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[74 FR 2704, Jan. 15, 2009, as amended at 81 FR 10761, Mar. 2, 2016]

Subpart B [Reserved]

PART 66—NATIONAL BIOENGINEERED FOOD DISCLOSURE STANDARD

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

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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, audiovisual, 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.

§ 66.3 Disclosure requirement and applicability.

(a) *General.* (1) A label for a bioengineered food must bear a disclosure indicating that the food is a bioengineered food or contains a bioengineered food ingredient consistent with this part.

(2) Except as provided in § 66.116 for voluntary disclosure, a label shall not bear a disclosure that a food is a bioengineered food or contains a bioengineered food ingredient if the records maintained in accordance with § 66.302 demonstrate that the food is not a bioengineered food or does not contain a bioengineered food ingredient.

(b) *Application to food.* This part applies only to a food subject to:

(1) The labeling requirements under the Federal Food, Drug, and Cosmetic Act (''FDCA''); or

(2) The labeling requirements under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act only if:

(i) The most predominant ingredient of the food would independently be subject to the labeling requirements under the FDCA; or

(ii) The most predominant ingredient of the food is broth, stock, water, or a similar solution and the second-most predominant ingredient of the food would independently be subject to the labeling requirements under the FDCA.

§ 66.5 Exemptions.

This part shall not apply to the food and entities described in this section.

(a) Food served in a restaurant or similar retail food establishment.

(b) Very small food manufacturers.

(c) A food in which no ingredient intentionally contains a bioengineered (BE) substance, with an allowance for inadvertent or technically unavoidable BE presence of up to five percent (5%) for each ingredient.

(d) A food derived from an animal shall not be considered a bioengineered food solely because the animal consumed feed produced from, containing, or consisting of a bioengineered substance.

(e) Food certified under the National Organic Program.

§ 66.6 List of bioengineered foods.

The List of Bioengineered Foods consists of the following: Alfalfa, apple (Arctic™ varieties), canola, corn, cotton, eggplant (BARI Bt Begun varieties), papaya (ringspot virus-resistant varieties), pineapple (pink flesh varieties), potato, salmon (AquAdvantage®), soybean, squash (summer, coat protein-mediated virus-resistant varieties), sugarbeet, and sugarcane (Bt insect-resistant varieties).

[88 FR 83311, Nov. 29, 2023]

§ 66.7 Updates to the List of Bioengineered Foods.

(a) *Updates to the List.* AMS will review and consider updates to the List on an annual basis and will solicit recommendations regarding updates to the List through notification in the FEDERAL REGISTER and on the AMS website.

(1) Recommendations regarding additions to and subtractions from the List may be submitted to AMS at any time or as part of the annual review process.

(2) Recommendations should be accompanied by data and other information to support the recommended action.

(3) AMS will post public recommendations on its website, along with information about other revisions to the List that the agency may be considering, including input based on consultation with the government agencies responsible for oversight of the products of biotechnology: USDA's Animal and Plant Health Inspection Service (USDA–APHIS), the U.S. Environmental Protection Agency (EPA), and the Department of Health and Human Services' Food and Drug Administration (FDA), and appropriate members of the Coordinated Framework for the Regulation of Biotechnology or a similar successor.

(4) AMS will consider whether foods proposed for inclusion on the List have been authorized for commercial production somewhere in the world, and whether the food is currently in legal commercial production for human food somewhere in the world.

(5) If AMS determines that an update to the List is appropriate following its

review of all relevant information provided, AMS will modify the List.

(b) *Compliance period.* Regulated entities will have 18 months following the effective date of the updated List of Bioengineered Foods to revise food labels to reflect changes to the List in accordance with the disclosure requirements of this part.

§ 66.9 Detectability.

(a) *Recordkeeping requirements.* Modified genetic material is not detectable if, pursuant to the recordkeeping requirements of § 66.302, the entity responsible for making a BE food disclosure maintains:

(1) Records to verify that the food is sourced from a non-bioengineered crop or source; *or*

(2) Records to verify that the food has been subjected to a refinement process validated to make the modified genetic material in the food undetectable; *or*

(3) Certificates of analysis or other records of testing appropriate to the specific food that confirm the absence of modified genetic material.

