

**DEPARTMENT OF AGRICULTURE****Agricultural Marketing Service****7 CFR Part 66**

[Doc. No. AMS–TM–17–0050]

RIN 0581–AD54

**National Bioengineered Food Disclosure Standard****AGENCY:** Agricultural Marketing Service, USDA.**ACTION:** Proposed rule.

**SUMMARY:** A recent amendment to the Agricultural Marketing Act of 1946 requires the Secretary of Agriculture (Secretary) to establish the national mandatory bioengineered (BE) food disclosure standard. The Agricultural Marketing Service (AMS) is proposing a new rule that would require food manufacturers and other entities that label foods for retail sale to disclose information about BE food and BE food ingredient content. The proposed rule is intended to provide a mandatory uniform national standard for disclosure of information to consumers about the BE status of foods. AMS seeks comments on the proposed rule. This proposed rule also announces AMS' intent to request approval by the Office of Management and Budget (OMB) of new information collection and recordkeeping requirements to implement the proposed BE food disclosure standard.

**DATES:** Comments on the proposed rule must be received by July 3, 2018. Pursuant to the Paperwork Reduction Act, comments on the information collection and recordkeeping burden must be received by July 3, 2018. AMS will conduct a webinar on this rulemaking, and further information regarding webinar details will be presented in a separate **Federal Register** notification.

**ADDRESSES:** Interested persons are invited to submit written comments concerning this proposed rule. Comments should be submitted via the Federal eRulemaking portal at [www.regulations.gov](http://www.regulations.gov). Comments may also be filed with the Docket Clerk, 1400 Independence Ave. SW, Room 4543-South, Washington, DC 20250; Fax: (202) 690–0338. All comments should reference the docket number and the date and page number of this issue of the **Federal Register** and will be available for public inspection in Room 4543-South, 1400 Independence Ave. SW, Washington, DC 20250 during regular business hours, or can be viewed at: [www.regulations.gov](http://www.regulations.gov).

**FOR FURTHER INFORMATION CONTACT:**

Email: [befooddisclosure@ams.usda.gov](mailto:befooddisclosure@ams.usda.gov); telephone: (202) 690–1300; or Fax: (202) 690–0338.

**SUPPLEMENTARY INFORMATION:** On July 29, 2016, Public Law 114–216 amended the Agricultural Marketing Act of 1946 (7 U.S.C. 1621 *et seq.*), as amended (amended Act), by adding Subtitles E and F. Subtitle E of the amended Act directs the Secretary to establish the National Bioengineered Food Disclosure Standard (NBFDS) for disclosing any BE food and any food that may be bioengineered. Subtitle E also directs the Secretary to establish requirements and procedures necessary to carry out the new standard. Additionally, the amended Act directs the Secretary to conduct a study to identify potential technological challenges related to electronic or digital disclosure methods. See 7 U.S.C. 1639b(c)(1). Subtitle F addresses Federal preemption of State and local genetic engineering labeling requirements. Subtitle F also specifies that certification of food under the U.S. Department of Agriculture's (USDA) National Organic Program (NOP) (7 CFR part 205) shall be considered sufficient to make claims about the absence of bioengineering in the food.

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**I. Introduction**

The Secretary delegated the authority for establishing and administering the NBFDS provided in the amended Act to the Agricultural Marketing Service (AMS). As part of the development of the proposed NBFDS, on June 28, 2017, AMS sought public input on 30 questions posted on its website (<https://www.ams.usda.gov/rules-regulations/be-questions>). The deadline for submitting input was August 25, 2017. AMS received over 112,000 responses from contributors with diverse backgrounds, including consumers; food manufacturers and retailers; farmers and processing operations; State and foreign governments; and associations representing various food manufacturers and retailers, farmers, and other interest groups. AMS posted the responses on its website. Pursuant to 7 U.S.C. 1639b(c), USDA, through Deloitte Consulting LLP, completed a study to identify potential technological challenges that may impact whether consumers would have access to the BE disclosure through electronic or digital disclosure methods. AMS posted the results of the study on its website on September 6, 2017 (<https://www.ams.usda.gov/reports/study-electronic-or-digital-disclosure>).

This notice of proposed rulemaking (NPRM) presents AMS' proposed requirements and procedures for the NBFDS to be codified at 7 CFR part 66. In developing this proposal, AMS was mindful that the purpose of the NBFDS is to provide a mandatory uniform disclosure standard for BE food to provide uniform information to consumers. In this regard, nothing in the disclosure requirements set out in this proposed rule conveys information about the health, safety, or environmental attributes of BE food

compared to non-BE counterparts. The regulatory oversight of USDA and other relevant Federal agencies ensures that food produced through bioengineering meets all relevant Federal health, safety, and environmental standards.

The responsibility to protect public health and the environment rests with the U.S. 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). The Coordinated Framework for Regulation of Biotechnology is a policy framework that summarized the roles and responsibilities of these three principal regulatory agencies with respect to regulating biotechnology products. Therefore, nothing in the requirements set out in this proposed rule for disclosure of BE food supports claims regarding the health, safety or environmental attributes of BE food compared to non-BE counterparts.

The proposed rule is intended to provide for disclosure of foods that are or may be bioengineered in the interest of consumers, but also seeks to minimize implementation and compliance costs for the food industry—costs that could be passed on to consumers. To that end, AMS has tried to craft requirements that are clear and straightforward, incorporating flexibility where appropriate. Public input has been invaluable to this effort, and public comments submitted in response to this proposed rule will be critical in the development of a final rule.

The discussion of the proposed NBFDS is divided into three parts: (1) Applicability; (2) disclosure; and (3) administrative provisions. In determining whether a product would be required to bear a disclosure under the NBFDS, potentially regulated entities should consult the following questions or undertake the following analysis:

- (1) Who is responsible for the disclosure? (Part III.A.1.)
- (2) Is the particular product at issue a "food"? (Part II.B.)
- (3) Does the food fall within the scope of the NBFDS? (Part II.B.)
  - a. Is the food subject to the labeling requirements under the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301?
  - b. Is the food subject to the labeling requirements under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products

Inspection Act (21 U.S.C. 1031 *et seq.*), with certain exceptions?

- (4) Is the food a BE food? (Part II.C.)
  - a. Does the food appear on either of the two AMS lists of BE foods that are commercially available in the U.S.? (Part II.D.)
  - b. Do other factors or conditions exist that affect the food's BE status? (Part II.C.2.)

(5) Does the amount of a bioengineered substance that may be present in the food exceed the threshold? (Part II.D.3.)

(6) Are there any applicable exemptions? (Part II.D.)

A full discussion of the above analysis follows, and AMS invites comment on the proposed requirements and procedures, alternatives that are offered, and on any specific questions that are raised for comment.

## II. Applicability: What is to be disclosed?

The amended Act directs USDA to promulgate regulations regarding foods required to bear a disclosure indicating that the food is bioengineered or may be bioengineered. 7 U.S.C. 1639b(b). At the outset, the amended Act establishes the scope of the NBFDS by defining "bioengineering" and "food," and by limiting the food subject to disclosure to those foods subject to the labeling requirements in the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.*, and to certain foods subject to labeling under three statutes administered by USDA's Food Safety and Inspection Service (FSIS).<sup>1</sup> 7 U.S.C. 1639 and 1639a. In proposed subpart A, AMS includes the definitions that would be pertinent to the proposed new regulatory section (part 66), describes the foods that would be subject to disclosure, and explains the exemptions that would be applicable.

### A. Definitions

Proposed § 66.1 lists the definitions that would apply to proposed part 66. Each term defined in proposed § 66.1 is discussed in the section of the NPRM where the term is used. For subpart A, the key terms are "bioengineered food," "bioengineered substance," "food," "label," "predominance," "similar retail food establishment," "very small food manufacturer," "list of commercially available bioengineered foods not highly adopted," and "list of commercially available bioengineered foods with a high adoption rate." Those terms are

<sup>1</sup> The three statutes are: the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), and the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

critical in determining what foods would require a BE food disclosure.

### B. Food Subject to Disclosure

To understand whether a food is subject to the labeling requirements of the amended Act, we must consider as a preliminary matter whether the product at issue is a "food." The amended Act codified the definition of "food" as "a food (as defined in section 321 of title 21) that is intended for human consumption."<sup>2</sup> 7 U.S.C. 1639(2). The proposed rule would adopt the same definition of "food" as used in the amended Act.

The FDCA defines "food" as ". . . (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." 21 U.S.C. 321(f). Ultimately, the U.S. Food and Drug Administration (FDA) has jurisdiction over the FDCA and has the authority to determine what is considered "food" under the FDCA. AMS intends to defer to FDA in interpreting the definition of "food." However, the amended Act limits the definition of food to articles used for human consumption and does not include articles used for animals. Therefore, although pet food and animal feed are "food" under the FDCA, such foods for animals would not be covered by this proposed regulation, pursuant to the amended Act. Chewing gum, is considered to be "intended for human consumption," and it is therefore considered a "food" for the purpose of the NBFDS.

Under the FDCA, the definition of "food" includes both articles used for food or drink and articles used for components of any such article. For instance, a raw agricultural commodity such as an apple constitutes food under FDCA. A processed item like a soup with the following ingredients—water, broccoli, vegetable oil, modified food starch, and wheat flour—is also a food, as are each of those ingredients. Other examples of "food" under the FDCA include dietary supplements, processing aids, and enzymes.

Not all food within the FDCA's definition would be within the scope of the NBFDS. The amended Act limits the disclosure to (1) food that is subject to the labeling requirements of the FDCA; or (2) food that is subject to the labeling requirements of the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products

<sup>2</sup> The original text of the amended Act referred to section 201 of the FDCA, but the reference was changed to section 321 of title 21 in the codification of the statute.

Inspection Act (21 U.S.C. 1031 *et seq.*), with certain exceptions, as set forth in the amended Act. *See* 7 U.S.C. 1639a. As for the FDCA, which is under FDA jurisdiction, the NBFDS would apply to all foods subject to its labeling requirement, including but not limited to raw produce, seafood, dietary supplements, and most prepared foods, such as breads, cereals, non-meat canned and frozen foods, snacks, desserts, and drinks. The amended Act also specifies that the NBFDS only applies to foods subject to the labeling requirements of the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*) if the most predominant ingredient of the food would independently be subject to the labeling requirements under the FDCA; or if 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. *See* 7 U.S.C. 1639a.

AMS is proposing to use the same methods FDA uses to identify predominance at 21 CFR 101.4(a)(1), which states: “Ingredients required to be declared on the label or labeling of a food, including foods that comply with standards of identity, except those ingredients exempted by § 101.100, shall be listed by common or usual name in descending order of predominance by weight on either the principal display panel or the information panel in accordance with the provisions of § 101.2. . . .” The proposed definition of “predominance” for the NBFDS follows this same approach. Thus, a multi-ingredient food product that contains meat, poultry, or egg product, subject to the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act, respectively, as the first ingredient of the ingredient list on the food label would not be subject to the NBFDS, per the amended Act.

A multi-ingredient food product that contains broth, stock, water, or similar solution as the first ingredient, and a meat, poultry, or egg product as the second ingredient on the food label would also not be subject to the NBFDS. For example, a canned ham where pork is the primary ingredient followed by other ingredients such as corn syrup, would not be subject to the NBFDS. Although the corn syrup may be bioengineered, because pork, which is subject to the labeling requirements of the Federal Meat Inspection Act, is the

predominant ingredient, the product is not subject to the NBFDS, pursuant to the amended Act. If, however, a meat, poultry, or egg ingredient is the third most predominant ingredient, or lower, the food would be subject to the NBFDS. For example, a soup with the following ingredient list—broth, carrots, chicken, etc.—would be subject to disclosure under the NBFDS, and the analysis as to whether it would be considered a “bioengineered food” subject to the NBFDS’s disclosure requirements would continue.

Seafood, except Siluriformes, and meats such as venison and rabbit are subject to the FDCA (and not the Federal Meat Inspection Act) and thus, a multi-ingredient food product that contains one of these as the first ingredient would be subject to the NBFDS. Thus, a multi-ingredient food product that contains one of these foods as either a first ingredient or a less predominant ingredient would require disclosure, unless the product is otherwise exempt (for example, due to the predominance of another ingredient, such as beef or chicken, as described above).

### C. Bioengineered Food

The amended Act delegates authority to the Secretary to establish the NBFDS regarding “bioengineered food.” 7 U.S.C. 1639b(a). This authority includes the ability to define “bioengineered food,” consistent with the statutory provisions that address this term. The amended Act also authorizes the Secretary to determine other terms that are similar to “bioengineering.” 7 U.S.C. 1639(1). AMS is not proposing any similar terms.

#### 1. Definition of “Bioengineering” and “Bioengineered Food”

The amended Act defines “bioengineering” with respect to a food, as referring to a food “(A) that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques; and (B) for which the modification could not otherwise be obtained through conventional breeding or found in nature.” 7 U.S.C. 1639(1). In accordance with its statutory mandate and for purposes of consistency, AMS proposes to directly incorporate this statutory definition into the definition of “bioengineered food” without further interpretation of what “bioengineering” means, but welcomes public comment on what could be considered to constitute “bioengineering.”

Responses to AMS’ 30 questions disclosed wide differences in public opinion about how the statutory

definition of “bioengineering” should be interpreted and applied to the definition of “bioengineered food.” Specifically, respondents offered conflicting views on highly refined foods and ingredients, and whether those products should fall within the definition, thus subjecting those foods and ingredients to disclosure. The following discussion provides an overview of the two prevailing viewpoints.

#### Position 1

One position adopted by respondents is that highly refined products do not “contain genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques.” These commenters reasoned that those products have undergone processes that have removed genetic material such that it cannot be detected using common testing methods; therefore, highly refined products do not fall within the statutory definition of “bioengineering” and are exempt from the standard’s disclosure requirement. Commenters cited scientific studies showing that modified genetic material (DNA) could not be detected using common testing methods on highly refined products after the refinement process.<sup>3</sup> Another argument is that by nature of the intended food product, these particular highly refined foods generally either do not contain nucleic acids or contain minute amounts of foreign material, which could result in incidental detection of DNA due to inadvertent transfer during the refinement process. Thus proponents of this argument conclude that presence of incidental or trace amounts of DNA should not be within the scope of the definition.

Commenters also stated that highly refined products made from BE crops, such as sucrose; dextrose; corn-starch;

<sup>3</sup> For example, with regard to sugar, some studies failed to detect transgenes during sugar crystallization processes in genetically modified sugar crops. *See* Joyce, P.A., Dinh, S.-Q., Burns, E.M. and O’Shea M.G. (2013), “Sugar from genetically modified sugar cane: Tracking transgenes, transgene products and compositional analysis”, *Proc. Int. Soc. Sugar Cane Technol.*, Vol. 28, pp. 1–9; *see also* Klein, J., Altenbuchner, J. and Mattes, R. (1998), “Nucleic acid and protein elimination during the sugar manufacturing process of conventional and transgenic sugar beets”, *J. Biotechnology*, Vol. 60, pp. 145–153; *see also* Oguchi, T., Chikagawa, Y., Kodama, T., Suzuki, E., Kasahara, M., Akiyama, H., Teshima, R., Futo, S., Hino, A., Furui, S. and Kitta, K. (2009), “Investigation of residual DNAs in sugar from sugar beet (*Beta vulgaris* L.)”, *J. Food Hyg. Soc. Japan*, Vol. 50, pp. 42–46; *see also* Taylor, G.O., Joyce, P.A., Sedl, J.M. and Smith, G.R. (1999), “Laboratory crystallised sugar from genetically engineered sugar cane does not contain transgene DNA”, *Proc. Aust. Soc. Sugar Cane Technol.*, Vol. 21, pp. 502.

high-fructose corn syrup; and corn, canola, and soybean oils, are chemically identical to those made from non-BE crops, regardless of the production method (bioengineered or conventional) used to produce the crops. For instance, according to commenters, refined sugar produced from bioengineered sugarbeets is—at the end of the refining process—exactly the same as refined sugar produced from non-bioengineered sugarbeets: both refined products are sucrose, and they are chemically and molecularly indistinguishable from one another.

In summary, proponents of these points of view argue that highly refined products are not within the scope of “bioengineering” because they do not “contain[] genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques,” and therefore do not require disclosure as “bioengineered food” under the NBFDS. *See* 7 U.S.C. 1639(1).

