

GMO Labeling

Regulatory and Legislative Overview

Prepared for

International Sweetener Colloquium

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Current Regulatory Structure

Federal - USDA

- National Organic Program (NOP)
 - Administered by USDA's Agricultural Marketing Service (AMS) under the Organic Foods Production Act.
 - Any agricultural product, whether raw or processed, that is marketed for human or livestock consumption and sold, labeled, or represented as "organic" must be produced and handled in accordance with a certification process established under the NOP regulations (7 CFR Part 205).

Current Regulatory Structure

Federal - USDA

- To be sold or labeled as “organic”, the product must be produced and handled without the use of “excluded methods”.
- “Excluded methods” = genetic engineering (GE)

Current Regulatory Structure

Federal - USDA

- “Excluded methods” = A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.

Current Regulatory Structure

Federal - FDA

- FDA reviews the safety and nutritional properties of new GE food products under its 1992 Statement of Policy: Foods Derived from New Plant Varieties
- Foods from GE plants must meet the same food safety requirements as foods derived from traditionally bred plants.
- Consultations with FDA are “voluntary”.
- 168 reviews conducted under the 1992 Policy for GE varieties of 17 different plants.

Current Regulatory Structure

Federal - FDA

- Alfalfa
- Canola
- Cotton
- Flax
- Plum
- Radicchio
- Soybean
- Sugar Beet
- Wheat
- Apple
- Cantaloupe
- Corn
- Papaya
- Potato
- Rice
- Squash
- Tomato

Current Regulatory Structure

Federal - FDA

- FDA's position on labeling of GE foods has not changed since 1992.
- FDA does not consider the methods used in the development of a new plant variety to be “material information” under the Federal Food, Drug, and Cosmetic Act (FFDCA).
- FDA believes that the new GE techniques are extensions at the molecular level of traditional breeding methods and will be used to achieve the same goals as pursued with traditional plant breeding.

Current Regulatory Structure

Federal - FDA

- FDA is not aware of any information showing that:
 - foods derived by these new methods differ from other foods in any meaningful or uniform way, or
 - as a class, foods developed by the new techniques present any different or greater safety concern than foods developed by traditional plant breeding.

Current Regulatory Structure

Federal - FDA

- For these reasons, FDA does not believe that the method of development of a new plant variety (including the use of new techniques such as recombinant DNA) is normally material information within the meaning of the FFDCA and would not usually be required to be disclosed in labeling.
- As with any food, if a new GE food differs from its non-GE counterparts in any material way (e.g., allergenicity, nutritional profile), labeling may be required.

Current Regulatory Structure

Federal - FDA

- On November 19, 2015, FDA denied petitions to mandate labeling of GE foods.
 - “consumer interest alone does not provide a sufficient basis to require labeling disclosing whether a food has been produced with or without the use of ... genetic engineering”
- FDA’s decisions affirm longstanding agency policy that there is no legal basis for mandating such disclosure on products that are essentially the same as their non-GE counterparts.

Current Regulatory Structure

Federal - FDA

- FDA also finalized its longstanding Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from GE Plants.
- The term “GMO” is itself a misnomer and potentially misleading.
 - All organisms are “genetically modified”.
 - If used, the term “GMO” should be properly and clearly qualified.

Current State Statutes

Vermont

- Act 120 enacted by Vermont on May 8, 2014.
- Requires manufacturers to label GE foods (with several notable exceptions including restaurant food, alcoholic beverages, and foods with GE content no more than 0.9% of the total weight of the food).
- Vermont sued in federal court on June 12, 2014, by:
 - Grocery Manufacturers Association
 - Snack Food Association
 - International Dairy Foods Association
 - National Association of Manufacturers

Current State Statutes

Vermont

- Suit contends that Act 120 is unconstitutional and imposes burdensome new speech requirements on food manufacturers and retailers.
- First amendment issues and all other claims (e.g., Commerce Clause, federal preemption) are scheduled to go to trial in U.S. District Court in or around April 2016.

Current State Statutes

Vermont

- Plaintiffs filed motion for a preliminary injunction on Sept. 11, 2014, to stop the law from going into effect.
- On April 27, 2015, the U.S. District Court denied the motion, allowing the law to take effect in July 2016.
- District Court's preliminary injunction decision is now on appeal to U.S. Court of Appeals for the Second Circuit.

Current State Statutes

Connecticut and Maine

- Laws requiring labeling of GE foods have been enacted in Connecticut (HB 6527) in 2013 and Maine (LD 718) in 2014.
- Laws will not take effect until at least five neighboring states in the northeast (including Connecticut and Maine) adopt mandatory GE food labeling laws.
 - Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont
 - Connecticut also requires aggregate population of these states to exceed 20 million

Proposed State and Local Bills

- Each year hundreds of anti-GE bills and ordinances are introduced in state legislatures and county and municipal councils.
- Many of these bills would require labeling of GE foods.

Proposed Federal Legislation

- Safe and Accurate Food Labeling Act of 2015 (H.R. 1599)
 - Introduced by Rep. Pompeo (R-KS)
 - Reported out by Energy & Commerce and Agriculture Committees
 - Passed on July 23, 2015 (275 to 150)
 - For: R – 230, D – 45
 - Against: R – 12, D – 138

Proposed Federal Legislation

- Safe and Accurate Food Labeling Act of 2015 (H.R. 1599)
 - Requires FDA to continue its voluntary consultation process and notify USDA when food from a GE plant meets safety standard.
 - USDA authorized to clear sale of GE food only after receiving notice from FDA.

Proposed Federal Legislation

- Safe and Accurate Food Labeling Act of 2015 (H.R. 1599)
 - Agricultural Marketing Act amended to require AMS to establish a voluntary national GE food certification program.
 - AMS to set national standards for sale and labeling of GE and non-GE foods by regulation.
 - Bill includes numerous exceptions, exemptions, and qualifications for the certification program and national standards.

Proposed Federal Legislation

- Safe and Accurate Food Labeling Act of 2015 (H.R. 1599)
 - State and local requirements for labeling of food as GE and non-GE are preempted unless they result from:
 - a voluntary program with standards identical to the national standards, or
 - a program that: provides for voluntary claims, was in effect before the date of enactment, and meets the national standards after 3 years.

Proposed Federal Legislation

- Safe and Accurate Food Labeling Act of 2015 (H.R. 1599)
 - Requires FDA to establish regulations for labeling of food as “natural”.
 - Regulations would preempt state and local labeling requirements.

Proposed Federal Legislation

- Anticipated Senate Bill
 - Agricultural Marketing Act amended to require AMS to establish a national voluntary GE food labeling standard.
 - State and local requirements for labeling of food as GE and non-GE preempted unless identical to the national voluntary standard.
 - Much simpler than House bill – details to be worked out in the rulemaking process.

Key Points to Consider

- GE foods on the market today have been reviewed by FDA and found to be as safe and nutritious as their non-GE counterparts, with no special labeling required.
- Labeling foods GE and non-GE is a marketing issue, not a safety issue.
- Differing federal, state, and local food labeling requirements significantly increase costs of production and distribution and lead to confusion and added costs for the consumer.
- Federal legislation is needed to resolve conflicting labeling requirements.

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