(b) *Validated refining process.* (1) Analytical testing that meets the standards described in paragraph (c) of this section must be used to validate that a refining process renders modified genetic material in a food undetectable.

(2) Once a refining process has been so validated, additional testing is not necessary to confirm the absence of detectable modified genetic material in food subsequently refined through that process, provided that no significant changes are made to the validated process and provided that records are maintained to demonstrate that the refining process has been validated and that the validated refining process is followed.

(c) *Standards of performance for detectability testing.* Analytical testing for purposes of detecting the presence of modified genetic material in refined foods pursuant to paragraph (a) of this section shall meet the following standard:

(1) Laboratory quality assurance must ensure the validity and reliability of test results;

(2) Analytical method selection, validation, and verification must ensure that the testing method used is appropriate (fit for purpose) and that the laboratory can successfully perform the testing;

(3) The demonstration of testing validity must ensure consistent accurate analytical performance; and

(4) Method performance specifications must ensure analytical tests are sufficiently sensitive for the purposes of the detectability requirements of this part.

§ 66.11 Severability.

If any provision of this part is declared invalid or the applicability thereof to any person or circumstances is held invalid, the validity of the remainder of this part or the applicability thereof to other persons or circumstances shall not be affected thereby.

§ 66.13 Implementation and compliance.

(a) *Implementation.* Except for small food manufacturers, the implementation date for this part is January 1, 2020. For small food manufacturers, the implementation date is January 1, 2021.

(b) *Voluntary compliance.* (1) Regulated entities may voluntarily comply with the requirements in this part until December 31, 2021.

(2) During this period, regulated entities may use labels that meet requirements of preempted State labeling regulations for genetically engineered food. Stickers or ink stamps may be applied to existing labels to provide appropriate bioengineered food disclosures provided that the stickers or ink stamps do not obscure other required label information.

(c) *Mandatory compliance.* All regulated entities must comply with the requirements of this part beginning on January 1, 2022.

Subpart B—Bioengineered Food Disclosure

§ 66.100 General.

(a) *Responsibility for disclosure.* (1) For a food that is packaged prior to receipt by a retailer, the food manufacturer or importer is responsible for ensuring

that the food label bears a bioengineered food disclosure in accordance with this part.

(2) If a retailer packages a food or sells a food in bulk, that retailer is responsible for ensuring that the food bears a bioengineered food disclosure in accordance with this part.

(b) *Type of disclosure.* If a food must bear a bioengineered food disclosure under this part, the disclosure must be in one of the forms described in this paragraph (b), except as provided in §§ 66.110 and 66.112.

(1) A text disclosure in accordance with § 66.102.

(2) A symbol disclosure in accordance with § 66.104.

(3) An electronic or digital link disclosure in accordance with § 66.106.

(4) A text message disclosure in accordance with § 66.108.

(c) *Appearance of disclosure.* The required disclosure must be of sufficient size and clarity to appear prominently and conspicuously on the label, making it likely to be read and understood by the consumer under ordinary shopping conditions.

(d) *Placement of the disclosure.* Except as provided in § 66.114 for bulk food, the disclosure must be placed on the label in one of the manners described in this paragraph (d).

(1) The disclosure is placed in the information panel directly adjacent to the statement identifying the name and location of the handler, distributor, packer, manufacturer, importer, or any statement disclosing similar information.

(2) The disclosure is placed in the principal display panel.

(3) The disclosure is placed in an alternate panel likely to be seen by a consumer under ordinary shopping conditions if there is insufficient space to place the disclosure on the information panel or the principal display panel.

(e) *Uniform Resource Locator (URL).* Except for disclosures made by small manufacturers and for disclosures on very small packages, a bioengineered food disclosure may not include an internet website URL that is not embedded in an electronic or digital link.

§ 66.102 Text disclosure.

