

maintained for a period of 1 year from the date the origin declaration is made at retail.

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Subpart B [Reserved]

PART 66—NATIONAL BIOENGINEERED FOOD DISCLOSURE STANDARD

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AUTHORITY: 7 U.S.C. 1621 *et seq.*

SOURCE: 83 FR 65871, Dec. 21, 2018, unless otherwise noted.

Subpart A—General Provisions

§ 66.1 Definitions.

Act means the Agricultural Marketing Act of 1946 (7 U.S.C. 1621 *et seq.*), as amended to include Subtitle E—National Bioengineered Food Disclosure Standard and Subtitle F—Labeling of Certain Food.

Administrator means the Administrator of the Agricultural Marketing Service, United States Department of Agriculture, or the representative to whom authority has been delegated to act in the stead of the Administrator.

AMS means the Agricultural Marketing Service of the United States Department of Agriculture.

Bioengineered food means—

(1) Subject to the factors, conditions, and limitations in paragraph (2) of this definition:

(i) A food that contains genetic material that has been modified through *in vitro* recombinant deoxyribonucleic acid (rDNA) techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature; *provided that*

(ii) Such a food does not contain modified genetic material if the genetic material is not detectable pursuant to § 66.9.

(2) A food that meets one of the following factors and conditions is not a bioengineered food.

(i) An incidental additive present in food at an insignificant level and that does not have any technical or functional effect in the food, as described in 21 CFR 101.100(a)(3).

(ii) [Reserved]

Bioengineered substance means substance that contains genetic material that has been modified through *in vitro* recombinant deoxyribonucleic acid (rDNA) techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature.

Compliance date means—

(1) *Mandatory compliance date*. Entities responsible for bioengineered food disclosure must comply with the requirements of this part by January 1, 2022.

(2) *Updates to the List of Bioengineered Foods*. When AMS updates the List of

Bioengineered Foods pursuant to § 66.7, entities responsible for bioengineered food disclosures must comply with the updates no later than 18 months after the effective date of the update.

Food means a food (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)) that is intended for human consumption.

Food manufacturer means an entity that manufactures, processes, or packs human food and labels the food or food product for U.S. retail sale.

Importer means the importer of record, as determined by U.S. Customs and Border Protection (19 U.S.C. 1484(a)(2)(B)), who engages in the importation of food or food products labeled for retail sale into the United States.

Information panel means that part of the label of a packaged product that is immediately contiguous to and to the right of the principal display panel as observed by an individual facing the principal display panel, unless another section of the label is designated as the information panel because of package size or other package attributes (e.g. irregular shape with one usable surface).

Label means a display of written, printed, or graphic matter upon the immediate container or outside wrapper of any retail package or article that is easily legible on or through the outside container or wrapper.

Labeling means all labels and other written, printed, or graphic matter:

(1) Upon any article or any of its containers or wrappers; or

(2) Accompanying such article.

List of Bioengineered Foods means a list, maintained and updated by AMS and provided in § 66.6, of foods for which bioengineered versions have been developed.

Marketing and promotional information means any written, printed, audio-visual, or graphic information, including advertising, pamphlets, flyers, catalogues, posters, and signs that are distributed, broadcast, or made available to assist in the sale or promotion of a product.

Predominance means an ingredient's position in the ingredient list on a product's label. Predominant ingredients are those most abundant by

weight in the product, as required under 21 CFR 101.4(a)(1).

Principal display panel means that part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale.

Processed food means any food other than a raw agricultural commodity, and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling.

Raw agricultural commodity means any agricultural commodity in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

Regulated entity means the food manufacturer, importer, or retailer that is responsible for making bioengineered food disclosures under § 66.100(a).

Secretary means the United States Secretary of Agriculture or a representative to whom authority has been delegated to act in the Secretary's stead.

Similar retail food establishment means a cafeteria, lunch room, food stand, food truck, transportation carrier (such as a train or airplane), saloon, tavern, bar, lounge, other similar establishment operated as an enterprise engaged in the business of selling prepared food to the public, or salad bars, delicatessens, and other food enterprises located within retail establishments that provide ready-to-eat foods that are consumed either on or outside of the retailer's premises.

Small food manufacturer means any food manufacturer with annual receipts of at least \$2,500,000, but less than \$10,000,000.

Small package means food packages that have a total surface area of less than 40 square inches.

Very small food manufacturer means any food manufacturer with annual receipts of less than \$2,500,000.

Very small package means food packages that have a total surface area of less than 12 square inches.