



## **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:** Final rule.

**SUMMARY:** This rule establishes the new national mandatory bioengineered (BE) food disclosure standard (NBFDS or Standard). The new Standard requires food manufacturers, importers, and other entities that label foods for retail sale to disclose information about BE food and BE food ingredients. This rule is intended to provide a mandatory uniform national standard for disclosure of information to consumers about the BE status of foods. Establishment and implementation of the new Standard is required by an amendment to the Agricultural Marketing Act of 1946.

**DATES:** *Effective Date:* This rule becomes effective [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**].

*Implementation Date:* January 1, 2020.

*Extended Implementation Date (for small food manufacturers):* January 1, 2021.

*Voluntary Compliance Date:* Ends on December 31, 2021.

*Mandatory Compliance Date:* January 1, 2022.

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**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 of Agriculture (Secretary) to establish the NBFDS for disclosing any food that is or may be bioengineered. 7 U.S.C. 1639b(a)(1). Subtitle E also directs the Secretary to establish requirements and procedures necessary to carry out the new Standard. 7 U.S.C. 1639b(a)(2).

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## **I. Introduction**

The Secretary delegated authority for establishing and administering the NBFDS to the Agricultural Marketing Service (AMS). To assist with development of the new Standard, AMS posted 30 questions for public consideration and comment on its website

(<https://www.ams.usda.gov/rules-regulations/public-input-bioengineered-food-disclosure->

questions) on June 28, 2017. Contributors from diverse backgrounds, including consumers, food manufacturers and retailers, farmers and processors, State and foreign governments, and various associations and other interested groups representing consumers and industry submitted over 112,000 responses. AMS posted the responses on its website.

AMS considered responses to the 30 questions in the development of a proposed rule, which was included in a notice of proposed rulemaking (NPRM) published in the Federal Register on May 4, 2018 (83 FR 19860). The NPRM outlined AMS's proposed requirements and procedures for the new Standard to be codified at 7 CFR part 66 and requested public comment on several regulatory alternatives offered for consideration. The public comment period closed on July 3, 2018. AMS received approximately 14,000 comments by the end of the comment period.

Subsequent to publication of the NPRM, AMS published two documents in the **Federal Register** related to this proceeding. The first, published on May 23, 2018 (83 FR 23827), announced the availability of a recorded webinar about the proposed NBFDS on AMS's website. The second, published on June 20, 2018 (83 FR 28547), made a correction to the Initial Regulatory Flexibility Analysis contained in the NPRM to clarify that the proposed rule was not expected to have a significant economic impact on a substantial number of small business entities.

AMS also published two supplemental documents related to the NBFDS. One, a Regulatory Impact Analysis and its supporting documents, was posted on Regulations.gov at <https://www.regulations.gov/document?D=AMS-TM-17-0050-2833>. The other, a graphic document showing alternative proposals for BE food disclosure labels, was posted on Regulations.gov at <https://www.regulations.gov/document?D=AMS-TM-17-0050-0003>, and on

AMS's website at

<https://www.ams.usda.gov/sites/default/files/media/ProposedBioengineeredLabels.pdf>.

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). AMS sponsored such a study, and the results were published on AMS's website (<https://www.ams.usda.gov/reports/study-electronic-or-digital-disclosure>) in September 2017. Public comments on the results of the study were solicited in conjunction with the NPRM. The Secretary's determination regarding this matter is discussed in Section III of this final rule.

Finally, Subtitle F of the amended Act addresses Federal preemption of State and local genetic engineering labeling requirements. 7 U.S.C. 1639i. 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.

The purpose of the NBFDS as contained in this final rule is to provide a mandatory disclosure standard for BE food, by which uniform information is provided to consumers. Nothing in the disclosure requirements set out in this final rule conveys information about the health, safety, or environmental attributes of BE food as compared to non-BE counterparts.