#### Position 2

Another viewpoint contends that the scope of the definition of “bioengineering” includes all foods produced from bioengineering, such as highly refined products. One basis for this viewpoint is that highly refined products, for example, a sugar beet, contains modified genetic material before it is processed; therefore, one could suppose the resulting product (sugar) would contain at least some trace amount of genetic material from the BE sugar beet. Whether genetic material is detectable may depend on the characteristics of the refinement process, as well as the sample and the testing method applied. Some commenters assert that although a test may not detect the modified genetic material, it does not necessarily mean that there is no modified genetic material in the food. In addition, proponents of this position argue that science is inconclusive about whether or not highly refined ingredients contain modified DNA, and they cite studies that genetic material can be found present in highly refined oils and sugars.<sup>4</sup> Therefore, these proponents

<sup>4</sup> A study published in 2014 found that minute quantities of sugar cane DNA were detected in raw sugar after industrial scale refining of sugar cane into raw sugar. *See* Cullis, C., Contento, A., Schell, M., DNA and Protein Analysis throughout the Industrial Refining Process of Sugar Cane. *International Journal of Agricultural and Food Research*, North America, 3, Jul. 2014. Available at: <https://www.sciencetarget.com/journal/index.php/IJAfr/article/view/437>.

With regards to oils, one study detected amplifiable DNA in all the stages of chemical refining of crude soybean oil by end-point and real-

believe there should be a presumption that these products meet the statutory definition of “bioengineering” and are therefore BE foods.

AMS invites comment on these two different positions on how to interpret the statutory definition of “bioengineering,” and thus the scope of the regulatory definition of “bioengineered food.” In particular, AMS is interested in any additional studies conducted on this issue, the cost of implementation under each policy, and whether certain policies describing the scope of foods subject to the disclosure standard would lower costs to affected entities. In addition, we request public comment on whether one position is a better interpretation of the statutory definition. For USDA’s estimate of the cost of implementation under each position, please see the accompanying Regulatory Impact Analysis.

#### Conventional Breeding

As to the component terms of the definition of “bioengineering,” AMS seeks comment on whether the NBFDS should include a definition for “conventional breeding,” and if so, what it should be. While AMS has not included a definition of “conventional breeding” in this proposal, we welcome comments on whether there should be a definition for “conventional breeding” and, if so, what that definition should be. Possible definitions could be “traditional breeding techniques, including, but not limited to, marker-assisted breeding and chemical or radiation-based mutagenesis, as well as tissue culture and protoplast, cell, or embryo fusion,” or “traditional methods of breeding or crossing plants, animals, or microbes with certain desired characteristics for the purpose of generating offspring that express those characteristics,” or EPA’s definition of conventional breeding in its regulations for plant-incorporated protectants in 40 CFR 174.3: “the creation of progeny through either: The union of gametes, *e.g.*, syngamy, brought together through processes such as pollination, including bridging crosses between plants and wide crosses, or vegetative reproduction. It does not include any of the following technologies: Recombinant DNA; other techniques wherein the genetic material is extracted from an organism and introduced into the genome of the recipient plant through, for example, micro-injection, macro-injection, micro-encapsulation; or cell fusion.” AMS seeks comment on

time PCR techniques. J. Costa, I. Mafra, J.S. Amaral, M. Beatriz, M.B.P.P. (2010).

whether a definition of “conventional breeding,” if included in the regulations implementing the NBFDS, should be limited to methods currently used to propagate or modify existing genetics.

#### “Found in Nature”

As to the component terms of the definition of “bioengineering,” AMS seeks comment on whether the NBFDS should include a definition for “found in nature,” and if so, what it should be. Although this concept is not included in the proposed regulatory text, AMS seeks comment on whether to consider intellectual property law as one potential method of determining whether a genetic modification could be found in nature. Based on a U.S. Supreme Court decision, the U.S. Patent and Trademark Office issued guidance to its examiners,<sup>5</sup> that products of nature are not patentable subject matter under 35 U.S.C. 101. AMS believes that there are similarities in how a product of nature is interpreted for purposes of patent eligibility and how a modification could be found in nature for purposes of determining whether a modification is bioengineered. Therefore, for purposes of this standard, AMS would be able to use intellectual property protection under 35 U.S.C. 101 to inform its decision about whether a modification “could not otherwise be found in nature” (for those food products that have been granted intellectual property protection). 7 U.S.C. 1639(1).

If we were to apply this concept, AMS would limit its consideration to patents under 35 U.S.C. 101, which excludes the intellectual property protections obtained by plant patents and plant variety protection certificates. AMS is aware that there are many non-BE plants that have intellectual property protection, including plant and utility patents, and is not suggesting that intellectual property protection means a plant is BE. Conversely, AMS is also aware that developers of many BE plants may not pursue intellectual property protection. Whether a modification has intellectual property protection under 35 U.S.C. 101 would be just one method in making a determination about whether a specific modification could be found in nature.

<sup>5</sup> *See* U.S. Patent and Trademark Office’s 2014 Interim Guidance on Patent Subject Matter Eligibility, 79 FR 74618, 74622–24 (Dec. 16, 2014), and the May 4, 2016, Memorandum from Deputy Commissioner for Patent Examination Policy to Patent Examining Corps titled “Formulating a Subject Matter Eligibility Rejection and Evaluating the Applicant’s Response to a Subject Matter Eligibility Rejection” (<https://www.uspto.gov/sites/default/files/documents/ieg-may-2016-memo.pdf>).

AMS invites comment on this approach of using intellectual property protections as a method in determining whether a modification could not otherwise be found in nature, including specific comments on whether it should distinguish between the different categories of patents available under 35 U.S.C. 101. AMS also invites comment on other possible definitions or methods of determining whether a specific modification could not otherwise be found in nature.

## 2. Lists of Bioengineered Foods

Recognizing the complexity of the definition of “bioengineering,” and in an attempt to make it easier and less burdensome for consumers and regulated entities alike to understand what products may need to be disclosed under the NBFDS, AMS has applied the definition of “bioengineered food” outlined above to determine which foods would be subject to BE disclosure by developing (1) a proposed list of BE foods that are commercially available in the United States with a high adoption<sup>6</sup> rate and (2) a proposed list of BE foods that are commercially available in the United States that are not highly adopted. Only foods or products on either of those lists or made from foods on either of the lists would be subject to disclosure under the NBFDS. Thus, regulated entities would only need to determine whether the consumer-facing end product, or an ingredient used in the end product, is on either of the lists or is produced using foods on either of the lists. Ultimately, the BE food lists would serve as the linchpin in determining whether a regulated entity would need to disclose a BE food under the NBFDS.

To compile the proposed lists, AMS considered data reported by USDA’s Economic Research Service (ERS),<sup>7</sup> data published by the International Service for the Acquisition of Agri-biotech Applications (ISAAA),<sup>8</sup> and FDA’s list of Biotechnology Consultations on Food from GE Plant Varieties.<sup>9</sup> AMS also considered input from industry stakeholders and consumers about which BE foods should require disclosure labeling. BE foods on the proposed initial lists (1) are included in FDA’s list of Biotechnology

Consultations on Food from GE Plant Varieties<sup>10</sup> (2) are produced anywhere in the world, and (3) are commercially available for retail sale in the United States. In proposing the lists, we are attempting to capture the foods on the market that meet the statutory definition of “bioengineering” based on existing technology. The various considerations and the definition we have proposed for “bioengineered food” earlier would be used to determine what foods would be required to bear a BE disclosure moving forward, when new technologies may emerge. (See Treatment of Technologies section, below.) AMS would maintain the lists on its website.

AMS is proposing that the following BE foods be considered highly adopted. Their U.S. adoption rates according to 2016 ERS and ISAAA data are included.

Commercially Available BE Foods—  
Highly Adopted  
Canola—90%  
Corn, Field—92%  
Cotton—93%  
Soybean—94%  
Sugar Beet—100%

Proposed § 66.1 would define this list as one maintained by AMS and as consisting of commercially available BE foods that have an adoption rate of eighty-five percent (85%) or more in the United States, as determined by the Economic Research Service or any successor agency. This list would be an acknowledgement that there is a subset of BE foods commercially available in the United States that are highly adopted in food production. ERS has reported that U.S. plantings of those crops have averaged more than 85 percent bioengineered cultivars since 2012. Thus, AMS believes it is reasonable to assume that foods produced from those crops are likely bioengineered and should be labeled accordingly. (See Disclosure section, below)

AMS intends that this particular list would identify crops and foods generally (*e.g.* field corn and soybean) and would not list the specific derivatives or all the varieties of the crops and foods (*e.g.* corn starch and soy meal). However, foods containing derivatives of the crops would be subject to the same disclosure

requirement as foods on the list. For example, since 92% of the field corn produced in the United States is bioengineered, foods made from or containing ingredients made from field corn are likely to contain BE corn. Those foods might include corn starch, cornmeal, corn syrup, grits, corn chips, corn tortillas, and corn cereal, among others, and would be subject to BE disclosure.

Some BE crops that are commercially available in the U.S would not be considered highly adopted, since their market prevalence does not appear to be 85 percent or more, as suggested by ERS and ISAAA reports, as well as other published industry information. For that reason, AMS proposes to also maintain a list of commercially available, but not highly adopted, BE foods. AMS proposes to include the following in that list:

Commercially Available BE Foods—  
Not Highly Adopted  
Apple, Non-browning cultivars  
Corn, Sweet  
Papaya  
Potato  
Squash, Summer varieties

Proposed § 66.1 would define this list as one maintained by AMS and as consisting of commercially available BE foods with an adoption rate of less than eighty-five percent (85%) in the United States, as determined by the Economic Research Service or any successor agency. Where practical, AMS would delineate the foods on the commercially available, but not highly adopted, BE foods list by specifying that only certain cultivars of those crops would be subject to the disclosure and recordkeeping requirements of the proposed rule. For instance, since information available at the time of this writing indicates that bioengineered versions of squash include only summer squash varieties,<sup>11</sup> summer squash would be the only squash included on the list of commercially available, but not highly adopted, BE foods. If BE cultivars of winter squashes were developed and made commercially available in the United States, AMS could revise the list to include them through the process described in the following section.

## List Maintenance and Revision

We are cognizant that biotechnology is a dynamic industry and that developments in biotechnology would likely render the lists obsolete over time if AMS does not update them periodically; thus, AMS would establish

<sup>6</sup> Adoption refers to the prevalence with which BE cultivars of a food crop are planted or produced in the United States, relative to the number of non-BE cultivars of the same crop in production.

<sup>7</sup> <https://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us.aspx>; accessed February 5, 2018.

<sup>8</sup> ISAAA Brief 52: Global Status of Commercialized Biotech/GM Crops: 2016.

<sup>9</sup> <https://www.accessdata.fda.gov/scripts/fdcci/set=Biocon>; accessed February 5, 2018.

<sup>10</sup> We note that not all bioengineered plant varieties for use in food have completed FDA’s Biotechnology Consultation on Food Derived from GE Plant Varieties program. Some have gone through the New Dietary ingredient, food additive petition or GRAS notice review processes (for example, GLA safflower), so FDA’s Biotech consultation program is not a complete list of all bioengineered food plants. We also note that FDA’s consultation process is voluntary and does not capture the full range of GE plant varieties on the market.

<sup>11</sup> ISAAA Brief 52: Global Status of Commercialized Biotech/GM Crops: 2016.

a process whereby the two lists would be reviewed and revised on an annual basis. Following a notification in the **Federal Register**, interested parties would be invited to recommend additions to and subtractions from the two lists and to provide data supporting those recommendations. Supporting data might include information about commercial availability through domestic production or importation. AMS would publish any recommendations, along with relevant data and other information submitted, on its website, and would solicit comments on the recommendations. AMS would review submissions and comments from interested parties, and would review available data from other sources to determine whether revisions to the lists would be appropriate. Final notification regarding revisions to the lists would be published in the **Federal Register**. Proposed § 66.7(c) would provide for an 18-month grace period to allow regulated entities time to revise food labels appropriately following revisions to the two lists of commercially available BE foods in the U.S.

#### Treatment of Technologies

As to specific technologies, AMS recognizes that technologies continue to evolve, and that food produced through a specific technology may or may not meet the definition of BE food. The proposed process for establishing and amending the BE food lists would provide a vehicle by which AMS could evaluate whether a particular crop meets the definition of “bioengineering.” As part of this process for amending the BE food lists, AMS would consult with the U.S. Government agencies responsible for oversight of the products of biotechnology—USDA—APHIS, EPA, FDA and appropriate similar successor members of the Coordinated Framework for the Regulation of Biotechnology—to understand if foods resulting from the new technologies would be consistent with the definition of “bioengineered food” and would be commercially available.

#### Request for Comments on the Lists

AMS solicits comments on several aspects of the proposed lists, including the composition of the lists and whether the proposed cutoff at 85 percent adoption rate would support the presumption that the food is BE and thus would be appropriate for identifying foods on the list of highly adopted BE foods. We are interested in whether another percentage rate would be more appropriate. We also seek

comments on the potential impact and any burdens associated with maintaining separate lists for high and non-high adoption BE foods.

It is possible that BE foods produced in the United States or in other countries do not appear on the proposed initial lists, but may be commercially available in the United States and should be added to the lists. AMS solicits input on the criteria used to create the lists, what foods should be listed, and on how best to identify those foods. AMS also seeks comments on whether the lists, as defined by foods commercially available in the United States, should be expanded to include foods produced in other countries, and if so, what would be the rationale to utilize an international list of foods for the NBFDS and what would be the sources for obtaining accurate data about BE foods produced abroad. AMS invites comments on how often the lists should be reviewed and revised, as well as timeframes for compliance when foods are added to or deleted from these two lists.

AMS is aware that there are food that have completed FDA’s voluntary premarket consultation process for food from GE plant varieties, or FDA’s new animal drug approval process, such as rice cultivars, pink-fleshed pineapple cultivars, and salmon, but we have not included them on the initial lists of commercially available foods because we have no indication that they are currently commercially available. AMS seeks comments on whether these foods should be included on the initial list of commercially available BE foods that are not highly adopted. As well, comments are sought on practical ways to distinguish subsets of BE cultivars from non-BE cultivars, so as to minimize the compliance burden for regulated entities.

AMS is aware that some foods produced through bioengineering may not necessarily be produced as crops in the same way that foods currently on the two lists are produced. For example, many enzymes, yeast, and a number of foods produced in controlled environments are produced using bioengineering. AMS seeks comments on whether such foods should be included on the lists and how AMS should describe them if added to either list. We request any information or data that may support the development of BE foods lists that promote the lowest cost policy and what the cost estimates of such lists may be.

#### 2. Factors and Conditions

In promulgating a regulation to carry out the standard, the amended Act

directs the Secretary to establish a process for requesting and granting a determination by the Secretary regarding other factors and conditions under which a food is considered a BE food. 7 U.S.C. 1639b(b)(2)(C). The amended Act does not specify the process by which the Secretary will determine other factors and conditions under which a food is considered a BE food; rather, it provides the Secretary with discretion in setting up such a process.

Proposed Subpart C would describe the process by which people can submit a request or petition for a determination regarding other factors or conditions. The acceptance of a request or petition for determination regarding a factor or condition would then culminate in rulemaking to incorporate the factor or condition into the “bioengineered food” definition. Rulemaking would allow for transparency and public participation in determining whether or not the definition of “bioengineered food” should be amended. Ultimately, the impact of adopting the proposed factors or conditions (as follows) would be to limit the scope of the definition of “bioengineered food,” thus potentially excluding certain products from disclosure.

Under proposed § 66.200, the determination process would begin with the submission of a request or petition for determination regarding other factors and conditions under which a food is considered a BE food in accordance with proposed § 66.204. Proposed § 66.204 describes the process for submitting a request or petition, including where to send the submission. The submission would need to include a description and analysis of the requested new factor or condition and any supporting document or data. Proposed § 66.204 would describe how to properly mark confidential business information that may be included to support the request, to ensure its confidentiality. Finally, proposed § 66.204 instructs that the submission would need to explain how the standards for consideration apply to the requested factor or condition.

