

Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants

Resources

- [Federal Register Notice](#)
- Docket No. [FDA-2000-D-0075](#) for commenting starting November 24, 2015
- News Release: [FDA takes several actions involving genetically engineered plants and animals for food](#)
- Consumer Update: [Genetically Engineered Salmon Is Safe, FDA Determines](#)
- Related Guidance: [Draft Guidance for Industry: Voluntary Labeling Indicating Whether Food Has or Has Not Been Derived from Genetically Engineered Atlantic Salmon](#)
- [Labeling of Food Derived from Genetic Engineering](#)
- [More Labeling Guidance](#)
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Additional copies are available from:
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Food Labeling and Standards Staff, HFS-800
Center for Food Safety and Applied Nutrition
Food and Drug Administration
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You may submit either electronic or written comments regarding this guidance at any time. Submit electronic comments to <http://www.regulations.gov>. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
Center for Veterinary Medicine**

Issued November 2015

Contains Nonbinding Recommendations

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Guidance for Industry [1] Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

Manufacturers often voluntarily provide information on their labels beyond the information required by the Federal Food, Drug, and Cosmetic Act (the FD&C Act) or FDA regulations. Their reasons for doing so may have to do with marketing or providing information of specific interest to their customers. This guidance addresses the voluntary labeling of plant-derived foods with information concerning whether the food was or was not produced using genetic engineering. Some consumers are interested in knowing whether a food was produced using genetic engineering and some manufacturers want to respond to this consumer interest. FDA is providing this guidance to assist food and feed manufacturers that wish to voluntarily label their plant-derived food products or ingredients (for humans or for animals) as having been made with or without bioengineering. FDA's main concern within the context of this guidance is that such voluntary labeling be truthful and not misleading.

In this guidance, we use the terms “genetic engineering” and “bioengineering” to describe the use of modern biotechnology. Modern biotechnology means the application of *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection of plants (Ref. 1). The term “modern biotechnology” may alternatively be described as “recombinant DNA (rDNA) technology” (Ref. 2), “genetic engineering” (Ref. 3), or “bioengineering.” These terms are often used interchangeably by industry, federal agencies, international bodies, and other interested stakeholders and are used in this guidance to refer to foods derived from new plant varieties developed using modern biotechnology. The term “genetic modification” is also sometimes used to refer to the use of modern biotechnology (e.g., Ref. 4), although FDA’s longstanding position, as discussed later in this guidance, is that such use of the term is less accurate because the term encompasses the broad spectrum of genetic alterations that can be made in plants (see, e.g., Ref. 5).

Because technically it is the plant that is genetically engineered rather than the food, for simplicity we use the term “food derived from genetically engineered plants” in this guidance to refer to products that are derived from genetically engineered plants. (For reasons discussed in more detail later in this guidance, FDA does not use the terms “genetically modified” or “genetically modified *organism*” (GMO) when referring to foods derived from genetically engineered plants.) Because section 201(f)(1) of the FD&C Act defines “food” in relevant part as “articles used for food or drink for man or other animals,” the food derived from genetically engineered plants addressed in this guidance include plant-derived foods for animals as well as such foods for humans.

FDA’s guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in agency guidances means that something is suggested or recommended, but not required.

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II. BACKGROUND

The FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any food that is misbranded. 21 U.S.C. § 331(a). Under section 403(a)(1) of the FD&C Act, a food is misbranded if its labeling is false or misleading in any particular. 21 U.S.C. § 343(a)(1). Section 201(n) of the FD&C Act (21 U.S.C. 321(n)) provides that labeling is misleading if, among other things, it fails to reveal facts that are material in light of representations made or suggested in the labeling, or material with respect to consequences that may result from the use of the food to which the labeling relates under the conditions of use prescribed in the labeling, or under such conditions of use as are customary or usual. 21 U.S.C. § 321(n). In a 1992 “Statement of Policy: Foods Derived from New Plant Varieties” (1992 Policy) (Ref. 5) FDA explained its interpretation of the FD&C Act with respect to foods derived from new plant varieties, including varieties developed using bioengineering. In the 1992 Policy, FDA stated that it was not aware of any information showing that bioengineered foods differ from other foods in any meaningful or uniform way, or that, as a class, foods developed by the new techniques present any different or greater safety concern than foods developed by traditional plant breeding (Ref. 5). Further, FDA concluded that the method of development of a new plant variety (including the use of new techniques such as rDNA technology) is generally not material information within the meaning of section 201(n) of the FD&C Act, and