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Labeling Genetically Engineered Foods: Current Legislation

Most Recent Senate Labeling Bill

On June 23, 2016, the chairman and ranking Member of the Senate Agriculture Committee proposed a bill (S.Amdt. 4937 to S. 764) that would amend the Agricultural Marketing Act of 1946 to give the U.S. Department of Agriculture (USDA) authority to establish a mandatory "national bioengineered food disclosure standard." S. 764 would authorize food manufacturers to adopt either text, a symbol, or an electronic/digital link for identifying bioengineered foods. Small food manufacturers would be permitted to use a website or phone number. Very small food manufacturers and restaurants would be exempt from the mandatory disclosure requirement. The bill is seen as a compromise between earlier House and Senate bills that would have authorized a national voluntary labeling standard. The Senate passed the labeling bill on July 7, 63-30. The House approved the Senate bill on July 14, 306-117. President Obama has stated that he would sign it.

Some supporters of the bill remain convinced that a mandatory disclosure implies that genetically engineered foods are potentially unsafe and that labeling is inconsistent with the science that has demonstrated no risks to health. The Food and Drug Administration (FDA) has repeatedly stated that, in the absence of a scientifically determined health effect or change in nutritional quality caused by the genetically engineered (GE) material, a food does not require a label simply because it was created through GE techniques. These supporters would prefer the voluntary labeling standard proposed in earlier labeling bills (see below).

As with several previous labeling bills, the current bill preempts the implementation of Vermont's mandatory labeling law, which took effect July 1, 2016, and prohibits other states from developing their own labeling bills. In criticizing the bill, opponents have pointed to the absence of any penalties for violating mandatory disclosure requirements and the potential disparate effects of digital labeling on rural, low-income, and elderly populations who may lack access to smartphones or adequate digital network coverage.

The bill authorizes USDA to conduct a study within a year of enactment that would identify potential technological factors that might affect consumer access to disclosure through electronic or digital methods. The required study would specifically address the availability of wireless or cellular networks, availability of landline telephones in stores, and particular factors that might affect small retailers and rural retailers.

Some opponents have pointed out that the bill's definition of "bioengineered food" (§291(1)) could be interpreted so narrowly as to exclude some foods made with newer recombinant DNA techniques. The bill defines a bioengineered food as one that contains genetic material modified through *in vitro* recombinant DNA techniques and for which the modification could not occur naturally or be developed through conventional plant breeding techniques. This definition is narrower, for example, than the one developed by Codex Alimentarius of the United Nations Food and Agricultural Organization that establishes internationally recognized food standards. The Codex definition includes *in vitro* recombinant DNA techniques in its definition but also other techniques of genetic engineering.

The bill leaves to USDA the discretion to determine what level of genetically engineered ingredients in a food product would trigger the mandatory disclosure requirement. Unlike other countries (e.g., Japan, Australia, European Union), the United States has not determined a level of GE material that would trigger a labeling requirement. Depending upon the level of GE material in the food, some opponents have claimed that GE foods could be exempt from the disclosure requirement (e.g., foods made with GE beet sugar, corn, or soy oil).

FDA and USDA Comments on the Senate Bill

In technical comments on the bill, FDA indicated its concern that implementing the mandatory disclosure under USDA regulations could conflict with FDA's labeling requirements. The bill permits information on GE content in a food product to be indicated through an electronic format rather than on the package label. FDA regulations require disclosure on the food package.

FDA also noted the narrowness of the "bioengineering" definition and stated their concern that the definition could limit the scope of coverage to foods that "could not otherwise be obtained through conventional breeding or found in nature." FDA noted that this criterion was unclear and would be difficult to demonstrate. FDA further noted that bill language regarding exceptions and inclusions was unclear. FDA, however, stated that it would defer to USDA on its interpretation of the bill because USDA would be the implementing agency.

In response to FDA's technical comments on the bill, Ranking Member Senator Stabenow asked the USDA general counsel to address the scope and applicability of the proposed GE labeling bill. Counsel responded in a June 29 letter stating that the definition of "bioengineered" provides the authority to include all the commercial GE crops used in food manufacture in the disclosure requirement. Counsel also stated that novel GE techniques (e.g., gene editing such as CRISPR) would be included in the definition if these techniques were used to produce plants or seeds with traits that could not be created with conventional breeding techniques. The "bioengineering" definition would also include RNAi techniques, most recently applied to a non-browning apple and potato.

On the issue of whether refined oils and sugars produced or developed from GE techniques could be excluded from the mandatory disclosure requirement, USDA stated that Section 291(1) provides authority to include foods that may or may not contain such products in the disclosure requirement. However, counsel further stated that, "as a practical matter," USDA would look not only at the definition of "bioengineering" but would also consider the authority provided in the establishment of the national bioengineered food disclosure standard (§293(b)(2)(B) and §293(b)(2)(C)) with respect to the amount of a GE substance present in the food, as well as other factors that might deem the product as a "bioengineered food."