A text disclosure must bear the text as described in this section. A text disclosure may use a plural form if applicable, e.g. if a food product includes more than one bioengineered food, then ''bioengineered foods'' or ''bioengineered food ingredients'' may be used.

(a) *Bioengineered foods.* If a food (including any ingredient produced from such food) is on the List of Bioengineered Foods, and records maintained by a regulated entity demonstrate that the food is bioengineered, the text disclosure must be one of the following, as applicable:

(1) ''Bioengineered food'' for bioengineered food that is a raw agricultural commodity or processed food that contains only bioengineered food ingredients; or

(2) ''Contains a bioengineered food ingredient'' for multi-ingredient food that is not described in paragraph (a)(1) of this section but contains one or more bioengineered food ingredients.

(b) *Predominant language in U.S.* Food subject to disclosure that is distributed solely in a U.S. territory may be labeled with statements equivalent to those required in this part, using the predominant language used in that territory.

§ 66.104 Symbol disclosure.

A symbol disclosure must replicate the form and design of Figure 1 to this section.

(a) The symbol is a circle with a green circumference, and a white outer band. The bottom portion of the circle contains an arch, filled in green to the bottom of the circle. The arch contains two light green terrace lines, sloping downward from left to right. On the left side of the arch is a stem arching towards the center of the circle, ending in a four-pointed starburst. The stem contains two leaves originating on the upper side of the stem and pointing towards the top of the circle. In the background of the leaves, at the top of the circle and to the left of center, is approximately one-half of a circle filled in yellow. The remainder of the circle is filled in light blue. The symbol must contain the words ''BIOENGINEERED.''

(b) If a food (including any ingredient produced from such food) is on the List of Bioengineered Foods, and records maintained by a regulated entity demonstrate that the food is bioengineered, or do not demonstrate whether the food is bioengineered, the symbol disclosure must be the following:

Figure 1 to § 66.104

(c) The symbol may be printed in black and white.

(d) Nothing can be added to or removed from the bioengineered food symbol design except as allowed in this part.

§ 66.106 Electronic or digital link disclosure.

If a required bioengineered food disclosure is made through an electronic or digital link printed on the label, the disclosure must comply with the requirements described in this section.

(a) *Accompanying statement.* (1) An electronic or digital disclosure must be accompanied by, and be placed directly above or below, this statement: ''Scan here for more food information'' or equivalent language that only reflects technological changes (e.g., ''Scan anywhere on package for more food information'' or ''Scan icon for more food information'').

(2) The electronic or digital disclosure must also be accompanied by a telephone number that will provide the bioengineered food disclosure to the consumer, regardless of the time of day. The telephone number instructions must be in close proximity to the digital link and the accompanying statement described in paragraph (a)(1) of this section, must indicate that calling the telephone number will provide more food information, and must be accompanied by the statement ''Call [1–000–000–0000] for more food information.''

(b) *Product information page.* When the electronic or digital link is accessed, the link must go directly to the product information page for display on the electronic or digital device. The product information page must comply with the requirements described in this paragraph (b).

(1) The product information page must be the first screen to appear on an electronic or digital device after the link is accessed as directed.

(2) The product information page must include a bioengineered food disclosure that is consistent with § 66.102 or § 66.104.

(3) The product information page must exclude marketing and promotional information.

(4) The electronic or digital link disclosure may not collect, analyze, or sell any personally identifiable information about consumers or the devices of consumers; however, if this information must be collected to carry out the purposes of this part, the information must be deleted immediately and not used for any other purpose.

§ 66.108 Text message disclosure.

The regulated entity must not charge a person any fee to access the bioengineered food information through text message and must comply with the requirements described in this section.

(a) The label must include this statement ''Text [command word] to [number] for bioengineered food information.'' The number must be a number, including a short code, that sends an immediate response to the consumer's mobile device.

(b) The response must be a one-time response and the only information in the response must be the appropriate bioengineered food disclosure described in § 66.102 or § 66.116.

(c) The response must exclude marketing and promotional information.

(d) A regulated entity that selects the text message option must comply with the requirements of this paragraph (d).