Because the amended Act provides no criteria for the Secretary to determine other factors and conditions under which a food is considered a BE food, for purposes of transparency, proposed § 66.202 describes the standards for consideration by which the Secretary’s designee, the AMS Administrator, would evaluate the request or petition. Given the already existing statutory definition of “bioengineering,” the first standard, in proposed paragraph (a), would require the requested factor or

condition to be within the scope of the definition of “bioengineering” in 7 U.S.C. 1639(1). The second standard, in proposed paragraph (b), would require the Administrator to evaluate the cost of implementation and compliance. In applying this second standard, the Administrator would evaluate the cost related to the factor or condition, the difficulty for affected food manufacturers and importers to implement the factor or condition, especially small businesses, and the difficulty AMS would have in monitoring compliance with the factor or condition. Proposed paragraph (c) would allow the Administrator to consider other relevant information as part of the evaluation. Relevant information for a particular proposed factor or condition would include its compatibility with the food labeling requirements of other Federal agencies or foreign governments. In determining compatibility with other requirements, AMS would consult with the U.S. Government agencies responsible for oversight of the products of biotechnology: USDA–APHIS, EPA, and FDA. Such information may allow AMS to align the NBFDS with the standards of other Federal agencies or foreign governments, which may facilitate interstate commerce and trade by allowing for recognition of compatible standards.

The Administrator would also consult with the United States Trade Representative (USTR) to ensure the request or petition regarding other factors and conditions related to BE disclosure requirements results in implementation in a manner consistent with international trade obligations as mandated by 7 U.S.C. 1639c(a). If the Administrator determines that the request or petition satisfies the standards for consideration, AMS would initiate rulemaking that seeks to amend the definition of “bioengineered food” in proposed § 66.1 to include the factor or condition.

Among public comments AMS received in response to the 30 questions were requests that we include certain factors or conditions for consideration. AMS believes that two of the submitted requests may satisfy the proposed standards and may constitute factors and conditions under which a food is considered a BE food. Those requests involved (1) whether incidental additives present in food should be considered “bioengineered food” and labeled accordingly; and (2) whether the modified genetic material in a highly refined food may be detected. The proposed definition of “bioengineered food” includes the first requested factor

or condition (incidental additives), but does not include the second (detection). AMS seeks comment on whether the final rule should incorporate one or both of them into the definition. The impact of adopting these factors or conditions would be to limit the scope of the definition of “bioengineered food,” thus potentially excluding certain products from disclosure.

#### a. Incidental Additives

The first factor or condition concerns a BE food that is an incidental additive. As described in 21 CFR 101.100(a)(3), incidental additives that are present in food at an insignificant level and do not have any technical or functional effect in the food are exempt from certain labeling requirements under the FDCA. Commenters in response to AMS’ 30 questions requested that incidental additives not be subject to disclosure under the proposed NBFDS because they are exempt from inclusion in the ingredient statement on a food label, according to 21 CFR 101.100(a)(3). AMS is aware that an ingredient that is required to be listed in the ingredient list in one instance may be used in another product as an incidental additive that is not required to be included in the ingredient list. Under this proposed factor or condition, such an item would only trigger disclosure when it is used as an ingredient that is included on the ingredient list, not when used as an incidental additive.

Application of this factor or condition would fall within the scope of the definition of “bioengineering” in 7 U.S.C. 1639(1), and thus meets the first standard for consideration. This factor or condition may also satisfy the second standard for consideration—cost of implementation and compliance. Aligning the disclosure requirements of the NBFDS with the ingredient declaration requirements under applicable FDA regulations may simplify compliance and reduce labeling costs for regulated entities. Finally, AMS finds it relevant that adoption of this factor or condition may be compatible with the food labeling requirements of other Federal agencies and some foreign governments.

The impact of adopting this proposed factor or condition as not being within the definition of “bioengineered food” would be to exclude certain incidental additives from disclosure. Based on public comments, AMS believes adopting this factor or condition may exempt a number of enzymes that are currently used in food production but not currently listed in the ingredient statement on a food label. However, based on those same comments, AMS is

aware that some enzymes may be used in a manner that requires them to be labeled on the ingredient statement. If this proposed factor or condition is adopted, AMS believes that enzymes that are required to be listed on the ingredient list would be subject to disclosure. As such, AMS seeks comment on whether, more generally, enzymes present in food should be considered “bioengineered food.” As a result, we are proposing that ingredients exempt from labeling pursuant to 21 CFR 101.100(a)(3) would not be required to be disclosed under this regulation, unless the incidental additive would require disclosure pursuant to other labeling requirements under the FDCA.

#### b. Undetectable Recombinant DNA

Several responses to the 30 questions requested that the NBFDS exclude food where the modified genetic material cannot be detected. Those responders cited research that found that refined sugar may not contain recombinant DNA.<sup>12</sup> Should AMS ultimately decide to include highly refined ingredients within the definition of “bioengineered food,” (see Part II.C.1 above) this factor or condition, if adopted, would be a means to potentially exclude products where modified genetic material cannot be detected.

Were AMS to ultimately adopt “Position 2” as discussed above, AMS believes that this requested factor or condition would be consistent with the statutory definition of “bioengineering” in that the food product would be presumed to contain modified genetic material. Therefore, in applying the standards for consideration, this factor or condition would be within the scope of the definition of “bioengineering” in 7 U.S.C. 1639(1).

This requested factor or condition may also satisfy the second standard as it could impact the cost of compliance. If regulated entities can demonstrate that the manufacturing process results in a final product where the modified genetic material cannot be detected and their records prove as such, food subjected to that process would no longer be considered a bioengineered food.

<sup>12</sup> See Klein, J., Altenbuchner, J. and Mattes, R. (1998), “Nucleic acid and protein elimination during the sugar manufacturing process of conventional and transgenic sugar beets”, *J. Biotechnology*, Vol. 60, pp. 145–153; see also Oguchi, T., Chikagawa, Y., Kodama, T., Suzuki, E., Kasahara, M., Akiyama, H., Teshima, R., Futo, S., Hino, A., Furu, S. and Kitta, K. (2009), “Investigation of residual DNAs in sugar from sugar beet (*Beta vulgaris* L.)”, *J. Food Hyg. Soc. Japan*, Vol. 50, pp. 41–43.



To demonstrate that modified genetic material cannot be detected, AMS proposes that regulated entities would need to maintain records showing that food subjected to a specific process has been tested for that purpose by a laboratory accredited under ISO/ICE 17025:2017 standards, using methodology validated according to Codex Alimentarius guidelines.<sup>13</sup> AMS seeks comment on inclusion of this proposed factor, which would exclude from the disclosure standard food products that demonstrate that modified genetic material cannot be detected, including how difficult it would be for regulated entities, especially small businesses, to implement it. We also seek comment on alternative suggestions for other methods of demonstrating that modified genetic material cannot be detected.

Finally, AMS understands that several foreign governments exempt food from BE disclosure where the bioengineered genetic material has been removed. For example, South Korea has a process to exempt food from disclosure if a food manufacturer submits a document confirming that a product or a raw ingredient does not contain a foreign DNA or protein; the supporting document can be based upon a test result or substance purification document. Australia and New Zealand do not require BE foods to be labeled as such when the BE food “has been highly refined where the effect of the refining process is to remove novel DNA or novel protein” and the final product does not differ from a non-BE version (Australia New Zealand Food Standards Code—Standard 1.5.2). If the final product is different from a non-BE version, such as high oleic soybean oil or high lysine corn, the product is subject to BE labeling. *Id.* AMS may consider compatibility with the standards of foreign countries that are the United States’ trading partners as relevant information in evaluating this requested factor or condition.

#### D. Exemptions

The amended Act includes two express exemptions to the disclosure

<sup>13</sup> Codex Alimentarius *Guidelines on Performance Criteria and Validation of Methods for Detection, Identification and Quantification of Specific DNA Sequences and Specific Proteins in Foods* (CAC/GL 74–2010).

requirement: food served in a restaurant or similar retail food establishment and very small food manufacturers. 7 U.S.C. 1639b(b)(2)(G). Proposed § 66.5 would incorporate those exemptions into the NBFDS. Therefore, food served in a restaurant or similar retail food establishment and very small food manufacturers would not be required to display any form of disclosure. The amended Act also authorizes the Secretary to “determine the amounts of a bioengineered substance that may be present in food, as appropriate, in order for the food to be a bioengineered food.” 7 U.S.C. 1639b(b)(2)(B). As discussed below, foods with amounts of BE substance below an established threshold level would also be exempt from disclosure under the NBFDS.

The amended Act also prohibits a food derived from an animal to be considered a BE food solely because the animal consumed feed produced from, containing, or consisting of a bioengineered substance. 7 U.S.C. 1639b(b)(2)(A). Finally, Subtitle F also specifies that certification of food under the U.S. Department of Agriculture’s (USDA) National Organic Program (NOP) (7 CFR part 205) shall be considered sufficient to make claims about the absence of bioengineering in the food. 7 U.S.C. 6524. AMS proposes that § 66.5 include these as regulatory exemptions.

#### 1. Food Served in a Restaurant or Similar Retail Food Establishment

The exemption in proposed § 66.5(a) would exempt food served in restaurants or similar retail food establishments from the NBFDS. In § 66.1, AMS is proposing to define “similar retail food establishment” as: “a cafeteria, lunch room, food stand, 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.” This definition would be consistent with the definition of “food service establishment” included in other labeling programs under the amended Act. See 7 U.S.C. 1638(3) and the regulations at 7 CFR 60.107 and 7 CFR

65.140, with minor modifications. AMS seeks comment on the scope of this definition.

#### 2. Very Small Food Manufacturers

Proposed § 66.1 would define “very small food manufacturer” as: “any food manufacturer with annual receipts of less than \$2,500,000.” This definition would apply to both domestic and foreign food manufacturers. The Small Business Administration does not have a definition of very small business that we can rely on as a starting point for defining “very small food manufacturer.” However, FDA exempts certain food from certain labeling requirements or subjects it to special labeling requirements if the food is offered for sale by certain persons who have annual gross sales made or business done in sales to consumers that are not more than \$500,000 under certain conditions. See 21 CFR 101.9(j)(1)(i) and 21 CFR 101.36(h)(1). More generally, the U.S. Census Bureau defines a “very small enterprise” for purposes of its annual *Statistics of U.S. Businesses* (SUSB) as a business having fewer than 20 employees.

To evaluate the impact of various definitions of “very small food manufacturer” we estimated the number of firms that would be covered by such an exemption, the number of products that would likely be exempt at various levels for which SUSB data is available, and the proportion of annual industry sales that would be exempt at each level. The number (proportion) of firms exempted gives us a sense of the level of relief we would be able to provide to small firms. The number of products gives us a sense of how much the costs of the rule would likely be reduced by an exemption at a given level (as well as the number of products that will not provide consumers with the additional bioengineering information). The proportion of sales gives us insight into how likely it is for a consumer to encounter an unlabeled product (that may otherwise require disclosure) in the marketplace.

The following tables show the cumulative percentage of firms, products (UPCs), and sales that would be exempt if the definition of “very small food manufacturer” were set at the top of each of the annual revenue ranges (based on the 2012 SUSB):



FOOD MANUFACTURERS

Establishment receipts threshold	Cumulative percent of firms exempt	Cumulative percent of products exempt	Cumulative percent of sales exempt
<100,000 .....	20	0	0
100,000–499,999 .....	45	1	0
500,000–999,999 .....	58	2	1
1,000,000–2,499,999 .....	74	4	1
2,500,000–4,999,999 .....	81	6	2
5,000,000–7,499,999 .....	84	7	3
7,500,000–9,999,999 .....	86	8	3

DIETARY SUPPLEMENT MANUFACTURERS

Establishment receipts threshold	Cumulative percent of firms exempt	Cumulative percent of products exempt	Cumulative percent of sales exempt
<100,000 .....	7.36	0.02	0.00
100,000–499,999 .....	16.75	0.12	0.10
500,000–999,999 .....	26.14	0.33	0.32
1,000,000–2,499,999 .....	45.18	1.54	1.26
2,500,000–4,999,999 .....	59.14	3.26	2.63
5,000,000–7,499,999 .....	62.18	3.83	3.15
7,500,000–9,999,999 .....	63.96	4.41	3.63

Applying the FDA exemptions at 21 CFR 101.9(j)(1)(i) and 21 CFR 101.36(h)(1), as described above, would exempt 45 percent of manufacturers, only one percent of products, less than 0.5 percent of sales for food manufacturers, only 17 percent of firms, and about a tenth of a percent of products and sales for dietary supplement manufacturers. In conducting the Regulatory Impact Analysis, we estimated the impacts of the U.S. Census Bureau’s definition of very small (less than 20 employees), and they fall somewhere between the \$2.5 million annual sales cutoff and the \$5 million annual sales cutoff. Both of these revenue cutoff levels for the definition of “very small food manufacturer” offer significantly greater relief for small manufacturers while still having a relatively minor impact on the amount of information available to consumers.

The proposed definition of “very small food manufacturer” as a food manufacturer with annual receipts less than \$2.5 million would provide regulatory relief to 74 percent of food manufacturers (45 percent of dietary supplement manufacturers) while reducing the products covered by four percent (two percent for dietary supplements) and number of purchases covered by only one percent for both food and dietary supplement manufacturers.

We seek comment on alternative revenue cutoffs of \$500,000 and \$5,000,000.

3. Threshold

The amended Act provides that the regulation promulgated by the Secretary “shall determine the amounts of a bioengineered substance that may be present in food, as appropriate, in order for the food to be a bioengineered food.” 7 U.S.C. 1639b(b)(2)(B). In establishing a proposed threshold to implement this section of the amended Act, AMS seeks to minimize costs and impacts on the domestic and international value chain while providing practicality and consistency for regulated entities and consumers regarding implementation. Respondents to AMS’ 30 questions offered a number of concepts to consider regarding thresholds, including different threshold levels for determining exemptions to the disclosure requirement (0.9, 5, and 10 percent), and different ways of calculating the threshold (by ingredient or by total weight).

In an effort to minimize costs for regulated entities, AMS is proposing and seeking comment on three different alternative thresholds, each of which would be verified through the regulated entity’s customary and reasonable business records. Regulated entities could apply the threshold to a particular product in order to demonstrate that a product is not subject to disclosure.

Details of the proposed alternatives are described below.

In the section authorizing the creation of a threshold, the amended Act uses but does not define the term “bioengineered substance.” See 7 U.S.C. 1639b(b)(2)(B). Therefore, AMS proposes a definition of “bioengineered substance” that incorporates the statutory definition of “bioengineering.” As set forth in § 66.1, “bioengineered substance” would mean “matter that contains genetic material that has been modified through *in vitro* recombinant deoxyribonucleic acid (DNA) techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature.”

a. Alternative 1–A (for § 66.5(c))

The first proposed alternative would establish that food in which an ingredient contains a BE substance that is inadvertent or technically unavoidable, and accounts for no more than five percent (5%) of the specific ingredient by weight, would not be subject to disclosure as a result of that one ingredient. Any other use of a food or food ingredient that contained a BE substance would be subject to disclosure.

Some food manufacturers that provided input to AMS advocated for this threshold because it would acknowledge the realities of the food supply chain. BE crops and non-BE crops are frequently grown in close proximity to each other, transported in

the same equipment, processed on the same machinery, and in some cases used by the same manufacturers. Because of this coexistence, allowing for an insignificant amount of a BE substance, when that amount is inadvertent or technically unavoidable, may be practical.

For purposes of the proposed rule, AMS would consider inadvertent or technically unavoidable presence to mean insignificant amounts of a BE substance in food that resulted from the coexistence of BE and non-BE foods in the supply chain. For example, if a non-BE corn flour contained trace amounts of BE corn that could have originated from corn grown in a neighboring field or residues left on transportation or processing equipment, those trace amounts would be considered inadvertent or technically unavoidable.

This alternative may align with existing industry practices. Under current practices, many food and ingredient suppliers separate BE and non-BE foods throughout the supply chain, beginning at the farm and continuing through the creation of a finished food product. AMS understands that there are existing industry standards and practices for keeping BE and non-BE food separate as they travel throughout the supply chain, and those standards and practices may be sufficient for complying with this proposed alternative threshold. However, some entities that are responsible for disclosure may not have adopted these standards and practices and would need to implement similar standards and practices to comply with this alternative threshold.

