) foods modified to contain proteins new to a particular food, but present in other foods; (3) foods modified to contain a higher (or lower) concentration of a protein native to that food; (4) foods modified to contain new, but unexpressed, DNA; (5) foods modified to exhibit improved nutrition or handling characteristics; and (6) food ingredients (e.g. vegetable oil or food starch) that are unchanged because, although the plant or animal was modified, no new substances are introduced into the ingredient itself.\textsuperscript{156}

With regard to the current narrow FDA position on labeling, it has been noted that “the FDA will be looking at the nucleic acid sequences effects on the composition of the food product rather than the DNA itself.”\textsuperscript{157} This statement must apply to any broader labeling standard as well, for it is not the addition of DNA by genetic engineering itself which should trigger a label. Instead, it is the resulting expression of the new DNA that must be the focus of a labeling requirement. Thus, any genetic engineering that unexpectedly changes the composition of a food in a manner that might present a health risk to a susceptible population should be labeled. By this measure, the first FDA modification, perhaps pointed at antibiotic resistance genes used as markers,\textsuperscript{158} would require labeling, because the presence of the resistance protein would be wholly unexpected by the consumer. As discussed, even in trace amounts such a protein may present substantial risks that bear on a consumer’s informed choice.\textsuperscript{159} Also the second FDA modification perhaps dealing with Brazil nut proteins inserted into soybeans,\textsuperscript{160} would require labeling under the same reasoning. Such labeling should include the identity of the novel protein. The third FDA modification, which increases the concentration of an existing constituent of the food, would trigger a labeling requirement because this could increase the concentration of an allergen or toxicant to a level that becomes significant to a susceptible population.

Conversely, genetic modifications that do not affect consumers’ expectation for composition of the food would not trigger a labeling requirement. Thus, the third FDA modification, which merely decreases the concentration of a previously existing constituent of the food, would not require labeling since the reduced presence of the constituent would not be expected to cause any reaction to a susceptible population.\textsuperscript{161}

\begin{footnotes}
\item[156.] See id.
\item[157.] Bohrer, supra note 35, at 660.
\item[158.] See id. at 673-74.
\item[159.] See supra Part II.
\item[160.] See Nordlee, supra note 22.
\item[161.] Note that the FDA still must require labeling if the altered level of a previously existing constituent resulted in significant change to the nutrient value or safety of the
\end{footnotes}
Also, the fourth FDA modification would merely introduce DNA, a normal constituent of all plants and animals, to a food, and therefore not change the expected composition of that food. Finally, modifications number five and six, because they do not result in new substances in the final food or ingredient, would not require labeling.6

Another concern is the form of the food in question, i.e., “is labeling appropriate for both fresh produce, processed foods, or both?”163 The answer is that both types of foods should be labeled if they meet the labeling criteria as defined above. This is a similar issue to that posed during the debate over the labeling of irradiated foods.164 In that case, the FDA required labeling of unprocessed foods, reasoning that irradiation could cause changes in the properties of such foods. Consumers might assume such food was not processed in this manner, so irradiation was deemed a material fact. In contrast, individual ingredients that had been irradiated prior to inclusion in processed foods required no labeling, as consumers would recognize that such foods had been processed. Such ingredients were only to be declared by their common name.165 In the case of genetically engineered foods, consumers will assume that soybeans are soybeans, whether fresh or in processed foods. The presence of something akin to a Brazil nut protein will not be anticipated simply because a food is processed, assuming Brazil nut is not either listed as an ingredient or as being present via genetic engineering.

A question related to the form of the food is, what labeling should be required “for a food derived from a plant that contains multiple traits that originated from different lines” or “for plant cultivars developed by traditional techniques . . . when one (or both) parent line(s) is developed from a progenitor line that was developed using ‘genetic engineering’ food, by employing current FDCA standards. See Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984, 22,993 (1992).

162. It should be noted that any exemption from a requirement for labeling presumes that no marker proteins (e.g., antibiotic resistance proteins) are contained in the food.


