

CRS Report for Congress

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Labeling of Genetically Modified Foods

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Summary

Congressional interest in the labeling of genetically modified foods (GM foods) has been rising. Congress took no action on the two bills introduced into the 106th Congress to mandate labeling of all genetically modified crops (GM crops) and foods, but will likely debate other proposals in the 107th Congress. The Food and Drug Administration (FDA) issued its current GM food labeling policy in May 1992. At that time, the agency determined that it would regulate GM foods no differently than foods created by conventional means because FDA considered them substantially equivalent to traditional foods and decided that no special label would be needed. In the intervening period, extensive public debate surrounding the genetic modification of foods has led some consumers to call for labeling of such products. On January 18, 2001, FDA published a draft guidance for industry on voluntary efforts to label GM foods. A label would permit consumers to choose to avoid purchasing or consuming them. At the same time, the agency proposed a rule that would make mandatory the current voluntary consultation process whereby the industry would have to formally notify the agency 120 days before releasing a food product onto the market and would have to supply certain safety test data to FDA. The federal government's role in regulating these foods is explained in CRS Report RL30198, *Food Biotechnology in the United States: Science, Regulation, and Issues*. Many oppose labeling because to make such labels "truthful and not misleading" all commodities would need to be segregated and tested, and the label would not have room to impart information that could not be distributed in other ways. This report focuses specifically on views surrounding the labeling of GM foods. It will be updated periodically as new legislative proposals are introduced.

Introduction

Questions about the safety of bioengineered foods or genetically modified foods (GM foods) have led a variety of observers (consumers, Members of Congress, food companies, and international environmental negotiators) to support the labeling of GM foods. These foods were developed using recombinant DNA and related techniques to alter the genetic makeup of living organisms that are destined for human consumption. These techniques allow scientists to identify and isolate one organism's genes for useful traits and insert them into another plant or animal. Although some of the modifications made by bioengineering could be accomplished through traditional breeding methods, these newer

techniques are more precise and predictable, can use genes from other species, and developers can create seeds having the desired traits faster than traditional methods. Currently, GM food crops planted and marketed by U.S. farmers include beets, corn, canola, cotton, rice, tomatoes, potatoes, soybeans and others. Each of these food products has been modified with added herbicide-tolerance and/or insect-resistance traits. Because of their unique nature, GM foods cross traditional regulatory regimes and involve several agencies with food safety mandates, including the FDA, the Department of Agriculture (USDA), and the Environmental Protection Agency (EPA), although only the FDA is in charge of regulating food labels.

Labeling of GM foods is being debated in Congress and in public forums. Two bills in the 106th Congress would have required mandatory labeling for all foods containing at least 0.1% ingredients of genetically modified organisms (GMOs).¹ In late 1999, FDA held three public meetings to solicit views on the most appropriate way to inform the public about GM foods. The views expressed at the meetings about labeling GM foods were described as polarized between those who wanted labeling and those who did not.² Bills are expected to be introduced in the 107th Congress that would mandate labeling.

Bioengineered foods shipped overseas will soon need documentation identifying them as such. On January 29, 2000, delegates from 140 governments finalized the Cartagena Protocol, known as the Biosafety Protocol.³ It requires exporters of bioengineered commodities used for food, feed, or for processing to label shipments with a declaration that the product “may contain” GMOs and that the products are not intended for release into the environment. The Protocol does not require exporters to segregate bioengineered products from traditional products. Some say this documentation is not “labeling” but a shipping documentation. A State Department spokesman stated that the Protocol was “a step toward depolarizing the debate about biotechnology.”⁴

Supporting and opposing views on the wider issues concerning the value and acceptance of GM foods are discussed in CRS Report RL30198, *Food Biotechnology in*

¹ One bill spelled out a system for each stage of food production whereby all persons with custody over the food (including the seed company, farmer, and food manufacturer) would have to label foods they know contain GMOs. If the food does not contain GMOs, they would have to issue a guaranty that the food does not contain GMOs. If the custodian of the food gave a false guaranty, there would be civil penalties up to \$100,000 for each violation.