For compliance, AMS would look to a regulated entity's records. If a regulated entity has records to demonstrate that they source non-BE ingredients, and can demonstrate through records that they take appropriate measures to separate BE and non-BE ingredients, then the presence of any BE substance would be considered inadvertent or technically unavoidable. Nevertheless, the product would be subject to disclosure if the amount of inadvertent or technically unavoidable BE substance in any one ingredient exceeded five percent by weight. Based on comments it has received, AMS believes this approach to determining compliance through recordkeeping would align with existing industry practices and records, which should minimize the amount of any new records that would need to be kept to demonstrate compliance.

#### b. Alternative 1–B (for § 66.5(c))

The second alternative proposal would establish that food, in which an ingredient contains a BE substance that is inadvertent or technically unavoidable, and accounts for no more than nine-tenths percent (0.9%) of the specific ingredient by weight, would not be subject to disclosure as a result of that one ingredient. Under this alternative, AMS would determine whether the use of a BE substance was inadvertent or technically unavoidable in the same way it would under alternative 1–A. Similarly, AMS would monitor compliance with the threshold by reviewing a regulated entity's records in the same way it would under alternative 1–A.

AMS believes this approach could be less permissive than alternative 1–A because only products with a lesser amount of a BE substance would be exempt from disclosure. Based on comments, AMS believes this alternative may align with some existing industry standards for the separation of BE and non-BE products, as well as the thresholds established by some U.S. trading partners. Because some regulated entities currently have processes in place to meet this proposed alternative, this alternative may reduce implementation costs for some regulated entities. However, some regulated entities may need to change their processes to comply with this alternative.

#### c. Alternative 1–C (for § 66.5(c))

In addition to the two alternative thresholds proposed above, AMS seeks comment on another approach. Some commenters suggested that AMS should allow regulated entities to use a small amount of BE ingredients up to a certain threshold, such as 5% of the total weight of the product, before being required to label a product with a BE disclosure. Under this approach, a regulated entity could use ingredients it knew were bioengineered, and not have to disclose under the NBFDS, as long as the total amount of all BE ingredients used in the product were not greater than 5% of the total weight of the product. AMS believes that this approach would likely decrease the number of foods subject to disclosure, and may require regulated entities to create and maintain records they do not currently keep.

AMS invites comments on the three alternative proposals, including on the administrative costs of creating and maintaining necessary records if they do not already exist. AMS also seeks specific comments on whether proposed

threshold amounts should be increased or decreased, and the calculation and verification methods of each proposal. AMS requests public comment on the threshold option that would present the lowest costs to regulated entities, and the estimated costs of such a policy.

#### 4. Animals Fed With Bioengineered Feed and their Products

The amended Act prohibits a food derived from an animal from being considered a BE food solely because the animal consumed feed produced from, containing, or consisting of a BE substance. 7 U.S.C. 1639b(b)(2)(A). Proposed § 66.5(d) would incorporate this statutory exemption. For example, eggs used in a baked good, where the eggs come from a chicken fed feed produced from BE corn and soy, would not be considered bioengineered solely on the basis of the chicken's feed.

#### 5. Food Certified Organic Under the National Organic Program

Subtitle F states that “In the case of food certified under the national organic program established under the Organic Foods Production Act of 1990 (7 U.S.C. 6501 *et seq.*), the certification shall be considered sufficient to make a claim regarding the absence of bioengineering in the food, such as ‘not bioengineered’, ‘non-GMO’, or another similar claim.” 7 U.S.C. 6524. Implicit in the statutory provision is that certified organic foods are not subject to BE disclosure. This implication, in conjunction with the Secretary's authority to consider establishing consistency between the NBFDS and the Organic Foods Production Act, permits a regulatory exemption for products certified organic under the NOP. See 7 U.S.C. 1639b(f). As such, proposed § 66.5(e) would exempt certified organic foods from BE disclosure, so food manufacturers, retailers, and importers of certified organic food would not be required to maintain additional records to demonstrate that the organic food is not bioengineered for purpose of the NBFDS regulations.

### III. Disclosure: What will the disclosure look like?

As statutorily required, the National Bioengineered Food Disclosure Standard, “for the purposes of regulations promulgated and food disclosures made pursuant to[], a bioengineered food that has successfully completed the pre-market Federal regulatory review process shall not be treated as safer than, or not as safe as, a non-bioengineered counterpart of the food solely because the food is bioengineered or produced or developed

with the use of bioengineering.” The amended Act provides three disclosure options for all food subject to the mandatory BE food disclosure, as well as additional options for small food manufacturers, and requires that the Secretary provide reasonable alternative disclosure options for food contained in small and very small packages. 7 U.S.C. 1639b(b)(2)(D), 1639b(b)(F), and 1639b(b)(E). In addition, the amended Act requires the Secretary to conduct a study to identify potential technological challenges that may impact whether consumers would have access to the bioengineering disclosure through electronic or digital disclosure methods and provides specific factors to be considered in the study. 7 U.S.C. 1639b(c)(1) and 1639b(c)(3). Based on the study, if the Secretary determines that consumers would not have sufficient access to the bioengineering disclosure through electronic or digital disclosure methods, the Secretary, after consultation with food retailers and manufacturers, shall provide additional and comparable disclosure options. 7 U.S.C. 1639b(c)(4).

Proposed subpart B specifies: (1) Who would be responsible for the BE food disclosure in proposed § 66.100; (2) the text disclosure in proposed § 66.102; (3) the symbol alternatives in proposed § 66.104; (4) the electronic or digital link disclosure in proposed § 66.106; (5) the text message disclosure in proposed § 66.108; (6) the disclosure options for small food manufacturers in proposed § 66.110; (7) the disclosure options for small or very small packages in proposed § 66.112; (8) the disclosure for foods sold in bulk containers in proposed § 66.114; (9) the voluntary disclosure in proposed § 66.116; and (10) other claims in § 66.118. As used in subpart B, the key terms include “information panel” and “label.” As defined in proposed § 66.1, these definitions would be consistent with those used in the National Organic Program (NOP) regulations, 7 CFR 205.2. In addition, the terms “marketing and promotional information,” “principal display panel,” “small package,” “very small package,” and “small food manufacturer,” are discussed in the section of the NPRM where the term is used.

#### A. General

##### 1. Responsibility for Disclosure

The amended Act permits a food to bear a disclosure that the food is bioengineered only in accordance with the regulations promulgated by the Secretary. 7 U.S.C. 1639b(b)(1). Proposed § 66.100(a) would identify

three categories of entities responsible for disclosure: food manufacturers, importers, and certain retailers. If a food is packaged prior to receipt by a retailer, either the food manufacturer or the importer would be responsible for ensuring that the food label bears a BE food disclosure in accordance with this part. If a retailer packages a food, then the retailer would be responsible for ensuring that the food bears a BE food disclosure in accordance with this part.

AMS believes that this approach would align responsibility for labeling with that currently required under other mandatory food labeling laws and regulations, including those administered by FDA and FSIS.

##### International Impact

Under the proposed rule, importers would be subject to the same disclosure and compliance requirements as domestic entities. Generally, importers of foods on either AMS list of commercially available BE foods would be required to make appropriate disclosures on the labels of BE foods and would be required to verify, with appropriate records, that imported foods on the lists that do not bear disclosures are not bioengineered. However, to facilitate international trade, AMS would consider establishing recognition arrangements with appropriate foreign government entities that have established labeling standards for BE food. Under such arrangements, each country could agree to recognize each other's standards as comparable. Such an arrangement would allow importers to sell products in the U.S. that comply with the source nation's labeling standard for BE food, and therefore the NBFDS. Similarly, the arrangements could enable U.S. exporters to sell products abroad that meet NBFDS requirements, without requiring additional actions to comply with the partner nation's labeling standard for BE food. Under a mutual recognition arrangement, an importer bringing food from a partner country into the U.S. that is labeled in compliance with that country's BE food labeling laws, would only need to demonstrate with records that the food came from the partner country. Similarly, U.S. exporters could sell U.S. foods that are compliant with the NBFDS into partner countries and need only to demonstrate that the food came from the U.S.

AMS would consider a number of factors before entering into mutual recognition arrangements. For example, AMS would consider whether the proposed partner nation's BE labeling requirement is mandatory, what threshold requirement is imposed, and

what food products are subject to BE labeling.

Imports of products from countries that do not have bioengineered food labeling regulations or with whom AMS had no mutual recognition arrangement would be subject to the disclosure and recordkeeping requirements of the NBFDS. U.S. exports to non-partner countries would need to continue to meet that country's import requirements.

AMS seeks comment on any impact this proposal might have on importers. Comments are specifically invited on the degree to which elements of the labeling regulations between partner countries should be comparable and on the factors that should be considered in determining whether the U.S. would recognize another nation's labeling regulations as comparable through a mutual recognition arrangement. In addition to seeking comment on this proposal, AMS seeks comment from all stakeholders regarding any unique issues associated with BE disclosure for imports and on any potential impacts on international stakeholders. AMS will also conduct a World Trade Organization (WTO) notification and would also welcome comments on any potential impacts offered by international stakeholders, recognizing the statutory authority and parameters of the amended Act.

##### 2. Appearance of Disclosure

Proposed § 66.100(c) would require the disclosure to 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. AMS believes these requirements would align with other mandatory food labeling requirements, including those administered by FDA (21 CFR 101.15) and FSIS (9 CFR 317.2(b)). While FDA uses the term “customary conditions of purchase,” 21 CFR 101.15, we have proposed to utilize the term “ordinary shopping conditions” as the statutory language references “shopping” in 7 U.S.C. 1639b(c)(4). AMS considered prescribing specific type sizes for different disclosure options, but determined that the number and type of disclosure options, combined with the variety of food package sizes, shapes, and colors, would make prescriptive requirements too difficult to implement. AMS believes that the proposed performance standard would likely provide the BE food disclosure information to consumers in an accessible manner, while allowing the entities responsible for the disclosure to

have flexibility in implementing the requirements.

### 3. Placement of Disclosure

Proposed § 66.100(d) would provide that the BE food disclosure be placed in one of the following places: The information panel adjacent to the statement identifying the name and location of the manufacturer/distributor or similar information; anywhere on the principal display panel; or an alternate panel if there is insufficient space to place the disclosure on the information panel or the principal display panel. Proposed § 66.100(d) would not apply to bulk foods (see proposed § 66.114). “Information panel” as defined in proposed § 66.1, would be consistent with the definitions found in the NOP regulations at 7 CFR 205.2, which largely reflect those found in FDA’s food labeling regulations at 21 CFR 101.2. “Principal display panel,” as defined in proposed § 66.1, would reflect the definition found in FDA’s food labeling regulations at 21 CFR 101.1. If there is insufficient space on either the information panel or the principal display panel, AMS proposes that the disclosure may be placed on an alternate panel likely to be seen by a consumer under ordinary shopping conditions.

AMS proposes locating the disclosure on the information panel or the principal display panel because we believe that is where consumers who are interested in additional food information typically look for information about their food. The information panel typically includes the nutrition fact panel, the ingredient list, the manufacturer/distributor name and address, and, if applicable, the country of origin. The principal display panel typically includes the statement of identity and the net quantity statement in addition to other marketing claims. AMS believes that placing the BE food disclosure near this existing information would be effective because consumers would be able to see all the disclosures, statements, and marketing claims in one common place on the label.

AMS proposes placing the disclosure adjacent to the manufacturer/distributor name and location statement. Such placement should avoid interfering with other required statements on the information panel. In addition to addressing consumer preference, AMS also considered the impact on food manufacturers of prescribing a specific location for the disclosure. We believe that the information panel would be an appropriate location for a mandatory BE food disclosure because food manufacturers are accustomed to

making statements and disclosures required by FDA and FSIS on the information panel. By also proposing that the disclosure may appear on the principal display panel, AMS acknowledges that some regulated entities may want to increase transparency or highlight specific traits from the BE food in tandem with the BE food disclosure. Pursuant to proposed § 66.118, regulated entities would be able to make other claims regarding bioengineered foods, provided that such claims are consistent with applicable federal law.

We believe this array of options would allow regulated entities adequate flexibility to tailor their chosen disclosures to most of their food package labels. However, in order to provide additional flexibility, AMS proposes a third option that would allow the placement of the disclosure on an alternate panel if there is insufficient space on the information panel or the principal display panel. The alternate panel would need to be visible to the consumer under ordinary shopping conditions to ensure the disclosure could be found without much effort.

### 4. How BE Food Lists Relate to Disclosure

The purpose of the proposed lists of BE foods is to provide entities responsible for disclosure with a straightforward method of determining whether a food is or may be bioengineered, and thus would require BE disclosure. For products that contain a food on either of the lists, regulated entities would either make a disclosure consistent with the NBFDS or not disclose if they believe the food is not required to have a BE disclosure. For foods that would not have a BE disclosure, regulated entities would need to maintain documented verification that the food is not a BE food or that it does not contain a BE food. (See Recordkeeping section). If a regulated entity chooses to disclose, that entity has several options (text, symbol, electronic or digital link, and/or text message, with additional options available to small food manufacturers or for small or very small packages), with differing requirements, as described below. Regardless of the disclosure form they elect to use, regulated entities can look to the lists of commercially available BE foods as a means by which to determine if the food would be required to have a BE disclosure. For foods that display a BE disclosure, regulated entities would not need to maintain documented verification that the food is a BE food or that it does contain a BE food beyond those records

that are believed to be currently maintained. AMS understands that all manufacturers and retailers maintain business records, such as purchase orders, invoices, and bills of lading, that verify information about the materials they source to make their products. AMS understands that importers maintain similar business records for the products they import.

### B. Text Disclosure

The amended Act allows for text disclosure of BE food as one option given to regulated entities. 7 U.S.C. 1639b(c)(4). At the outset, for all on-package text disclosure options and alternatives, AMS proposes using the terms “bioengineered food” or “bioengineered food ingredient.” AMS considered using alternative phrases, such as “genetically modified” or “genetically engineered.” However, AMS is not proposing any similar terms because we believe that the statutory term, “bioengineering,” adequately describes food products of the technology that Congress intended to be within the scope of the NBFDS.

AMS proposes to differentiate between BE food and BE food ingredients through the on-package text disclosure alternatives. We believe this approach would recognize that some foods are entirely a product of bioengineering and that some foods are a mix of BE and non-BE food ingredients.

#### 1. High Adoption Bioengineered Food

Proposed § 66.102 would require use of the statements “Bioengineered food” or “Contains a bioengineered food ingredient” for disclosure of BE food and BE food ingredients that appear on the list of BE foods with a high adoption rate. A food on this list would be presumed to be a BE food, absent documentation that would verify otherwise (see Recordkeeping section). AMS believes that this is a reasonable presumption because, at 85 percent or higher adoption rate, there is a high likelihood that the food would be bioengineered. Additionally, given the high adoption rate, it is likely that farmers who are producing a non-BE variety of a crop on the list are doing so intentionally and are marketing their product as such. For those reasons, we are not proposing to allow foods on, or foods produced from crops on, this list to bear a “may” disclosure.

For BE food or BE food ingredients that appear on the high-adoption list, entities would be required to use one of two alternative statements. The first statement—“Bioengineered food”—would be for raw agricultural products

that meet the proposed definition of “bioengineered food,” as well as for processed products that only contain BE food ingredients (e.g. BE cornmeal). The second statement—“Contains a bioengineered food ingredient”—would be for all other foods. AMS believes this statement would cover all multi-ingredient products that contain both BE food ingredients and non-BE food ingredients (e.g. processed food products such as cereals). Regardless of which statement is applicable, the disclosure must be legible under ordinary shopping conditions.

## 2. Non-High Adoption BE Food

AMS is proposing that regulated entities would disclose the presence or possible presence of BE food and BE food ingredients that are on the list of BE foods commercially available, but not highly adopted, in the United States using the following statements: “Bioengineered food,” “May be bioengineered food,” “Contains a bioengineered food ingredient,” or “May contain a bioengineered food ingredient.” The default presumption would be that any foods on the non-high adoption BE food list may be bioengineered, and regulated entities would have discretion to use any of these disclosure options.

The use of the more affirmative statements, “Bioengineered food” or “Contains a bioengineered food ingredient” for food on the non-high adoption BE food list would be used at the discretion of the regulated entity. For example, one manufacturer who packages ears of sweet corn for retail sale may not have records indicating the corn is bioengineered, but since sweet corn is on the list of non-highly adopted BE foods, would be able to disclose that

their packaged corn is “bioengineered food.”