Again, labeling would be required whenever genetic engineering unexpectedly changes the composition of a food in a manner that might present a health risk to a susceptible population. For example, a cultivar resulting from the breeding of a transgenic soybean parent with a traditional parent would require labeling if the cultivar contained the Brazil nut protein or antibiotic resistance protein of the transgenic parent.

The FDA is also concerned with the circumstances when labeling would be appropriate given that, for example, “most commercially produced tomatoes have introduced genetic traits derived from related weedy species.” Specifically, the FDA asks if there is a basis in science to differentiate between genes added by genetic engineering techniques and those added by traditional breeding techniques. As previously noted, few modern agricultural products can escape being described as “genetically modified.” The prototypical educated consumer must assume that a modern grocery store tomato contains genes derived from a number of closely related species. As noted, traditional genetic manipulation does not present the risk of surprise in a food’s composition presented by genetic engineering. Thus, labeling becomes appropriate because genetic engineering is used to reach beyond these closely related species.

Finally, the FDA has noted the logistical difficulties with “labeling foods derived from ‘genetically engineered’ commodities (such as wheat or corn) at every stage of the food chain which extends from the farm to the grocery store.” Specifically, the FDA questions the feasibility and costs of such an effort. In terms of feasibility, there is one U.S. company developing the technology to detect the presence of genetically modified foods. Current technology has the ability to identify genetically engineered corn at a level of one part in 10,000. Given the intense interest in such detection, particularly in Europe, the pace of innovation in this regard will likely continue to accelerate. The ability to test foods for genetic modification will provide the feasibility to monitor

167. Id. at 25,840.
168. See id.
169. See supra Part II.
171. See id.
compliance with any labeling standard.

In terms of cost, there is little doubt there is some cost to any labeling effort. Infrastructure must be put into place for necessary record keeping and monitoring. Further, segregation into separate genetically engineered and non-genetically engineered pools will increase handling costs for food. For example, agricultural commodities that have been segregated by virtue of being free of genetic engineering currently cost as much as sixty-five cents more per bushel in Europe than do unsegregated commodities. This calls attention to the fact there is a market ready to demand food free of biotechnical advances and willing to pay for the privilege. Further, this emphasizes that the costs of labeling genetically engineered foods are inevitable, at least in the world market. Such costs will further escalate given labeling initiatives in individual states.

In short, the feasibility and costs of such an effort are irrelevant. Labeling of genetically engineered foods is becoming a fact, and the costs will be borne by the consumer. The concern must turn from avoiding these costs to minimizing them. The best method for minimizing the costs of this labeling will be to avoid a proliferation of labeling standards through promulgation of a U.S. national standard which preempts individual state action, and for the FDA to provide leadership towards harmonization at the international level.

VIII. CONCLUSION

It is not doubted that genetic engineering will remain a key tool in the effort to produce a more abundant and nutritious food supply, and it is not argued here that the benefits of genetic engineering of foods do not far outweigh the inherent risks. However, given the level of risk

174. See GMO-free Soybeans to Cost EU 15 pct More—Expert, REUTERS NEWS SERV., Sept. 25, 1997 (discussing costs of segregating and testing soybeans to be certified free of genetically modified organisms). See also Scott, supra note 173 (noting this cost applies to corn as well as soybeans).

175. At least one company has pledged to fill this demand. Morris Tabaksblat, chairman of the Dutch division of Unilever, recognizing that “if we fail to respect consumers' views, we should not be doing our jobs properly,” pledged that Unilever would find non-genetically engineered foods for those consumers who wish to buy them. Christopher Lyddon, Unilever Says Gene Food is Weapon Against Hunger, REUTERS NEWS SERV., Oct. 16, 1997.

176. See supra Part V.

177. See supra Part IV.
presented by these novel foods, a labeling requirement for genetically engineered foods is certainly scientifically justifiable. The potential health risks of genetically engineered foods provide the FDA with the necessary statutory authority to mandate labeling under the FDCA. Beyond the question of protecting public health, labeling of genetically engineered foods is necessary to develop public confidence in these novel foods. Finally, by reconsidering its stand on labeling genetically engineered foods, the FDA can provide both a single national labeling standard and provide leadership in the development of a single international labeling standard.

MICHAEL A. WHITTAKER