(1) The regulated entity must not collect, analyze, or sell any personally identifiable information about consumers or the devices of consumers.

(2) The regulated entity must not use any information related to the text message option for any marketing purposes.

(3) If any information must be collected to carry out the purposes of this part, the information must be deleted as soon as possible and not be used for any other purpose.

§ 66.109 Required disclosure with actual knowledge.

Notwithstanding any provision in this subpart, if a food manufacturer (other than a very small food manufacturer), a retailer, or an importer has actual knowledge that the food is a bioengineered food or contains a bioengineered food ingredient, it must disclose that the food is bioengineered or contains a bioengineered food ingredient, as applicable, using appropriate text, symbol, electronic or digital link disclosure, or text message.

§ 66.110 Small food manufacturers.

A small food manufacturer must make the required bioengineered food disclosure using one of the bioengineered food disclosure options permitted under §§ 66.102, 66.104, 66.106, and 66.108 or as described in this section.

(a) The label bears the statement: ''Call for more food information,'' which accompanies a telephone number that will provide the bioengineered food disclosure to the consumer, regardless of the time of day. Disclosure via telephone number must include a bioengineered food disclosure that is consistent with § 66.102 in audio form and may be pre-recorded.

(b) The label bears the statement: ''Visit [URL of the website] for more food information,'' which accompanies a website that meets the requirements of § 66.106(b). Disclosure via website must include a bioengineered food disclosure that is consistent with § 66.102 or § 66.104 in written form.

§ 66.112 Small and very small packages.

In addition to the disclosures described in this subpart, for food in small and very small packages, the required disclosure may be in the form described in paragraph (a), (b), or (c) of this section.

(a) The label bears the electronic or digital disclosure described in § 66.106, and replaces the statement and phone number required in § 66.106(a) with the statement ''Scan for info.''

(b) The label bears a number or short code as described in § 66.108(a), and replaces the statement with ''Text for info.''

(c) The label bears a phone number as described in § 66.110(a), and replaces the statement with ''Call for info.''

(d) For very small packages only, if the label includes a preexisting Uniform Resource Locator for a website or a telephone number that a consumer can use to obtain food information, that website or telephone number may also be used for the required bioengineered food disclosure, provided that the disclosure is consistent with § 66.102 or § 66.104 in written or audio form, as applicable.

§ 66.114 Food sold in bulk containers.

(a) Bioengineered food sold in bulk containers (e.g., display case, bin, carton, and barrel), used at the retail level to present product to consumers, including a display at a fresh seafood counter, must use one of the disclosure options described in § 66.102, § 66.104, § 66.106, or § 66.108.

(b) The disclosure must appear on signage or other materials (e.g., placard, sign, label, sticker, band, twist tie, or other similar format) that allows consumers to easily identify and understand the bioengineered status of the food.

§ 66.116 Voluntary disclosure.

(a) *Disclosure of bioengineered food by exempt entities.* If a food on the List of

Bioengineered Foods is subject to disclosure, a very small food manufacturer, restaurant, or similar retail food establishment may voluntarily provide that disclosure. The disclosure must be in one or more of the forms described in this paragraph (a).

(1) A text disclosure, in accordance with § 66.102.

(2) A symbol disclosure, in accordance with § 66.104.

(3) An electronic or digital link disclosure, in accordance with § 66.106.

(4) A text message disclosure, in accordance with § 66.108.

(5) Appropriate small manufacturer and small and very small package disclosure options, in accordance with §§ 66.110 and 66.112.

(b) *Disclosure of foods derived from bioengineering.* For foods or food ingredients that do not meet paragraph (1) of the definition of bioengineered food in § 66.1, that do not qualify as a factor or condition under paragraph (2) of the definition of bioengineered food in § 66.1, that are not exempt from disclosure under § 66.5, and that are derived from a food on the List of Bioengineered Foods, regulated entities may disclose such foods with one of the disclosures described in this paragraph (b).

(1) A text disclosure with the following statement: ''derived from bioengineering'' or ''ingredient(s) derived from a bioengineered source.'' The word ''ingredient(s)'' may be replaced with the name of the specific crop(s) or food ingredient(s).