Another manufacturer may produce canned sweet corn, and may have records that enable it to distinguish between BE and non-BE sweet corn inventories. Nevertheless, since sweet corn is on the list of non-highly adopted BE foods, the manufacturer would be able to use the “may be bioengineered” disclosure.

A manufacturer could prefer to use the “may contain a bioengineered food ingredient” disclosure when it sources squash from several suppliers. For instance, the manufacturer knows some suppliers provided BE squash, but isn’t sure whether other suppliers provided BE squash. If the manufacturer does not track which squash goes into which food product, the manufacturer would be able to use the “may contain a bioengineered food ingredient” disclosure for all its products that contain squash.

This approach acknowledges that the food supply chain is complex, and many entities could be sourcing both BE and non-BE versions of the same food or food ingredients from the non-highly adopted BE foods list and comingling those foods or combining those ingredients to form the final products. This approach attempts to avoid imposing additional costs on regulated entities by offering flexibility.

Regardless of which statement is chosen, the disclosure must be legible under ordinary shopping conditions.

AMS seeks comment on several aspects of the proposed text disclosure options, including any use of the “may be” or “may contain” disclosures. For example, should regulated entities be permitted to use a “may” disclosure for foods on the highly-adopted BE foods

list? Should regulated entities be permitted to use a “may” disclosure for foods on the non-highly adopted BE foods list even if their records provide certainty that the foods are bioengineered? In addition, comments are requested on the potential impact of this proposal on recordkeeping activities, sourcing challenges, labeling costs, etc.

For BE food that is distributed solely in a U.S. territory, AMS proposes in § 66.102(c) that disclosure statements equivalent to those above be allowed in the predominant language of that territory. AMS believes this approach would make the BE food disclosure more accessible in territories where the predominant language is something other than English. AMS also believes this would allow regulated entities who only distribute food in a given territory to respond to consumer demand. AMS invites comments on ideas that would make the proposed on-package text disclosure options more accessible.

### C. Symbol Disclosure

A symbol is another form of BE food disclosure regulated entities can use as set forth in the amended Act. 7 U.S.C. 1639b(c)(4). AMS proposes three alternative symbols with variations of those symbols, and invites comment on each alternative and its variation. The three symbols are designed to communicate the bioengineered status of a food in a way that would not disparage biotechnology or suggest BE food is more or less safe than non-BE food. Regulated entities would be able to use each alternative symbol to designate BE food, food that contains a BE food ingredient, a food that may be a BE food, or a food that may contain a BE food ingredient.



The first proposed alternate symbol is a circle with a green

circumference, and the capital letters “BE” in white type located slightly below the center of the circle. The bottom portion of the circle contains an arch, filled in green, that resembles a rounded hill. Above that arch, about halfway through the height of the circle, is a second arch, filled in darker green, that resembles a second rounded hill. On the left side of the second arch, near the left side of the circle, is a stem coming from the second arch and arching towards the center of the circle, ending in a four-pointed starburst. The stem has two leaves coming from the upper side of the stem and pointing towards the top of the circle. At the top of the circle, to the left of center, in the background of the leaf, is a portion of a yellow circle that resembles a sun.

The remainder of the circle is filled in light blue, resembling the sky.

#### 1. Alternative 2–A

The first proposed alternate symbol is a circle with a green circumference, and the capital letters “BE” in white type located slightly below the center of the circle. The bottom portion of the circle contains an arch, filled in green, that resembles a rounded hill. Above that arch, about halfway through the height of the circle, is a second arch, filled in darker green, that resembles a second rounded hill. On the left side of the second arch, near the left side of the circle, is a stem coming from the second

arch and arching towards the center of the circle, ending in a four-pointed starburst. The stem has two leaves coming from the upper side of the stem and pointing towards the top of the circle. At the top of the circle, to the left of center, in the background of the leaf, is a portion of a yellow circle that resembles a sun. The remainder of the circle is filled in light blue, resembling the sky.

#### 2. Alternative 2–B

The second proposed alternative symbol is a filled, green circle with the

lower-case letters “be” in white type, slightly above the center of the circle. Just below the letters is an inverted, white arch, beginning just below the middle of the “b” and ending just below the middle of the “e.” Around the outside of the circle are ten (10) triangular leaves spread equally around the perimeter of the circle. The leaves transition from light green at the top of the circle to shades of yellow and orange on the sides, ending with dark orange leaves on the bottom of the circle.



The second proposed alternative symbol is a filled, green circle with the lower-case letters “be” in white type, slightly above the center of the circle. Just below the letters is an inverted, white arch, beginning just below the middle of the “b” and ending just below the middle of the “e.” Around the outside of the circle are ten (10) triangular leaves spread equally around the perimeter of the circle. The leaves transition from light green at the top of the circle to shades of yellow and orange on the sides, ending with dark orange leaves on the bottom of the circle.

### 3. Alternative 2–C

The third proposed alternative symbol is a circle with a circumference made up of 12 separate, equally-spaced segments. The segments gradually transition from

yellow at the top of the circle to dark orange at the bottom of the circle. The interior of the circle is a white background with the lowercase letters “be” in green type, located slightly above the center of the circle. Below the

letters is an inverted, green arch, beginning below the center of the “b” and ending below the center of the “e.” Inside the middle of the “b” is a bifurcated leaf.



The third proposed alternative symbol is a circle with a circumference made up of 12 separate, equally-spaced segments. The segments gradually transition from yellow at the top of the circle to dark orange at the bottom of the circle. The interior of the circle is a white background with the lowercase letters “be” in green type, located slightly above the center of the circle. Below the letters is an inverted, green arch, beginning below the center of the “b” and ending below the center of the “e.” Inside the middle of the “b” is a bifurcated leaf.

AMS recognizes that a multi-colored product label may increase printing costs or disrupt product design in other ways. Therefore, similar to use of the USDA Organic seal under the NOP, AMS proposes to allow regulated entities to use a black and white version of the symbol. Regardless of colors, the symbol would still be required to meet the appearance and placement requirements in proposed § 66.100. AMS invites comment on other reasonable modifications that would make the symbol easier to include on food packages, while still communicating the BE food disclosure to consumers. We also invite comment

on whether the word “Bioengineered” should be incorporated into the design of the chosen disclosure symbol. We also seek comment on whether the phrase “May be” should be incorporated into the design of one of the disclosure symbols above to account for “may” disclosures.

A supplemental document to this NPRM will contain the proposed symbols in full color as well as other variations of the symbols incorporating the words “bioengineered” and “may be.” The document may be viewed in the docket for this rulemaking at [regulations.gov](http://www.regulations.gov). As statutorily required, the National Bioengineered Food

Disclosure Standard, “for the purposes of regulations promulgated and food disclosures made pursuant to[,], a bioengineered food that has successfully completed the pre-market Federal regulatory review process shall not be treated as safer than, or not as safe as, a non-bioengineered counterpart of the food solely because the food is bioengineered or produced or developed with the use of bioengineering.” As with all other forms of disclosure, this requirement applies to the proposed symbols. AMS requests public comment, particularly available research findings and factual information, on the interpretation of



each of the proposed symbol disclosures, specifically with regard to the following topics: (1) Perceptions, beliefs, or feelings in response to each of the proposed symbols; and (2) interpretation of the proposed symbols (*i.e.* what message a consumer would think each symbol is communicating). We are aware that some entities may have completed or expect to complete before the end of the comment period research, investigative studies, surveys and/or focus groups with the intention of evaluating consumer perceptions of disclosure symbols. We would be glad to receive through the public comment process any information such entities would like to provide to further inform this rulemaking.

#### *D. Electronic or Digital Link Disclosure*

The third disclosure option available for regulated entities to use is an electronic or digital link disclosure. 7 U.S.C. 1639b(b)(2)(D), 1639b(d). The amended Act requires that the use of an electronic or digital link to disclose BE food must be accompanied by the statement “Scan here for more food information” or equivalent language that reflects technological changes. 7 U.S.C. 1639b(d)(1). This statutory requirement would be incorporated in proposed § 66.106(a)(1). AMS recognizes that electronic and digital links currently used on food products in the marketplace take different forms and the amended Act allows for equivalent statements that reflect technological changes. Current technology includes, among others, quick response codes that are detectable by consumers and digital watermark technology that is imperceptible to consumers, but can be scanned anywhere on a food package using a smart phone or other device. Consequently, AMS proposes two examples of alternative statements that could appear above or below an electronic or digital link to direct consumers to the link to the BE food disclosure. The proposed examples are: “Scan anywhere on package for more food information” and “Scan icon for more food information.” Each would reflect changes in technology but still would provide consumers with the instruction necessary to access the disclosure. We are not including examples for all statements that reflect changes in technology, and we invite comments on other statements that may reflect changes in electronic or digital link technology.

Proposed § 66.106(a)(2) would incorporate the amended Act’s requirement to include a telephone number that provides access to the BE food disclosure. 7 U.S.C. 1639b(d)(4).

The proposal would further require that the disclosure be available regardless of the time of day, and that the telephone number be located in close proximity to the electronic or digital link. The proposal would also require that the statement “Call for more food information” be utilized.

The amended Act requires the electronic or digital link to provide the bioengineering disclosure on the first product information page accessed through the link, without any marketing or promotional material. 7 U.S.C. 1639b(d)(2). Proposed § 66.106(b) would incorporate this requirement. The proposal would define marketing or promotional material to mean “any written, printed, audiovisual, or graphic information—including advertising, pamphlets, flyers, catalogues, posters, and signs—distributed, broadcast, or made available to assist in the sale or promotion of a product.” This definition would be consistent with that in the NOP regulations at 7 CFR 205.2.

AMS proposes that the disclosure on the product information page conform to the requirements of the text disclosure in proposed § 66.102 or the symbol disclosure in proposed § 66.104. AMS believes that using a uniform, consistent approach to the disclosure language and symbol would make it easier for consumers to understand the disclosure, whether that language or symbol appears on a food label or an electronic or digital device. AMS also believes that this approach would make compliance easier for entities responsible for disclosing and ensuring consistency in the communication of required disclosure information.

If the entity responsible for the disclosure chooses to use an electronic or digital link, the amended Act requires the entity not collect, analyze, or sell any personally identifiable information about consumers or their devices. 7 U.S.C. 1639b(d)(3)(A). Under proposed § 66.106(b)(4), if such information must be collected in order to fulfill the disclosure requirements, that information would need to be deleted immediately and not used for any other purpose. 7 U.S.C. 1639b(d)(3)(B). AMS believes this language in the amended Act is self-explanatory and did not propose additional language in the proposed rule.

AMS received requests to allow additional information about BE food to be included in the disclosure. The proposed regulations would not prohibit such additional information, but if the information is presented to the public, it must be done outside of the landing page that includes the BE food disclosure.

#### *E. Study on Electronic or Digital Disclosure and a Text Message Disclosure Option*

The amended Act requires the Secretary to conduct a study to identify potential technological challenges that may impact whether consumers would have access to the bioengineering disclosure through electronic or digital disclosure methods. 7 U.S.C. 1639b(c)(1). The Department contracted with Deloitte Consulting LLP to perform the study, received the study results from Deloitte Consulting LLP on July 27, 2017, and made the study available to the public on September 6, 2017, at <https://www.ams.usda.gov/reports/study-electronic-or-digital-disclosure>. AMS invites comment on the study and its results.

As required by the amended Act, the study considered five factors: The availability of wireless internet or cellular networks; the availability of landline telephones in stores; challenges facing small retailers and rural retailers; the efforts that retailers and other entities have taken to address potential technology and infrastructure challenges; and the costs and benefits of installing in retail stores electronic or digital link scanners or other evolving technologies that provide bioengineering disclosure information. 7 U.S.C. 1639b(c)(3). The amended Act also requires the Secretary, after consultation with food retailers and manufacturers, to provide additional and comparable options to access the bioengineering disclosure, should the Secretary determine that consumers, while shopping, would not have sufficient access to the bioengineering disclosure through electronic or digital disclosure methods. 7 U.S.C. 1639b(c)(4). The Secretary is reviewing the study and its results to decide whether to make that determination and will consider comments received when making that determination.

Although the study is under review and no determination has been made, AMS is proposing an additional disclosure option, should the Secretary determine that consumers, while shopping, would not have sufficient access to the bioengineering disclosure through electronic or digital disclosure methods. Proposed § 66.108 describes the one additional option—a text message. This text message option would operate similarly to the electronic or digital disclosure under proposed § 66.106, but it would not rely on broadband access and would not require consumers to have smart phones in order to access the disclosure. Entities responsible for disclosure that

choose this option would be required to include a statement on the package that instructs consumers to “Text [number] for more food information,” where the number would be a phone number or short code. An automated response would immediately provide the disclosure using text in conformance with § 66.102. Similar to the electronic or digital disclosure, the text message would not be allowed to contain marketing or promotional material and would not collect, analyze, or sell any personally identifiable information unless it would be necessary to complete the disclosure, immediately deleted, and not used for any other purpose. Additionally, the proposed rule would not allow the entity responsible for the disclosure to charge the consumer a fee to access the disclosure information.

#### F. Small Food Manufacturers

The amended Act provides two additional disclosure options for small food manufacturers: (1) A telephone number accompanied by appropriate language to indicate that the phone number provides access to additional information; and (2) an internet website address. 7 U.S.C. 1639b(b)(2)(F)(ii). In addition, in the case of small food manufacturers, the amended Act provides that the implementation date not be earlier than one year after the implementation date for regulations promulgated in accordance with the NBFDS. See 7 U.S.C. 1639b(b)(2)(F)(i).

##### 1. Definition

AMS proposes to define “small food manufacturer” as “any food manufacturer with less than \$10 million in annual receipts but \$2,500,000 or more in annual receipts.” This definition would be similar to FDA’s proposed rule to extend the compliance dates for manufacturers with less than \$10 million in annual food sales (see 82 FR 45753). AMS seeks comment on this proposed definition.

Proposed § 66.110 provides two additional options that would be made available to small food manufacturers in addition to the text, symbol, electronic or digital link, or text message disclosure options. The two proposed options are disclosure by telephone number and by internet website.

##### 2. Telephone Number

Under proposed § 66.110(a), if a small food manufacturer chooses to use a telephone number to disclose the presence of a BE food or BE food ingredients, text accompanying the telephone number would need to state “Call for more food information.” The

telephone number would need to provide the BE food disclosure regardless of the time of day. Disclosure via telephone number would include a BE food disclosure that is consistent with proposed § 66.102 in audio form. AMS believes that the requirement to provide the BE food disclosure at any time of day would be reasonable, given the different hours that consumers shop for groceries and the varying time zones in the United States. Because the disclosure by telephone can be accomplished through a recorded message, AMS does not believe that requiring the disclosure to be available at any time of day would increase the burden on small food manufacturers.

##### 3. Internet Website

Under proposed § 66.110(b), if the small food manufacturer chooses to use an internet website to disclose the presence of BE food or BE food ingredients, text would need to accompany the website address on the label stating, “Visit [Uniform Resource Locator of the website] for more food information.” The website would need to meet the requirements for a product information page in proposed § 66.106(b). Disclosure via website would include a bioengineered food disclosure that is consistent with proposed § 66.102 or § 66.104 in written form. AMS believes that implementing the internet website option for small food manufacturers in conformance with the requirements for the electronic or digital disclosure product information page would give small food manufacturers the flexibility to disclose in a way that is cost effective for a small business, while providing disclosure to consumers and the same level of protection for personally identifiable information.

#### G. Small and Very Small Packages

The amended Act requires the Secretary to provide alternative reasonable disclosure options for food contained in small or very small packages. 7 U.S.C. 1639b(b)(2)(E). In order to ensure consistency with existing labeling requirements, as defined in the proposed rule, the definition of “small packages” was taken from FDA labeling requirements at 21 CFR 101.9(j)(17). The definition of “very small package” was also taken from FDA labeling requirements at 21 CFR 101.9(j)(13)(i)(B). Under proposed § 66.112, AMS included three options that it believes would be feasible for small and very small packages: A modified version of the electronic or digital link disclosure in proposed § 66.106; a modified version of the text

message in proposed § 66.108; and a modified version of the phone number disclosure in proposed § 66.110. In addition, for very small packages, regulated entities would be allowed to use a label’s preexisting Uniform Resource Locator or telephone number for disclosure.