² Statement by Joseph A. Levitt, Director, Center for Food Safety and Applied Nutrition, Food and Drug Administration, Department of Health and Human Services before the Senate Health, Education, Labor, and Pensions Committee, September 26, 2000.

³ On June 4, 1993, President Clinton signed the Convention on Biological Diversity, an international agreement negotiated at the 1992 Earth Summit in Rio de Janeiro under the auspices of the United Nations. This diversity agreement, ratified so far by 174 countries **but not by the United States**, calls for protecting a variety of plants and animals found in the wild. A second meeting in Indonesia in November 1995, at the Conference of the Parties to the Convention on Biological Diversity (COP-2), countries agreed to fund negotiations for a “biosafety protocol.”

⁴ Pollack, Andrew. “130 Nations Agree on Safety Rules for Biotech Food.” *New York Times*, January 30, 2000. p. A1 and A6. Also see CRS Report RL30594, *Biosafety Protocol for Genetically Modified Organisms: Overview*, by Alejandro E. Segarra and Susan R. Fletcher. July 5, 2000.

the United States: Science, Regulation, and Issues. This paper briefly describes FDA's food labeling policies and its policy rationale regarding the labeling of GM foods. It also discusses gives the views of supporters and opponents of labeling.

Current FDA Labeling Policies

FDA is responsible for establishing standards for the labeling of all foods except for meat, poultry, and some egg products. The Federal Food, Drug, and Cosmetic Act (FFDCA) gives FDA broad authority to regulate foods by prohibiting the entry into interstate commerce of adulterated or misbranded foods. It is the legal responsibility of food manufacturers to produce foods that are not adulterated, unsafe, filthy, or produced under unsanitary conditions. The Act also requires that "food additives" not be marketed unless they have FDA's approval or are considered generally-recognized-as-safe (GRAS).⁵

FFDCA prohibits (in §403 Misbranded Food) statements in labels or labeling that are "false or misleading in any particular," and requires disclosure of "material" information on the label which gives the statement of identity or common/usual name of the food; the quantity of contents; the name and place of business of manufacturer, packer, or distributor; the ingredient information including any additives; and nutrition information. FDA does not require, however, prior approval for food labels nor does the FFDCA authorize FDA to require label warnings on food products, although the presence of a potential allergen must be included. FDA also gives informal advice to food manufacturers on labeling, if asked, and issues threats of enforcement actions against products whose labels fail to comply with regulatory requirements.

Current FDA Labeling Policy for GM Foods

FDA determined in May 1992 that the scientific and regulatory issues posed by bioengineered food are not substantively different from those raised by non-bioengineered foods. Thus, FDA generally regulates GM foods no differently than foods created by conventional means. Nevertheless, FDA determined that there could be circumstances with GM foods that would require special review.⁶ These are:

- ! the gene transfer produces unexpected genetic effects;
- ! the levels of toxicants in the food are significantly higher than present in other edible varieties of the same species that have not been modified;
- ! nutrients in the bioengineered food differ from those in traditional varieties;
- ! the sources of the newly introduced genetic material come from a food plant associated with allergies found in humans;
- ! the food from the new variety differs significantly in composition from food of non-modified varieties;

⁵ Affirmation petitions for "generally-recognized-as-safe" (GRAS) status must be filed to gain FDA's formal agreement with a sponsor's independent determination that a substance is GRAS. A manufacturer may file a food additive petition even if FDA considers a substance GRAS.

⁶ U.S. Food and Drug Administration. Statement of Policy: Foods Derived From New Plant Varieties. *Federal Register*, v. 57, no. 104, May 29, 1992. p. 22984-23005.

- ! the food contains marker genes that theoretically could reduce the therapeutic effects of clinically useful antibiotics;
- ! the modified plants are developed to make substances like pharmaceuticals or polymers, as well as food; or
- ! the food is to be used for animal feed and has changes in nutrients or toxicants from the non-modified version.