In fact, the regulatory oversight by USDA and other Federal Government agencies ensures that food produced through bioengineering meets all relevant Federal health, safety, and environmental standards. The agencies responsible for oversight of the products of biotechnology include: USDA's Animal and Plant Health Inspection Service (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 (Coordinated Framework) is a policy framework that summarizes the roles and responsibilities of these three principal regulatory agencies with respect to regulating biotechnology products.

The final rule is intended to provide for disclosure of foods that are or may be bioengineered to consumers, but also seeks to minimize implementation and compliance costs for the food industry – costs that could be passed on to all 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; public comments submitted in response to the proposed rule were critical to the development of the final rule.

The following discussion of the NBFDS is divided into three parts: (1) applicability; (2) disclosure; and (3) administrative provisions.

## **II. Applicability**

The amended Act directs USDA to promulgate regulations regarding foods required to bear a disclosure indicating that the food is 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 mandatory disclosure to those foods subject to the labeling requirements of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 301 *et seq.*) and to certain foods subject to labeling under the Federal Meat Inspection Act (FMIA)(21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (PPIA)(21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (EPIA)(21 U.S.C. 1031 *et seq.*) administered by the Food Safety and Inspection Service (FSIS). 7 U.S.C. 1639 and 1639a. Definitions pertinent to the new part 66, descriptions of foods that are subject to disclosure, and explanations of applicable exemptions are included in subpart A of the new regulatory section.

Section 66.3 sets forth the general requirements for disclosure. Section 66.3(a) requires that labels for bioengineered food must bear a BE disclosure consistent with the requirements of part 66. Section 66.3(a)(2) prohibits labels for food that is not bioengineered from bearing a BE disclosure unless the food may bear a voluntary disclosure under § 66.116, based on records maintained under § 66.302.

#### *A. Definitions*

Section 66.1 lists the definitions that apply to new part 66. For subpart A, the key terms are “bioengineered food,” “bioengineered substance,” “food,” “label,” “predominance,” “similar retail food establishment,” “very small food manufacturer,” and “List of Bioengineered Foods.” These terms are critical in determining what foods require a BE disclosure.

#### *B. Food Subject to Disclosure*

Whether a food is subject to the labeling requirements of the amended Act, depends as a preliminary matter on 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>1</sup> 7 U.S.C. 1639(2). The final rule adopts 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, FDA has jurisdiction over the FDCA and has the authority to determine what is considered “food” under the FDCA. AMS has deferred to FDA in interpreting the definition of “food.” However, the amended Act limits the definition of food for purposes of the NBFDS to articles used for human consumption and does not include articles used for animals.

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<sup>1</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.

Therefore, although pet food and animal feed are “food” under the FDCA, such foods for animals are not covered by this regulation, pursuant to the amended Act. Chewing gum is considered to be “intended for human consumption,” and 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 falls 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 requirements of the three FSIS statutes previously mentioned, with certain exceptions. *See* 7 U.S.C. 1639a. As for the FDCA, which is under FDA jurisdiction, the NBFDS applies to all foods subject to its labeling requirements, 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. Distilled spirits, wines, or malt beverages as defined by the Federal Alcohol Administration Act (FAA Act) are foods under the FDCA but are not subject to the NBFDS because they are subject to the labeling provisions of the FAA Act rather than the labeling requirements of the FDCA. Alcoholic beverages not subject to the labeling provisions of the FAA Act, such as wines with less than seven percent alcohol by volume and beers brewed without malted barley and hops, would be subject to the NBFDS. The amended Act also specifies that the NBFDS only applies to foods

subject to the labeling requirements of the three FSIS statutes 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(c)(2).