For the modified version of the electronic or digital link, proposed § 66.112(a) would allow entities responsible for disclosure to utilize the electronic or digital link in proposed § 66.106, but replace the statement “Scan here for more food information” and accompanying phone number required in proposed paragraph (a) of that section with the statement “Scan for info.” AMS believes that shortening the statement and removing the phone number may make the electronic or digital link disclosure small enough to fit on small and very small packages.

For the modified version of the text message, proposed § 66.112(b) would allow entities responsible for disclosure to utilize the text message in proposed § 66.108, but replace the statement “Text [number] for more food information” with “Text for info.” AMS believes that shortening the statement may make the text message disclosure small enough to fit on small and very small packages.

Similarly, AMS believes that a phone number with a short statement could be small enough to fit on small and very small packages. Proposed § 66.112(c) would require the disclosure to meet the requirements of proposed § 66.110, but would replace the statement “Call for more food information” with “Call for info.”

AMS recognizes that very small packages have limited surface area on which to bear labels. Under proposed § 66.112(d), for very small packages, if the preexisting label includes a Uniform Resource Locator for a website or a telephone number that a person can use to obtain other food information, that website or telephone number may also be used for the BE food disclosure, provided that the disclosure is consistent with proposed § 66.102 in written or audio form.

During the formulation of this proposed rule, stakeholders representing food manufacturers who use small and very small packages indicated that using the symbol under proposed § 66.104 could be a viable disclosure option. Accordingly, the proposed symbol and other disclosure options available to all entities responsible for disclosure would still be available to those who package foods in small and very small packages. AMS believes providing the additional

options described above would provide needed flexibility for disclosure on small and very small food packages.

#### H. Foods Sold in Bulk Containers

Because bulk products, such as cornmeal in a bin or unpackaged produce, are frequently displayed without packaging and placed on display by retailers, rather than food manufacturers or importers, AMS proposes that retailers would be responsible for complying with the BE food disclosure of bulk food. AMS believes this approach is similar to the approach AMS has used previously, and that retailers would be accustomed to ensuring that bulk food appears with appropriate signage.

AMS proposes in § 66.114(a) that the BE food disclosure on bulk foods be allowed to appear using any of the options for on-package disclosure, including: Text, symbol, electronic or digital link, or text message (if applicable). The disclosure would be required to appear on signage or other materials (stickers, bindings, etc.) on or near the bulk item. AMS believes the requirement that the signage or materials include the disclosure would allow consumers to easily identify and understand the bioengineered status of the food. Retailers who use an electronic or digital link would be required to place any sign or image to be scanned in a place readily accessible by consumers. For all other disclosure options, AMS believes that signs currently used on or near bulk items, when supplemented with the BE food disclosure, would be sufficient to comply with the requirements of the amended Act.

#### I. Voluntary Disclosure

AMS received questions from the public about whether voluntary disclosure would be an option for food that would not be subject to the NBFDS disclosure. We recognize that some entities responsible for disclosure may want to provide a BE disclosure even though they are exempted, *e.g.* very small food manufacturers, to provide information that their consumers may seek. The amended Act at 7 U.S.C. 1639b(b)(1) provides that, “[a] food may bear a disclosure that the food is bioengineered only in accordance with regulations promulgated by the Secretary in accordance with this subchapter.” In accordance with this provision, and to ensure that entities responsible for disclosure would have the option to disclose bioengineering information regarding foods that may not be subject to mandatory disclosure, AMS is proposing provisions in the

NBFDS that would allow for such voluntary labeling for food that meets the definition of “bioengineering” in the statute. 7 U.S.C. 1639(1).

The labeling framework described in proposed § 66.116 would allow for the voluntary use of disclosure methods as provided for foods that would be required to be labeled under the NBFDS. For example, a very small food manufacturer would be able to use an on-package text, an electronic disclosure, the BE symbol, a text message disclosure (if applicable), or a combination of the options to disclose BE food. It is important to note that when regulated entities take advantage of the disclosure provisions in § 66.116, they would be required to comply with the disclosure requirements for text, symbol, digital or electronic link, or text message disclosure, as applicable. AMS is proposing this requirement to minimize consumer confusion.

### IV. Administrative Provisions: Recordkeeping & Enforcement

#### A. Recordkeeping Requirements

##### 1. What Records Are Required

The amended Act requires each person subject to mandatory BE food disclosure under the proposed standard to maintain records such as the Secretary determines to be customary or reasonable in the food industry to establish compliance with the standard. *See* 7 U.S.C. 1639b(g)(2). Persons required to keep such records would include food manufacturers, importers, retailers who label bulk foods or package and label foods for retail sale, and any other entities responsible for labeling for retail sale foods on the BE food lists. Proposed § 66.302(a)(1) would therefore require that entities responsible for disclosure maintain records that are customary or reasonable to demonstrate compliance with the BE food disclosure requirements. So long as the records would contain sufficient detail as to be readily understood and audited as set forth in proposed § 66.302(a)(2), AMS anticipates that each entity subject to the disclosure requirement would decide for itself what records and records management protocol are appropriate, given the scope and complexity of individual businesses, as well as the food being produced.

Commenters who provided input to AMS during the development of this proposed rule suggested that AMS pattern recordkeeping requirements for the NBFDS on other AMS regulations. Many commenters agreed that the records already customarily kept in the course of normal business, such as

under those other AMS programs, should be adequate to satisfy recordkeeping needs under the BE food disclosure standard. Commenters also suggested that identity preservation records, organic certification records, genetic marker testing records, and records related to product labels and food product formulations should be maintained, with the caveat that company product formulations and recipes should remain confidential.

Commenters agreed that the NBFDS's recordkeeping requirements should be adapted to the scope of the new standard and should not present an unreasonable burden to entities who must comply with the standard. Some commenters suggested that the NBFDS adopt recordkeeping requirements specified in FDA's Food Safety Modernization Act rules or in USDA's Food Safety Inspection Service regulations, but most suggested that because the proposed standard is not related to food safety, recordkeeping requirements consistent with other AMS marketing programs would be more appropriate.

##### 2. How Recordkeeping Applies to Disclosure

As described in the *Disclosure* section, AMS would maintain two lists: (1) A list of commercially available BE foods with a high adoption rate and (2) a list of commercially available BE foods not highly adopted. AMS understands that all manufacturers and retailers maintain business records, such as purchase orders, invoices, and bills of lading, that verify information about the materials they source to make their products. AMS understands that importers maintain similar business records for the products they import. Such records must be maintained for foods on either of these lists. As explained further below, entities responsible for disclosure would be required to maintain records necessary to substantiate compliance with the standards for individual disclosure options, including the type and wording of the disclosure used, and to substantiate the claim included in the disclosure or implied by absence of a disclosure statement. Entities choosing not to disclose that foods are or may be bioengineered may need additional records if existing records are not sufficient to substantiate non-disclosure.

##### a. Non-Disclosure of Foods on Either List

As set forth in proposed § 66.302(b), AMS proposes that regulated entities who offer for retail sale foods on either list of commercially available BE foods,

but do not disclose that the products are BE foods or contain bioengineered food ingredients, would be required to maintain documentation that verify the foods are not bioengineered. Such documentation might include supply chain documents, purchase orders, sales confirmations, bills of lading, supplier attestations, purchase receipts, written records, labels, contracts, brokers' statements, analytical testing results, or process certifications.

AMS believes these types of records are regularly kept and maintained by food manufacturers, importers or food retailers. Thus, we expect that documentation normally maintained showing that a crop, ingredient, or finished food product is not a bioengineered food would satisfy the standard's recordkeeping requirements. For example, a food manufacturer uses soy sauce as an ingredient in barbecue sauce. Soy sauce is produced from soybeans, a proposed highly adopted BE food in the United States. The default assumption would be that the food is bioengineered or contains a BE food ingredient and must include a BE food disclosure on the label. However, in this case, the manufacturer has sourced soy sauce produced from non-BE soybeans. Therefore, the food manufacturer would not make a BE disclosure, but would be required to maintain documented verification, such as a contract with its supplier that shows it ordered finished products that are not bioengineered. These records may be subject to USDA audit as provided in § 66.402. (See Enforcement section, below.)

Foods or ingredients not included on either list of commercially available BE foods would not be subject to the disclosure standard. Records required to demonstrate that such foods are not BE would consist simply of an indication of the food type (*e.g.*, peaches).

#### b. Disclosure of Foods on Either List

AMS proposes that entities making affirmative disclosures for BE food on either list of BE foods would only need to maintain records to show that their product contains a food or food ingredient on one of the BE food lists. For instance, a food manufacturer uses cornmeal, a food made from field corn, which is a high adoption rate food, in a muffin mix and includes a BE food disclosure on the label. The food manufacturer would not need records to show that the corn was bioengineered, as it would be on the high adoption rate list; that manufacturer would only need to maintain a record that shows that the food contained cornmeal.

As described in the *Disclosure* section above, "may" disclosure statements

could be used for any foods that are on the list of commercially available, but not highly adopted, BE foods. Recordkeeping to substantiate a "may" claim would only need to demonstrate that the food is on the list. Such a disclosure might be preferred by entities whose sources vary throughout the year and who may procure both BE and non-BE foods. Rather than switching labels to reflect which type of food or ingredient is used, which could create additional costs, entities could use one label—the "may" option—to cover either possibility. As such, recordkeeping requirements would not change—records maintained would only need to demonstrate that that particular food is on the list. The intent of this recordkeeping provision is to give regulated entities some degree of flexibility and to acknowledge the complexities of the food supply chain.

#### 3. Other Recordkeeping Provisions

As set forth in proposed § 66.302(a)(3), records would have to be maintained for at least two years after the food's distribution for retail sale. Commenters suggested a range of record retention periods, from as short as 12 months to as long as indefinitely. But many commenters stated that two years would be a reasonable amount of time to maintain records, given product inventories and expected shelf lives. It should be noted that records related to detectability testing, as described in section II.C.3.b. above and if adopted, may need to be retained longer than other records in order to provide ongoing evidence that foods manufactured under a particular process do not have detectable modified genetic material. Such records would be valid and should be retained for as long as the processor makes no changes to the process. Commenters almost unanimously agreed that records could be electronic or hard copy, as preferred by individual companies, and that records could be stored at any location, as long as they were readily accessible. Finally, some commenters recommended that no new records or forms be developed or required under the proposed standard.

Proposed § 66.304 sets forth the provisions for AMS' access to records. A few commenters suggested that regulated entities be required to produce records on demand, while others recommended that regulated entities be given as much as 45 days to produce records. But some commenters thought one or two weeks' notice would be adequate and in keeping with the nature and scope of the proposed standard. Under proposed § 66.304(a), entities

would have five business days to provide records to AMS upon request, unless AMS extends the deadline. Under proposed § 66.304(b), if AMS needs to access the records at the entity's place of business, AMS would provide prior notice of at least three days. AMS would examine the records during normal business hours, and entities would make such records available during those times. AMS would review the records during audits and examinations, as appropriate, to verify compliance with the standard's disclosure requirements. Proprietary business information, including product formulations and recipes, would be kept confidential by USDA, consistent with the Freedom of Information Act, 5 U.S.C. 552 *et seq.* Under proposed § 66.304(c), if an entity fails to provide AMS access to records, AMS would determine that the entity did not comply with the access requirement and that AMS could not confirm whether the entity is in compliance with the disclosure standard. This determination would be made public, as described in the *Enforcement* section below.

#### Request for Comments on Recordkeeping Provisions

AMS seeks comments on several aspects of the proposed recordkeeping requirements of the NBFDS, including:

(1) The types of customary and reasonable records kept by the various entities proposed to be regulated under this standard, and the costs associated with maintaining such records;

(2) Whether regulated entities should be required to verify the BE status of foods that bear the "bioengineered" or "contains a bioengineered ingredient" disclosure for foods on that list, through more than just a record showing that a particular food or ingredient is on the list;

(3) Whether regulated entities that choose to disclose the BE status of foods through any of the disclosure options should be required to maintain records regarding whether inputs are BE or not.

(4) Whether the lists should be consolidated into one list of commercially available foods and the "may" disclosure be made available for all BE foods. With consolidation of the list, entities labeling foods on the BE list would not be required to maintain records as long as they display any of the disclosure options. AMS seeks comment on the potential impact and any burdens associated with consolidating the lists into one list of commercially available BE foods;

(5) The proposed timelines for providing records if requested by AMS

for review during an audit or investigation; and

(6) The types of recordkeeping policies that could further reduce costs for affected entities and what the cost estimates would be for such policies.

#### *B. Enforcement*

The amended Act specifies that failure to make a BE food disclosure as required by the NBFDS is prohibited. *See* 7 U.S.C. 1639b(g)(1). Proposed § 66.400 would capture this prohibition. AMS' enforcement authority is limited under the amended Act, as it authorizes AMS to enforce compliance with the standard through records audits and examinations, hearings, and public disclosure of the results of audits, examinations, and hearings. *See* 7 U.S.C. 1639b(g)(3). Moreover, the amended Act expressly states that the Secretary shall have no authority to recall any food subject to the NBFDS "on the basis of whether the food bears a disclosure that the food is bioengineered." 7 U.S.C. 1639b(g)(4).

AMS received input about the compliance and enforcement aspects of the proposed standard from numerous stakeholders. Most stakeholders supported establishing compliance and enforcement procedures similar to those under other AMS marketing programs. They suggested AMS take action in response to specific complaints about possible violations of the standard. Stakeholders indicated that AMS should notify entities about records audits and provide opportunities for regulated entities to appeal AMS findings and make corrections before posting results of compliance investigations online.

Other stakeholders advocated use of more aggressive measures, such as conducting unannounced audits of regulated entities' records or imposing steep fines for non-compliance with the disclosure standard. The amended Act does not authorize civil penalties for violations, and AMS believes the other suggestions to be impractical. Therefore, the proposed rule does not include those suggestions.

The amended Act authorizes AMS to conduct audits or examinations of records. Proposed § 66.402 describes the process for receiving and reviewing complaints about possible violations of the disclosure standard and sets forth the audit procedure. Any interested person can file a written statement or complaint with the Administrator. If the Administrator determines that further investigation of a complaint is warranted, an audit or examination may be made of the entity responsible for the BE food disclosure. After completing the audit or examination of the records,

AMS would make its findings available to the entity that was audited. The entity would then have an opportunity to object to the findings and to request a hearing within 30 days of receiving the results of the audit or examination. As part of the request for a hearing, the entity would be required to file its objections to the findings and explain the basis of its objections. Under proposed § 66.404, the Administrator or designee would conduct the hearing, which may include an oral presentation. The Administrator or designee would be able to affirm or revise the findings of the audit or examination of records. After the conclusion of the hearing, or after 30 days from the entity's receipt of the finding, if the entity does not request a hearing, AMS would make public a summary of the results, including findings, of the audit or examination under proposed § 66.406. The decision to make this summary public would constitute final agency action for purposes of judicial review.

#### *C. Proposed Effective and Initial Compliance Dates*

We intend that any final rule resulting from this rulemaking would become effective 60 days after the date of the final rule's publication in the **Federal Register**, with a compliance date of January 1, 2020, and with a delayed compliance date of January 1, 2021, for small food manufacturers. The proposed compliance date of January 1, 2020, is intended to align with FDA's proposed rule to extend the compliance dates for the changes to the Nutrition Facts and Supplement Facts label final rule and the Serving Size final rule from July 26, 2018, to January 1, 2020, for manufacturers with \$10 million or more in annual food sales. *See* 81 FR 33741, 82 FR 45753. We recognize that it may take entities time to analyze products for which there may be new mandatory requirements under the NBFDS, make required changes to their labels, review and update their records, and print new labels. The proposed compliance dates are intended to provide a balance between the time industry will need to come into compliance with the new labeling requirements and the need for consumers to have the information in a timely manner. We invite comment on the proposed compliance dates.

#### *D. Use of Existing Label Inventories*

In an effort to reduce costs and burdens, AMS believes that regulated entities using food labels should have an opportunity to use up their current foods labels for a period of time. Therefore, AMS is proposing that regulated entities may use labels printed

by the initial compliance date, regardless of whether they comply with the NBFDS, until the regulated entity uses up remaining label inventories, or until January 1, 2022, whichever date comes first. AMS is not proposing to require regulated entities to change the labels of food products that have entered the stream of commerce prior to January 1, 2022. For example, if a food manufacturer used the last of its existing labels on December 1, 2021, and the product entered the stream of commerce the following week, the food manufacturer would not have to change the labels on the food products if those products remain on the store shelf after January 1, 2022. We invite comment on this approach.