(2) A symbol disclosure using the following symbol:

Figure 1 to § 66.116

(3) An electronic or digital link disclosure, in accordance with § 66.106, provided that the disclosure is the text described in paragraph (b)(1) of this section or the symbol in Figure 1 to this section.

(4) A text message disclosure, in accordance with § 66.108, provided that the response is the text described in paragraph (b)(1) of this section or the symbol in Figure 1 to this section.

(5) Appropriate small manufacturer and small and very small package disclosure options, in accordance with §§ 66.110 and 66.112, provided that the disclosure is the text described in paragraph (b)(1) of this section or the symbol in Figure 1 to this section.

(c) *Appearance of disclosure.* The disclosure should be of sufficient size and clarity to appear prominently and conspicuously on the label, making it likely to be read and understood by the consumer under ordinary shopping conditions.

(d) *Recordkeeping.* Reasonable and customary records should be maintained to verify disclosures made under this section, in accordance with § 66.302.

§ 66.118 Other claims.

Nothing in this subpart will prohibit regulated entities from making other claims regarding bioengineered foods, provided that such claims are consistent with applicable Federal law.

Subpart C—Other Factors and Conditions for Bioengineered Food

§ 66.200 Request or petition for determination.

(a) Any person may submit a request or petition for a determination by the Administrator regarding other factors

and conditions under which a food is considered a bioengineered food. A request or petition must be submitted in accordance with § 66.204.

(b) The request or petition may be supplemented, amended, or withdrawn in writing at any time without prior approval of the Administrator, and without affecting resubmission, except when the Administrator has responded to the request or petition.

(c) If the Administrator determines that the request or petition satisfies the standards for consideration in § 66.202, AMS will initiate a rulemaking that would amend the definition of ''bioengineered food'' in § 66.1 to include the requested factor or condition.

(d) The Administrator's determination that the request or petition does not satisfy the standards for consideration in § 66.202 constitutes final agency action for purposes of judicial review.

§ 66.202 Standards for consideration.

In evaluating a request or petition, the Administrator must apply the applicable standards described in this section.

(a) The requested factor or condition is within the scope of the definition of ''bioengineering'' in 7 U.S.C. 1639(1).

(b) The Administrator must evaluate the difficulty and cost of implementation and compliance related to the requested factor or condition.

(c) The Administrator may consider other relevant information, including whether the requested factor or condition is compatible with the food labeling requirements of other agencies or countries, as part of the evaluation.

§ 66.204 Submission of request or petition.

(a) *Submission procedures and format.* A person must submit the request to the Agricultural Marketing Service in the form and manner established by AMS.

(b) *Required information.* The request or petition must include the information described in this paragraph (b).

(1) Description of the requested factor or condition.

(2) Analysis of why the requested factor or condition should be included in considering whether a food is a bioengineered food, including any relevant information, publications, and/or data. The analysis should include how the Administrator should apply the standards for consideration in § 66.202.

(3) If the request or petition contains Confidential Business Information (CBI), the submission must comply with the requirements of this paragraph (b)(3).

(i) The requester or petitioner must submit one copy that is marked as ''CBI Copy'' on the first page and on each page containing CBI.

(ii) The requester or petitioner must submit a second copy with the CBI deleted. This copy must be marked as ''CBI Redacted'' on the first page and on each page where the CBI was deleted.

(iii) The submission must include an explanation as to why the redacted information is CBI.

Subpart D—Recordkeeping

§ 66.300 Scope.

This subpart applies to records regarding mandatory and voluntary disclosures under this part for foods offered for retail sale in the United States.

§ 66.302 Recordkeeping requirements.

(a) *General.* (1) Regulated entities must maintain records that are customary or reasonable to demonstrate compliance with the disclosure requirements of this part.

(2) The records must be in electronic or paper formats and must contain sufficient detail as to be readily understood and audited by AMS.

(3) Records must be maintained for at least two years beyond the date the food or food product is sold or distributed for retail sale.