An example of this special review process focused on the Flavr Savr tomato. In an effort to keep tomatoes fresher and longer on the vine, the Calgene Corporation genetically modified a strain of tomato to reduce activity of a particular enzyme (polygalacturonase) that affects softening of outer tissue during ripening. Because Calgene used an antibiotic marker as part of the modification process, a small amount of a non-tomato protein was produced in the Flavr Savr tomato. FDA viewed that protein as a food additive since it would not be found in an unmodified tomato and therefore, changed the tomato's composition. As a result, Calgene petitioned FDA and gained food additive approval for the protein in May 1994. Once approved, all labels listed the protein as an ingredient. In other cases, the composition of the GM product was deemed different enough from its unmodified counterpart to necessitate a different label. For example, FDA required the renaming of a soybean oil whose fatty acid composition had been altered by engineering. The new name, "high oleic acid" describes differences in the oil but not its production method.

On January 18, 2001, FDA published in the *Federal Register* a "Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering" and is seeking comments. In this document, FDA reaffirmed that it would not require special labeling of all bioengineered foods because the use of bioengineering, or its absence, does not itself cause a material difference in the food. However, the agency did suggest that because of the strongly divergent views on labeling, manufacturers may consider providing more information about bioengineered food. The information given, however, must be shown to be truthful and not misleading. To avoid false or misleading statements about the absence of bioengineered ingredients (because there are no established threshold levels of bioengineered constituents or ingredients in foods), or to avoid implying that one food is superior to others, FDA suggests not using statements such as "GM free" or "biotech free." The agency does suggest the word "biotechnology" is preferred by some consumers over "genetic engineering" or "genetic modification." It also claims that if validated testing is available, it can be used to verify whether the label is true. Or manufacturers could keep records to document the reasons why a food's label is truthful. On the same day, FDA published a proposed rule that would make mandatory the current voluntary consultation process whereby the industry would have to formally notify the agency 120 days before releasing a food product onto the market and would have to supply safety test data to FDA.

Views on Labeling of Genetically Modified Foods

Most consumers are very sensitive to the safety of the food they and their families eat and want to be confident that the food products they consume are wholesome and will cause them no harm. Most U.S. consumers trust FDA to ensure the safety of all foods whatever method was used to produce them. However, some concerned consumers, supported worldwide by various environmental groups including Greenpeace, question whether GM foods have been tested properly to ensure their safety from risks such as

unknown allergens or toxins or for potential impact on the environment and biodiversity. They believe that government agencies should carefully review and approve the data from safety tests conducted by developers of GM foods. They also believe that foods produced through this technology could radically change the food supply of this country. These consumers and others have demanded the “right-to-know” which foods have been bioengineered. They want access to information on a label that would allow them to identify these products.⁷ Supporters of labeling these foods claim that such labeling would allow them to have the knowledge to choose to avoid their purchase or consumption.⁸ Other supporters compare this labeling with knowing how much fat is in a food product. To them, a label is not automatically a danger or hazard claim. They just want to know that the food they are eating was made through bioengineering.

Other consumers support mandatory labeling due to religious, ethical, or other strong personal values. These consumers, who routinely purchase specialty foods produced and labeled to abide by religious law or environmental concern, are accustomed to foods which identify their production process, i.e., certified kosher, halal, or organic production, on their label. These consumers want the GM production process identified so they can distinguish these products from those produced without the use of this technology. Labeling would allow these consumers the opportunity to choose to avoid certain foods.

Most seed producers, farmers, and food manufacturers oppose government mandated labeling requirements. They maintain that since companies producing seeds or plants already test products extensively for safety, and strive to maintain the reputation of their brands, labeling is unnecessary. They also claim that their compliance with FDA’s 1992 GM labeling policy ensures that should the GM food contain any modification in nutrients, toxins, or allergens from traditional foods, it would be labeled as such.