## **V. Rulemaking Analyses and Notices**

### *Paperwork Reduction Act*

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), AMS is requesting OMB approval for a new information collection totaling 11,163,755 hours for the reporting and recordkeeping requirements contained in this proposed rule. Below, AMS has described and estimated the annual burden, *i.e.*, the amount of time and cost of labor, for entities to prepare and maintain information to participate in this proposed labeling program. The amended Act provides authority for this action.

*Title:* National Bioengineered Food Disclosure Standards for Manufacturers and Other Entities that Label Food for Retail Sale.

*OMB Number:* 0581–NEW.

*Expiration Date of Approval:* To be assigned by OMB.

*Type of Request:* Intent to establish a new information collection.

*Abstract:* The information collection requirements in this request are essential to foster documentation supporting information disclosure for consumer assurance, and to administer the amendment to the Agricultural Marketing Act of 1946.

The amended Act requires the Secretary to establish the NBFDS. AMS is the agency that would develop the new rule for manufacturers, importers, and retailers to ensure that bioengineered food bears a bioengineered food disclosure in accordance with the rule.

Entities subject to the mandatory disclosure requirement would be required to retain records that are customarily generated in the course of business. Such records may include, but would not be limited to, supply chain documents, purchase orders, sales confirmations, bills of lading, purchase

receipts, written records, labels, contracts, brokers' statements, analytical testing results, and process certifications that would substantiate claims about a food's bioengineering status. Records may also include others that are preexisting and readily available, such as identity preservation records, organic certification records, genetic marker testing records, and records related to product labels and food product formulations. Each entity subject to the disclosure requirement would decide for itself what records and records management protocol are appropriate, given the scope and complexity of the individual business, as well as the food being produced.

Enforcement would include AMS reviewing existing ingredient records and calculations, as needed, to verify compliance with the proposed standard. Records would have to be maintained in hardcopy or electronic format for at least two years after the food's distribution for retail sale. Entities would have five business days to provide records to AMS upon request, unless AMS extends the deadline. AMS would be required to provide prior notice of at least three days for onsite access to records.

The information collected would be used only by authorized representatives of USDA, including AMS, and would be maintained confidential to prevent inadvertent release of company information.

#### Cost of Compliance

AMS expects each entity (respondents) would need to submit and maintain information in order to satisfy the requirement of the proposed NBFDS regulation. AMS expects respondents to modify packaging for products that have been found to need disclosure. After this one-time burden, a recurring paperwork burden is expected to demonstrate compliance with the NBFDS regulation. For both one-time and annual burden, we describe the general evaluation and recordkeeping activities and estimate: (1) The hours spent, per response, completing the paperwork requirements of this labeling program; (2) the number of respondents; (3) the estimated number of responses per respondent; and (4) the total annual burden on respondents. This information is multiplied by the average wage to calculate the labor costs of implementing the labeling program.

#### 1. One-Time Paperwork Costs

*Estimate of Burden:* Public reporting burden for this collection of information is estimated to average 1 hour per response.

*Estimated Number of Respondents:* 166,975.

*Estimated Number of Responses per Respondent:* 41.0

*Estimated Total Annual Burden on Respondents:* 6,845,975 hours.

AMS estimates the annual initial cost per respondent will be \$1,384.57 per year. This estimate is based on an estimated 41.0 labor hours per year at \$33.77 per hour. The source of the hourly rate is the National Compensation Survey: Occupational Employment and Wages, May 2016, published by the Bureau of Labor Statistics. The rate is the mean hourly wage for compliance officers. The cost of the estimated total annual burden on respondents is expected to be \$231.2 million. This calculation is the number of estimated burden hours times the hourly rate.

#### 2. Annual Recordkeeping Costs

*Estimate of Burden:* Public reporting burden for this collection of information is estimated to average 1 hour per response.

*Estimated Number of Respondents:* 239,913.

*Estimated Number of Responses per Respondent:* 4.7

*Estimated Total Annual Burden on Respondents:* 1,127,591 hours.

AMS estimates the annual recordkeeping cost per respondent will be \$158.72 per year. This estimate is based on an hourly rate of \$33.77 per hour. The source of the hourly rate is the National Compensation Survey: Occupational Employment and Wages, May 2016, published by the Bureau of Labor Statistics. The rate is the mean hourly wage for compliance officers. The cost of the estimated total annual burden on respondents is expected to be \$38.1 million. This calculation is the number of estimated burden hours times the hourly rate.

*Comments:* AMS is inviting comments from all interested parties concerning the information collection and recordkeeping required as a result of the proposed amendments to 7 CFR part 66. Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including

the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments that specifically pertain to the information collection and recordkeeping requirements of this action should be sent to the Docket Clerk, 1400 Independence Ave. SW, Stop 0264, Washington, DC 20250-0268 and to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, 725 17th Street NW, Room 725, Washington, DC 20503. Comments on the information collection and recordkeeping requirements should reference the date and page number of this issue of the **Federal Register**. All responses to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record. The comment period for the information collection and recordkeeping requirements contained in this proposed rule is 60 days.

#### E-Gov

USDA is committed to complying with the E-Government Act by promoting the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

#### Civil Rights Review

AMS has considered the potential civil rights implications of this rule on minorities, women, or persons with disabilities to ensure that no person or group shall be discriminated against on the basis of race, color, national origin, gender, religion, age, disability, sexual orientation, marital or family status, political beliefs, parental status, or protected genetic information. This review included persons that are employees of the entities that are subject to these regulations. This proposed rule does not require affected entities to relocate or alter their operations in ways that could adversely affect such persons or groups. Further, this proposed rule would not deny any persons or groups the benefits of the program or subject any persons or groups to discrimination.

A 60-day comment period is provided to allow interested persons to respond to this proposed rule. All written comments received in response to this proposed rule by the date specified will be considered.

C. Executive Orders 12866, 13563, and 13771

USDA is issuing this rule in conformance with Executive Orders 12866 and 13563, which direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits, which include potential economic, environmental, public health and safety effects, distributive impacts, and equity. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

USDA estimates that the costs of the proposed NBFDS would range from \$598 million to \$3.5 billion for the first year, with ongoing annual costs of between \$114 million and \$225 million. The annualized costs in perpetuity would be \$132 million to \$330 million at a three percent discount rate and \$156 million to \$471 million at a seven percent discount rate. These results assume that the final rule includes a provision for the use of existing label inventories that extends to January 1, 2022; without such a provision, the total annualized cost are \$164 million to \$410 million and \$236 million to \$559 million at discount rates of three and seven percent respectively.

These cost estimates represent the cost of the proposed standard relative to a baseline in which there are no requirements for the labeling of food containing bioengineered foods or ingredients. This estimate encompasses three options for the definition of very small food manufacturers: Less than \$2,500,000 annual receipts (proposed definition); less than \$500,000 annual receipts (alternative A); and less than \$5,000,000 annual receipts (alternative B). Very small food manufacturers are exempted from the NBFDS, and the NBFDS utilizes the definition of small food manufacturers to mean any food manufacturer with less than \$10 million in annual receipts but \$2,500,000 or more in annual receipts. Small food manufacturers have an extra year for compliance. This cost estimate also includes three thresholds for separation costs: Not more than 5 percent of a specific ingredient by weight and only inadvertent introduction allowed; not more than 0.9 percent (0.9%) of a specific ingredient by weight and only inadvertent introduction allowed; and, a threshold of less than 5 percent of total additive weight. This estimate includes costs of disclosure for highly refined foods (such as oils and sugars) with no detectable rDNA. This estimate excludes

the costs of disclosure for incidental additives.

The proposed NBFDS is not expected to have any benefits to human health or the environment. Any benefits to consumers from the provision of reliable information about BE food products are difficult to measure. Under some, but not all, potentially informative analytic baselines (see the accompanying regulatory impact analysis for this proposed rule), a more clear-cut benefit of the NBFDS is that it eliminates costly inefficiencies of a state-level approach to BE disclosure. We estimate the size of these benefits by focusing on Vermont's BE labeling law because that law had been signed into law before the NBFDS was passed. The avoided costs of the Vermont law are a direct benefit of the NBFDS. We estimate that the total cost of the Vermont BE labeling law would have been between \$2 billion and \$6.9 billion for the first year with ongoing cost similar to the NBFDS. The annualized benefits from replacing the Vermont BE labeling law would be between \$126 million and \$333 million at a three percent discount rate and between \$190 million and \$565 million at a seven percent discount rate.

In addition to the pre-statutory (baselines 2a, 2b and 3) and simplistic post-statutory (baseline 1) baselines discussed in greater detail in the accompanying regulatory impact analysis for this proposed rule, a more nuanced post-statutory baseline would reflect the least costly rule that would comply with the requirements of the NBFDS; this is because the issuance of a federal regulation is necessary for preemption of state-level labeling requirements to be maintained in the long-run. Inefficiency-avoidance benefits would be zero under this analytic approach, but the costs could be lower than under the simplistic post-statute baseline (and lower than the costs summarized throughout most of this RIA). The use of this baseline would also be consistent with OMB's Regulatory Impact Analysis guidelines (Circular A-4), which states that, while agencies should generally use a pre-statute baseline, a post-statute baseline allows agencies to "evaluate those areas where the agency has discretion." This action's designation under E.O. 13771 will be informed by comments received in response to this proposed rule. Details on the estimates of costs and cost savings of this rule can be found in the economic analysis in the accompanying regulatory impact analysis.

This rule meets the definition of an economically significant regulatory action under Executive Order 12866, as

it is likely to result in a rule that would have an annual effect on the economy of \$100 million or more, and thereby triggers the requirements contained in Executive Order 13771. See OMB's Memorandum titled "Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017, titled 'Reducing Regulation and Controlling Regulatory Costs'" (February 2, 2017).

This proposed rule has been reviewed by OMB. USDA seeks comments and data on the estimated impacts of this rulemaking that may affect its designation under Executive Order 12866 and the Congressional Review Act. USDA also requests public comment on the estimated impacts of the rule, specifically whether there is information or data that may inform whether or not the market will experience a decrease in BE products/ingredients and what the impacts of the disclosure standard are on consumer choice and purchasing behaviors. In addition, USDA seeks comments and request any data or information on what impacts the disclosure standard may have on current and future innovation in the areas of crop biotechnology and food manufacturing and how such impacts on innovation may affect rural communities.

Regulations must be designed in the most cost-effective manner possible to obtain the regulatory objective while imposing the least burden on society. This proposed rule would establish a national mandatory bioengineered food disclosure and labeling provisions for certain human foods that are bioengineered or contain bioengineered ingredients. The national standard is necessary to replace similar laws enacted by various states, which were superseded by the amended Act. The rule is intended to meet public demand for consistent label information.

#### *D. Initial Regulatory Flexibility Analysis*

##### 1. Introduction

We have examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601-612). If a rule has significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities consistent with statutory objectives. We have tentatively concluded that the proposed rule, if finalized, will have a significant economic impact on a substantial number of small entities.



2. Economic Effects on Small Entities  
 a. Number of Small Entities Affected

Guidance on rulemaking recommends SBA's definition of small business as it applies to the relevant economic sector, which for this rule are NAICS 311, 312,

and 325, with indirect effects on sectors 115, 424, 445 and 446. SBA recently revised the definition for small businesses, as shown in Table 2. This table also provides the number of firms classified as small and large business for each 6-digit NAICS expected to be

impacted by the rule—164,329, or 98 percent of 166,975 total firms. With the new SBA definitions of small business, the share of manufacturers now classified as small is 96 percent (26,213 out of 27,176 total manufacturing firms).

TABLE 2—NUMBER OF SMALL FIRMS DIRECTLY AFFECTED BY PROPOSED RULE BY NAICS

[Data from the 2012 economic census]

2012 NAICS code	Meaning of 2012 NAICS code	SBA size standard	Number of firms			Percentage of industry defined as small (%)
			Total	Large	Small	
311211	Flour milling	1,000 Employees	165	13	152	92.1
311212	Rice milling	500 Employees	50	9	41	82.0
311213	Malt manufacturing	500 Employees	19	2	17	89.5
311221	Wet corn milling	1,250 Employees	31	6	25	80.6
311224	Soybean and other oilseed processing.	1,000 Employees	84	14	70	83.3
311225	Fats and oils refining and blending	1,000 Employees	90	14	76	84.4
311230	Breakfast cereal manufacturing	1,000 Employees	37	9	28	75.7
311313	Beet sugar manufacturing	750 Employees	15	6	9	60.0
311314	Cane sugar manufacturing*	1,000 Employees	35	4	31	88.6
311340	Nonchocolate confectionery manufacturing.	1,000 Employees	426	16	410	96.2
311351	Chocolate and confectionery manufacturing from cacao beans.	1,250 Employees	161	7	154	95.7
311352	Confectionery manufacturing from purchased chocolate.	1,000 Employees	1,110	13	1,097	98.8
311411	Frozen fruit, juice, and vegetable manufacturing.	1,000 Employees	148	16	132	89.2
311412	Frozen specialty food manufacturing	1,250 Employees	389	29	360	92.5
311421	Fruit and vegetable canning	1,000 Employees	575	28	547	95.1
311422	Specialty canning	1,250 Employees	106	6	100	94.3
311423	Dried and dehydrated food manufacturing.	750 Employees	167	17	150	89.8
311511	Fluid milk manufacturing*	1,000 Employees	246	33	213	86.6
311512	Creamery butter manufacturing	750 Employees	30	5	25	83.3
311513	Cheese manufacturing	1,250 Employees	390	14	376	96.4
311514	Dry, condensed, and evaporated dairy product manufacturing.	750 Employees	133	27	106	79.7
311520	Ice cream and frozen dessert manufacturing.	1,000 Employees	347	19	328	94.5
311612	Meat processed from carcasses*	1,000 Employees	1,202	33	1,169	97.3
311615	Poultry processing*	1,250 Employees	307	31	276	89.9
311710	Seafood product preparation and packaging.	750 Employees	497	15	482	97.0
311811	Retail bakeries	500 Employees	6,423	17	6,406	99.7
311812	Commercial bakeries	1,000 Employees	2,321	58	2,263	97.5
311813	Frozen cakes, pies, and other pastries manufacturing.	750 Employees	205	21	184	89.8
311821	Cookie and cracker manufacturing	1,250 Employees	309	16	293	94.8
311824	Dry pasta, dough, and flour mixes manufacturing from purchased flour.	750 Employees	375	27	348	92.8
311830	Tortilla manufacturing	1,250 Employees	334	5	329	98.5
311911	Roasted nuts and peanut butter manufacturing.	750 Employees	208	15	193	92.8
311919	Other snack food manufacturing	1,250 Employees	307	12	295	96.1
311920	Coffee and tea manufacturing*	750 Employees	410	14	396	96.6
311930	Flavoring syrup and concentrate manufacturing.	1,000 Employees	138	9	129	93.5
311941	Mayonnaise, dressing, and other prepared sauce manufacturing.	750 Employees	303	18	285	94.1
311942	Spice and extract manufacturing	500 Employees	344	28	316	91.9
311991	Perishable prepared food manufacturing.	500 Employees	640	40	600	93.8
311999	All other miscellaneous food manufacturing.	500 Employees	567	35	532	93.8
312111	Soft drink manufacturing	1,250 Employees	244	21	223	91.4
312112	Bottled water manufacturing*	1,000 Employees	219	10	209	95.4
312113	Ice manufacturing*	750 Employees	310	5	305	98.4

TABLE 2—NUMBER OF SMALL FIRMS DIRECTLY AFFECTED BY PROPOSED RULE BY NAICS—Continued  
[Data from the 2012 economic census]

2012 NAICS code	Meaning of 2012 NAICS code	SBA size standard	Number of firms			Percentage of industry defined as small (%)
			Total	Large	Small	
312120	Breweries	1,250 Employees	843	4	839	99.5
312130	Wineries	1,000 Employees	2,519	12	2,507	99.5
312140	Distilleries	1,000 Employees	231	3	228	98.7
325411	Medicinal and botanical manufacturing.	1,000 Employees	394	24	370	93.9
445110	Supermarkets and other grocery (except convenience) stores.	\$32.5 Million	42,107	702	41,405	98.3
445120	Convenience stores	\$29.5 Million	23,086	39	23,047	99.8
445210	Meat markets	\$7.5 Million	4,880	27	4,853	99.4
445220	Fish and seafood markets	\$7.5 Million	1,929	20	1,909	99.0
445230	Fruit and vegetable markets	\$7.5 Million	2,716	42	2,674	98.5
445291	Baked goods stores	\$7.5 Million	2,470	18	2,452	99.3
445292	Confectionery and nut stores	\$7.5 Million	1,952	30	1,922	98.5
445299	All other specialty food stores	\$7.5 Million	4,018	27	3,991	99.3
445310	Beer, wine, and liquor stores	\$7.5 Million	28,386	392	27,994	98.6
446110	Pharmacies and drug stores	\$27.5 Million	18,852	306	18,546	98.4
446191	Food (health) supplement stores	\$15 Million	4,786	7	4,779	99.9
446199	Other health and personal care stores.	\$7.5 Million	7,389	270	7,119	96.3
Total			166,975	2,646	164,329	98.4

\* These products denote those sectors of the industry that, based on the proposal, are less likely to be required to disclose pursuant to the NBFDS.