Earlier Labeling Bills

An earlier Senate bill (S. 2609) would also have amended the Agricultural Marketing Act of 1946 to require USDA establish a new voluntary framework governing the use of labels claiming either the absence or use of GE foods or food ingredients. The bill did not pass a cloture vote in March. Separately, the House passed H.R. 1599 in July 2015. It would also create a new voluntary labeling framework by amending the Federal Food, Drug, and Cosmetic Act (FFDCA) and amending the Agricultural Marketing Act of 1946 to create a Genetic Engineering Certification process under USDA. Both bills would preempt any state or political subdivision of a state from establishing its own labeling law for foods containing GE material that differed from federal requirements.

The earlier Senate bill would have given USDA discretionary authority to establish labeling standards but, like the House-passed bill, would have prohibited language expressing or implying a higher quality or safer food based on whether the food was developed though GE technologies.

Several other bills requiring mandatory labeling of GE foods have been proposed in Congress but have not been considered by any committees. The Biotechnology Food Labeling Uniformity Act (S. 2621) would amend the FFDCA to require that a food contain a label or symbol on a Nutrition Facts panel indicating that the food was produced by or derived from GE ingredients and would preempt state labeling laws. Other legislation would amend the FFDCA to require labeling GE salmon (Genetically Engineered Salmon Risk Reduction Act, S. 738) or any genetically engineered fish (H.R. 393). The Genetically Engineered Food Right-to-Know Act (H.R. 913/S. 511) would amend the FFDCA to classify a food as misbranded if it does not contain a label indicating that GE materials were used in its production.

Labeling Under the FFDCA

The FFDCA prohibits interstate commerce of any food that is misbranded. A food is misbranded if its labeling is false or misleading. A label is misleading if, among other things, it fails to reveal facts that are "material" regarding representations made or suggested in the labeling or "material" with respect to consequences that could result from the use of the food.

In its 1992 *Statement of Policy: Foods Derived from New Plant Varieties*, FDA stated that it was not aware of any information showing that GE foods differed from other foods in any meaningful way or that, as a class, foods developed by GE techniques presented any different or greater safety concern than foods developed by traditional plant breeding. FDA concluded that the method used to develop a new plant variety, including the use of GE technologies, is generally not regarded as "material."

Under the 1986 Coordinated Framework for Regulation of Biotechnology, FDA is responsible for reviewing GE plants and animals and foods derived from them for their safety for human and animal consumption. FDA does not require that the food be labeled based solely on the method used to produce it. Only where disclosure of the fact that a food is derived from a GE organism was necessary to protect public health or safety would FDA, under current law, require a label to that effect.

Under its 1992 guidelines, FDA permits voluntary labeling of foods that have or have not been derived from GE plants. Many food companies currently label their foods to indicate that they do not contain GE ingredients. As long as such voluntary labels are neither false nor misleading, they are lawful under the FFDCA. However, no systematic national standard for voluntary GE labeling exists other than the FFDCA prohibition against false or misleading claims. One standardized exception in current use is the National Organic Program (NOP) label that indicates that a food product is produced under NOP standards, which prohibit the use of GE ingredients.

State Labeling Laws

In 2014, Vermont became the first state to pass a mandatory GE labeling law that became effective on July 1, 2016. Connecticut and Maine also passed mandatory GE labeling laws in 2013 and 2014, respectively, but they will not go into effect until five contiguous states also pass mandatory GE labeling laws. Other state legislatures (e.g., New Jersey, Alaska, Hawaii, Iowa, Illinois, Massachusetts) are also considering mandatory labeling laws. Some states (e.g., Michigan, North Dakota) have also enacted legislation urging the U.S. Congress to pass a uniform labeling standard. California, Colorado, and Washington had mandatory labeling ballot initiatives in recent years. Each was defeated.

Opponents of labeling argue that there are no scientific reasons to require mandatory labeling of a GE food product. Labeling opponents have feared that in the absence of a national labeling law, each state could pass its own specific labeling requirements for GE foods, requiring costly management changes in commodity supply chains to comply with different state laws. Proponents of labeling strongly support a mandatory labeling standard, citing the consumers' right to know. Continued opposition to the Senate labeling bill is expected to move to USDA's rulemaking process.

For more information, see CRS Report RL32809, *Agricultural Biotechnology: Background, Regulation, and Policy Issues*; andCRS Report R43705, *Legal Issues with Federal Labeling of Genetically Engineered Food: In Brief*.

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