Many who oppose mandatory labeling also claim that such a policy would constitute a significant restraint on trade if producers want to make a “GM-free” claim. As suggested in the draft guidance described above, FDA does not recommend this type of claim. To verify such a claim, commodities would have to be separated into two lots: those produced from GM seed and those produced from conventional seed. To provide accurate information and compliance, elaborate and costly record keeping systems of segregating bioengineered foods would be needed at all stages of production (including

⁷ In 1996, in a ruling which applies only to three states, Vermont, Connecticut, and New York, the U.S. Court of Appeals for the Second Circuit held that food labeling cannot be compelled just because consumers want the “right-to-know” information. In overturning a Vermont law that required labeling of dairy products from cows treated with recombinant bovine somatotropin (BST), the court found that such regulation to satisfy the public’s “right to know” is a constitutional violation of commercial free speech. The court wrote, “Were the consumer interest alone sufficient, there is no end to the information that states could require manufacturers to disclose about their production methods Absent, however, some indication that this information bears on a ... human health or safety concern, the manufacturers cannot be compelled to disclose it. Instead, those consumers should exercise the power of their purses by buying products from manufacturers who voluntarily reveal it.” *International Dairy Foods Association, et al. v. Amestoy*, 92 F. 3d 67 (2nd Cir. 1996) and in Henry I. Miller, “Genetic Engineering,” *Science*, v. 284, no. 5419, May 28, 1999. p. 1471-1472.

⁸ U.S. Department of Agriculture’s final rule for the labeling of organic foods will provide consumers with a food supply that does not contain GM foods.

seed development, planting, harvesting, distribution, processing, and packaging). Because of the pervasive use of bioengineered foods in food production, such segregation and traceability would also require extensive DNA testing at each step of the food production process and third party verification (either by the government or the private sector) of the final product. By imposing segregation and testing on the entire agricultural system, costs of providing this information would increase. In addition, the increase in the unit costs within the food system, might make small firms less viable and encourage industry consolidation.⁹

In September 2000, StarLink corn containing a Cry9C protein, a protein approved only for use in animal feed, turned up in taco shells. Without approval for human use, or exemption from approval, the Cry9C protein is considered an adulterant. The current regulatory system would still not necessarily have caught this adulterant in human food, even if there had been a mandatory labeling program. In December 2000, FDA published a sampling and testing guidance for the industry so that testing results could be used to verify the labeling of corn with or without the Cry9C protein.

Other opponents of GM food labeling are concerned about the risk of “crowding out” or confusing other important information on the product label. Because the presence of too much information on a label makes it difficult to effectively transmit knowledge about potential concerns, they believe that adding what they deem as extraneous information on the label could have negative effects. Opponents of labeling also have hypothesized that consumers who know little about the issue might assume that any information included on a label constituted an implied hazard warning. As a result, if GM products are so labeled, these consumers might avoid them based on a judgement of implied risk.

Many industry groups support the current voluntary labeling policy towards GM foods which allows manufacturers to label voluntarily features that appeal to consumers, as long as they are truthful and not misleading, and could satisfy consumer desires for label information. However, these groups also claim that a label is limited as to the level of detail it can contain. Since different consumers care about different things and all information cannot be given on a label, some groups have *suggested* that information could be provided through a variety of sources. Some food industry groups are particularly interested in having FDA create guidelines and quantitative thresholds for “GM free” claims so this label can be verified, can be considered truthful, and not somehow imply that GM foods may be unsafe. With such controversy surrounding consumer acceptance of these GM foods and their labeling, some industry groups are questioning whether they want to use GM products in their retail foods.¹⁰

⁹ “Biotech Crops Hold Potential to Increase Food Prices, says Fed.” *SCI Policy Report*, January 3, 2000.

¹⁰ Food industry manufacturers always consider whether any new food has an obvious consumer benefit, makes the food function better, or would make a difference in sales.