3. Definitions

a. Small Business

The definition of small business for the Initial Regulatory Flexibility Analysis are those codified in 13 CFR 121.201.

b. Delay for Small Food Manufacturers

For the purposes of the implementation of the delay for “small food manufacturers,” AMS proposes that USDA adopt a definition of *small food manufacturer* that would align with FDA. AMS has attempted to be as consistent as possible with other similar existing regulations in order to minimize the cost burden on the industry.

The proposed definition of *small food manufacturer* is: “any food manufacturer with less than \$10 million in annual receipts but \$2,500,000 or

more in annual receipts.” This definition would be similar to FDA’s criteria for allowing an extended compliance period in its recent revision requirements for food labeling (Docket numbers FDA–2012–N–1210 and FDA–2004–N0258). FDA determined that 95 percent of food manufacturers would fall into this category, or roughly 32,345 firms. FDA also determined that 48 percent of the UPCs would be owned by the firms classified using this criteria as small businesses.

The alternative definition analyzed is a business (including any subsidiaries and affiliates) with fewer than 500 employees.

b. Exemptions for Very Small Food Manufacturers

AMS proposes to define *very small food manufacturer* as “any food manufacturer with annual receipts of

less than \$2,500,000.” We also analyzed the following scenarios for comparison:

*Alternative A:* A food manufacturer with less than \$500,000 in annual receipts.

*Alternative B:* A food manufacturer with less than \$5,000,000 in annual receipts.

Currently, there are roughly 18,530 businesses that would fall into the very small category under the proposed definition; 11,170 businesses that would fall into the very small category under *Alternative A*; and, 20,440 businesses that would fall into the very small category under *Alternative B*. This is out of an estimated 27,176 total firms.

Table 3, below, presents data showing the number of establishments by size classification according to the different definitions of very small, small, and large manufacturers. AMS is seeking comment on the proposed definitions.

TABLE 3—NUMBER OF MANUFACTURERS FOR ALTERNATIVE SIZE CLASSIFICATIONS

Size Classification Options for Manufacturers	Number of Firms		
	Very Small	Small	Large
All manufacturing establishments	27,176		
<i>Small Firm Criteria:</i> Firms with less than \$10 million in annual food sales (FDA definition)	N/A	23,029	4,147

TABLE 3—NUMBER OF MANUFACTURERS FOR ALTERNATIVE SIZE CLASSIFICATIONS—Continued

<i>Very Small Firm Alternatives</i>			
<i>Very small alternative A:</i> Firms with less than \$500,000 in annual receipts .....	11,527	11,502	4,147
<i>Very small alternative B:</i> Firms with less than \$5,000,000 in annual receipts .....	21,581	1,448	4,147
<i>Very small proposed definition:</i> Firms with less than \$2,500,000 in annual receipts .....	19,455	3,574	4,147

N/A means no definition was determined for this size category.

c. Costs to Small Entities

We compared the maximum annualized cost in our analysis of the proposed rule to the revenue of firms in each size category (by receipts) using 2012 Census data. There was no category that would not be excluded under any of the definitions of very small food manufacturer under consideration for which costs were greater than one percent of revenues.

Summary

Under the Regulatory Flexibility Act (5 U.S.C. 606(b)), we tentatively conclude that the proposed rules will have a significant economic impact on a substantial number of small entities. The statutory exemption of very small food manufacturers further reduces the impact on the entities that are likely to face the highest costs relative to revenue.

D. Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. Executive Order 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on: (1) Policies that have tribal implications, including regulations, legislative comments or proposed legislation; and (2) other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

The Agricultural Marketing Service has assessed the impact of this rule on Indian tribes and determined that this rule may, to our knowledge, have tribal implications that require tribal consultation under E.O. 13175. AMS invites Tribal Leaders to consult on the tribal implications of this proposed rule, and AMS will work with the Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions, and modifications identified

herein are not expressly mandated by Congress.

E. Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. The proposed rule is not intended to have retroactive effect. The amended Act specifies that no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food or seed in interstate commerce any requirement relating to the labeling or disclosure of whether a food is bioengineered or was developed or produced using bioengineering for a food subject to the proposed national bioengineered food disclosure standard that is not identical to the mandatory disclosure requirements under the proposed standard. With regard to other Federal statutes, all labeling claims made in conjunction with this regulation must be consistent with other applicable Federal requirements. There are no administrative procedures that must be exhausted prior to any judicial challenge to the provisions of this rule.

F. Executive Order 13132

This rule has been reviewed under Executive Order 13132, Federalism. Executive Order 13132 directs agencies to construe, in regulations and otherwise, a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence to conclude that Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute. The amended Act includes an express preemption of State law. Sections 293(e) and 295(b) provide that no State may directly or indirectly establish or continue with any food or seed requirement relating to the labeling or disclosure of whether the food or seed is bioengineered or was developed or produced using bioengineering, including any requirement for claims that a food or seed is or contains an ingredient that was developed by or

produced using bioengineering. After USDA establishes the NBFDS, States may adopt standards that are identical to the NBFDS, and States may impose remedies for violations of their standards, such as monetary damages and injunctive relief.

With regard to consultation with States, as directed by Executive Order 13132, USDA notified the governors of each U.S. State of the amended Act's purpose and preemption provisions by letter in August 2016. Copies of the letters may be viewed at <https://www.ams.usda.gov/rules-regulations/gmo>.

List of Subjects in 7 CFR Part 66

Agricultural commodities, Bioengineering, Food labeling, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, USDA proposes to amend 7 CFR chapter 1 by adding part 66 to read as follows:

**PART 66—NATIONAL BIOENGINEERED FOOD DISCLOSURE STANDARD**

**Subpart A—General Provisions**

- Sec.
- 66.1 Definitions.
- 66.3 Disclosure requirement and applicability.
- 66.5 Exemptions.
- 66.7 Process for revision of lists.

**Subpart B—Bioengineered Food Disclosure**

- 66.100 General.
- 66.102 Text disclosure.
- 66.104 Symbol disclosure.
- 66.106 Electronic or digital link disclosure.
- 66.108 Text message disclosure.
- 66.110 Small food manufacturers.
- 66.112 Small and very small packages.
- 66.114 Foods sold in bulk containers.
- 66.116 Voluntary disclosure.
- 66.118 Other claims.
- 66.120 Use of existing label inventories.

**Subpart C—Other Factors and Conditions for Bioengineered Food**

- 66.200 Request or petition for determination.
- 66.202 Standards for determination.
- 66.204 Submission of request or petition.

**Subpart D—Recordkeeping**

- 66.300 Scope.  
 66.302 Recordkeeping requirements.  
 66.304 Access to records.

**Subpart E—Enforcement**

- 66.400 Prohibited act.  
 66.402 Audit or examination of records.  
 66.404 Hearing.  
 66.406 Summary of results.

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

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

(2) A food that meets 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) or any successor regulation.

(ii) [Reserved].

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

*Compliance date* means—

(1) *Initial compliance date.* (i) Except for small food manufacturers, entities responsible for bioengineered food disclosure must comply with the requirements of this part by January 1, 2020.

(ii) Small food manufacturers must comply with the requirements of this part by January 1, 2021.

(2) *Updates to the bioengineered food lists.* When AMS updates the list of commercially available bioengineered foods not highly adopted and/or the list of commercially available bioengineered foods with a high adoption rate pursuant to § 66.7, entities responsible for bioengineered food disclosure must comply with the updates no later than six 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 commercially available bioengineered foods not highly adopted* means a list, maintained by AMS, of commercially available bioengineered foods with an adoption rate of less than eighty-five percent (85%) in the United States, as determined by the Economic Research Service or any successor agency.

*List of commercially available bioengineered foods with a high adoption rate* means a list, maintained by AMS, of commercially available bioengineered foods with an adoption rate of eighty-five percent (85%) or more in the United States, as determined by the Economic Research Service or any successor agency.

*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.

*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, 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 less than \$10 million in annual receipts but \$2,500,000 or more in annual receipts.

*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.* 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.

(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. Alternative 1–A (for paragraph (c))

(c) Food in which an ingredient contains a bioengineered substance that is inadvertent or technically unavoidable, and accounts for no more than five percent (5%) by weight of the specific ingredient.

Alternative 1–B (for paragraph (c))

(c) Food in which an ingredient contains a bioengineered substance that is inadvertent or technically unavoidable, and accounts for no more than nine-tenths percent (0.9%) by weight of the specific ingredient.

Alternative 1–C (for paragraph (c))

(c) Food in which the ingredient or ingredients that contain a bioengineered substance account for no more than five percent (5%) of the total weight of the food in final form.

(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 organic under the National Organic Program.

#### § 66.7 Process for revision of lists.

Lists of bioengineered foods that are commercially available in the United States as identified by the Agricultural Marketing Service will be maintained as follows:

(a) *Current lists.* Current lists will be published and maintained on AMS' website.

(b) *Updates to the lists.* AMS will announce its intention to review and update the lists annually through notification in the **Federal Register** and on the AMS website.

(1) Recommendations regarding additions to and subtractions from the list may be submitted within the timeframe and to the address(es) specified in the notification.

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

(3) AMS will post public recommendations, along with information about other revisions to the lists 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, on its website. AMS will invite interested persons to submit comments and additional relevant information regarding the proposed changes during a specified timeframe.

(4) Following its review of all relevant information provided, AMS will determine what revisions should be made to the lists and will publish the updated lists in the **Federal Register** and on the AMS website.

(c) *Compliance grace period.* Regulated entities will have 18 months following the effective date of the updated lists to make any necessary changes to food labels in accordance with the disclosure requirements of this part.

### 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 for in §§ 66.110 and 66.112 of this subpart.

(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 buyer 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 buyer 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) *High adoption bioengineered foods.* Unless records support non-disclosure pursuant to § 66.302(b), if a food (including any ingredient produced from such food) is on the list of bioengineered foods that are commercially available and highly adopted, 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) *Non-high adoption bioengineered foods.* Unless records support non-disclosure pursuant to § 66.302(b), if a food (including any ingredient

produced from such food) is on the list of bioengineered foods that are commercially available, but not highly adopted, the text disclosure must be “may be a bioengineered food,” “may contain a bioengineered food ingredient,” “bioengineered food,” or “contains a bioengineered food ingredient,” as appropriate.

(c) *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.

The symbol described in this section may be used to designate bioengineered food, food that contains a bioengineered food ingredient, a food that may be a bioengineered food, or a food that may contain a bioengineered food ingredient. The bioengineered food symbol must replicate the form and design of the example in Figure 1 to § 66.104:

##### *Alternative 2–A*

(a) Using a circle with a green circumference, and the capital letters “BE” in white type located slightly below the center of the circle. The bottom portion of the circle contains an arch, filled in green to the bottom of the circle. Approximately halfway through the height of the circle is a second arch, filled in darker green to the top of the first arch. Beginning on the left side of the second arch is stem arching towards the center of the circle, ending in a four-pointed starburst above the space between the letters “B” and “E.” 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.

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

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

#### Figure 1 to § 66.104



##### *Alternative 2–B*

(a) Using a filled, green circle with the lower-case letters “be” in white type, slightly above the center of the circle.

Just below the letters is an inverted, white arch, beginning just below the middle of the “b” and ending just below the middle of the “e.” The outside of the circle includes ten (10) triangular leaves spread equally around the perimeter of the circle. The leaves transition from light green at the top of the circle to yellow and orange on the sides, ending with dark orange leaves on the bottom of the circle.

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

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

#### Figure 1 to § 66.104



##### *Alternative 2–C*

(a) Using a circle with a circumference made up of 12 separate, equally-spaced segments. The segments gradually transition from yellow at the top of the circle to dark orange at the bottom of the circle. The interior of the circle is a green background with the lowercase letters “be”, in white type, located slightly above the center of the circle. Below the letters is an inverted, green arch, beginning below the center of the “b” and ending below the center of the “e.” Inside the middle of the “b” is a bifurcated leaf.

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

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

#### Figure 1 to § 66.104



#### § 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 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 following statement: “Call 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 material.

(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 entity responsible for the bioengineered food disclosure 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 [number] for more food information.” The number must be a number, including a short code, that is capable of sending an immediate response to the consumer’s mobile device.

(b) The only information in the response must be the bioengineered food disclosure described in § 66.102.

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

(d) A manufacturer who selects the text message option 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 as soon as possible and not be used for any other purpose.

**§ 66.110 Small food manufacturers.**

A small food manufacturer may 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 of this subpart or 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.

(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) of this subpart. 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, 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 Foods sold in bulk containers.**

(a) Bioengineered food sold in bulk containers, 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) *Applicability and disclosure.* Bioengineered foods that are not subject to mandatory disclosure under this part may be labeled in accordance with this section.

(b) *Type of disclosure.* The disclosure must be in one or more of the forms described in this paragraph (b).

(1) An on-package text disclosure, in accordance with § 66.102.

(2) The 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.

(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 buyer under ordinary shopping conditions.

(d) *Recordkeeping.* Reasonable and customary records should be maintained to verify disclosures made under this section.

**§ 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.

**§ 66.120 Use of existing label inventories.**

Products that are manufactured, labeled, and entered into the stream of commerce prior to January 1, 2022, or until regulated entities use up remaining label inventories as of the initial compliance date, whichever date comes first, may be sold using their existing food labels.

**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 Secretary 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 factor or condition.

(d) An 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.

(c) The Administrator may consider other relevant information, including whether the 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 factor or condition.

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



(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 for food on the lists maintained by AMS of bioengineered foods commercially available in the United States.

##### § 66.302 Recordkeeping requirements.

(a) *General.* (1) Entities subject to this subpart must maintain records that are customary or reasonable to demonstrate compliance with the bioengineered food disclosure requirements of this part.

(2) The records must contain sufficient detail as to be readily understood and audited.

(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.

(b) *Records supporting non-disclosure.* If a food is on either AMS-maintained list of bioengineered foods commercially available in the United States and does not bear a bioengineered food disclosure, entities subject to this subpart must maintain records that include documented verification that the food is not a bioengineered food or that it does not contain a bioengineered 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 AMS could not confirm whether the entity is in compliance with the bioengineered food disclosure standard for purposes of § 66.402 of this part.

#### Subpart E—Enforcement

##### § 66.400 Prohibited act.

It is a violation of section 293 of the Act 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. 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 or examination may be made of the records of the entity responsible for the bioengineered food disclosure under § 66.100(a) of this part.

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

(d) At the conclusion of the audit or examination of records, AMS will make the findings of the audit or examination

of records available to the entity that was the subject of the audit or examination of record.

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

##### § 66.404 Hearing.

(a) Within 30 days of receiving the results of an audit or examination of records to which the entity that was the subject of the audit or examination of record 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 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, the response, and any supporting documents, and may allow the entity that was the subject of the audit or examination of records 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.

##### § 66.406 Summary of results.

(a) If the entity that was the subject of the audit or examination of records 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 audit or examination of records.

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

Dated: April 30, 2018.

**Bruce Summers,**  
*Acting Administrator.*

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