(4) Examples of customary or reasonable records that could be used to demonstrate compliance with the disclosure requirements of this part include, but are not limited to: Supply chain records, bills of lading, invoices, supplier attestations, labels, contracts, brokers' statements, third party certifications, laboratory testing results, validated process verifications, and other records generated or maintained

by the regulated entity in the normal course of business.

(b) *Recordkeeping requirements.* (1) If a food (including an ingredient produced from such food) is on the List of Bioengineered Foods, the regulated entity must maintain records regarding that food or food ingredient.

(2) If a food (including an ingredient produced from such food) bears a bioengineered food disclosure based on actual knowledge and is not on the List of Bioengineered Foods, regulated entities must maintain records for such food or food ingredient.

§ 66.304 Access to records.

(a) *Request for records.* When AMS makes a request for records, the entity must provide the records to AMS within five (5) business days, unless AMS extends the deadline.

(b) *On-site access.* If AMS needs to access the records at the entity's place of business, AMS will provide prior notice of at least three (3) business days. AMS will examine the records during normal business hours, and the records will be made available during those times. Access to any necessary facilities for an examination of the records must be extended to AMS.

(c) *Failure to provide access.* If the entity fails to provide access to the records as required under this section, the result of the audit or examination of records will be that the entity did not comply with the requirement to provide access to records and that AMS could not confirm whether the entity is in compliance with the bioengineered food disclosure standard for purposes of § 66.402.

Subpart E—Enforcement

§ 66.400 Prohibited act.

It is a violation of 7 U.S.C. 1639b for any person to knowingly fail to make a bioengineered food disclosure in accordance with this part.

§ 66.402 Audit or examination of records.

(a) Any interested person who has knowledge of or information regarding a possible violation of this part may file a written statement or complaint with the Administrator.

(1) Written statements or complaints filed with the Administrator must include the following:

(i) Complete identifying information about the product in question;

(ii) A detailed explanation of the alleged regulatory violation; and

(iii) Name and contact information of the person filing the statement or complaint.

(2) Written statements or complaints should be addressed to Director, Food Disclosure and Labeling Division, AMS Fair Trade Practices Program, 1400 Independence Avenue SW, Washington, DC 20250; or submitted through the NBFDS Compliance Portal on the AMS website at *https://www.ams.usda.gov/be*.

(3) The Administrator will determine whether reasonable grounds exist for an investigation of such complaint.

(b) If the Administrator determines that further investigation of a complaint is warranted, an audit, examination, or similar activity may be conducted with respect to the records of the entity responsible for the disclosures.

(c) Notice regarding records audits or examinations or similar activities will be provided in accordance with § 66.304(a) and (b).

(d) At the conclusion of the audit or examination of records or similar activity, AMS will make the findings available to the entity that was the subject of the investigation.

(e) If the entity that is the subject of the audit or examination of records or similar activity objects to any findings, it may request a hearing in accordance with § 66.404.

§ 66.404 Hearing.

(a) Within 30 days of receiving the results of an audit or examination of records or similar activity to which the entity that was the subject of the investigation objects, the entity may request a hearing by filing a request, along with the entity's response to the findings and any supporting documents, with AMS.

(b) The response to the findings of the audit or examination of records or similar activity must identify any objection to the findings and the basis for the objection.

(c) The AMS Administrator or designee will review the findings of the audit or examination of records or similar activity, the response, and any supporting documents, and may allow the entity that was the subject of the investigation to make an oral presentation.

(d) At the conclusion of the hearing, the AMS Administrator or designee may revise the findings of the audit or examination of records or similar activity.

§ 66.406 Summary of results.

(a) If the entity that was the subject of the audit or examination of records or similar activity does not request a hearing in accordance with § 66.404, or at the conclusion of a hearing, AMS will make public the summary of the final results of the investigation.

(b) AMS's decision to make public the summary of the final results constitutes final agency action for purposes of judicial review.

PART 70—VOLUNTARY GRADING OF POULTRY PRODUCTS AND RABBIT PRODUCTS

Subpart A—Grading of Poultry Products and Rabbit Products

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