FDA's method of determining predominance relies on weight of the ingredients, as does FSIS's. The NBFDS uses the same methods FDA uses to determine predominance at 21 CFR 101.4(a)(1), which provides that 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. Thus, a multi-ingredient food product that contains meat, poultry, or egg product (including beef broth, if identified as a composite ingredient), subject to the FMIA, the PPIA, or the EPIA, 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 stew where pork is the primary ingredient followed by other ingredients such as sweet corn, would not be subject to the NBFDS. The corn may be bioengineered, but pork, which is subject to the labeling requirements of the FMIA, is the predominant ingredient, so the canned stew product is not subject to the NBFDS, per the amended Act. If, however, a meat, poultry, or egg product 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 (catfishes), and meats such as venison and rabbit are subject to the FDCA (but not the Federal Meat Inspection Act). Thus, a multi-ingredient food product that contains one of these as the first ingredient would be subject to the NBFDS. A multi-ingredient product that contained one of these as the second most predominant ingredient or lower, could also require disclosure, unless the product is otherwise exempt (for example, due to the predominance of another ingredient such as chicken or beef, 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).

#### *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 is directly incorporating this statutory definition into the definition of “bioengineered food”.

The NPRM invited public comment on two different interpretations of the statutory definition of “bioengineering” and on the scope of the regulatory definition of “bioengineered food.” Specifically, comments were solicited on whether refined foods and ingredients should be subject to disclosure under the NBFDS.

The first interpretation, identified as Position 1 in the NPRM, stated that refined products do not “contain genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques” because the refining process rendered genetic material undetectable using common testing methods. The second interpretation, identified as Position 2 in the NPRM, stated that the scope of the definition of “bioengineering” applies to all foods produced from bioengineering, such as refined products.

AMS adopts Position 1 with some modifications. The statutory definition of “bioengineering” makes clear that food must “contain[] genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques. . .” to be labeled as a “bioengineered food.” AMS believes that the definition of “bioengineering” sets forth the scope of the mandatory disclosure and, therefore, is incorporated into the definition of “bioengineered food.” A commenter suggested that AMS adopt a definition of “highly refined” if it adopts Position 1. We did not do so because the final rule does not use that term.

AMS has chosen to adopt the definition of “bioengineered food” that hews closely to the plain language of the amended Act. This definition references § 66.9 to explain how a regulated entity may demonstrate that a food, including a refined food ingredient, does not contain detectable modified genetic material. AMS has revised the proposed definition of “bioengineered food” to reflect its interpretation of the amended Act that foods with undetectable modified genetic material are not bioengineered foods.

Whether a food or food ingredient contains modified genetic material may vary depending on the refining process used to produce the food. For refined foods that are derived from bioengineered crops, no disclosure is required if the food does not contain detectable modified genetic material.

Commenters discussed how testing might be used to detect the presence of modified genetic material in a food. Some commenters stated that testing for modified genetic material would be difficult to enforce, expensive, and present barriers to international trade. These commenters stated that regulated entities may choose to make a BE disclosure rather than conduct testing, thereby resulting in different labels for similar food products.

Other commenters supported the use of testing to determine detectability and offered ideas regarding testing methods and standards to determine the presence or absence of detectable modified genetic material. A few commenters asked AMS to establish minimal standards regarding the analytical tools used for detecting, identifying, and quantifying modified genetic material. Some commenters also urged AMS to update the NBFDS as scientific detection methods evolve, and a few further recommended that AMS maintain publicly available guidance documents or lists of scientifically validated genetic testing methods to ensure testing consistency in the marketplace.

AMS acknowledges there are multiple ways to determine whether a food or ingredient contains detectable modified genetic material. Because the amended Act authorizes examinations, audits, and similar activities with respect to records for enforcement of the NBFDS (7 U.S.C. 1639b(g)(2)-(3)), AMS added provisions in § 66.9 that describe how regulated entities can use records to demonstrate that modified genetic material is not detectable. Regulated entities are in the best position to know about the products they are sourcing and the

refinement processes they have undergone. An entity's records, therefore, can be used to demonstrate that modified genetic material is not detectable.

First, as provided in § 66.9(a)(1), regulated entities can demonstrate that modified genetic material is not detectable with records verifying that the food is sourced from a non-bioengineered crop or other food source, such as non-bioengineered salmon.

Second, as provided in § 66.9(a)(2), regulated entities can demonstrate that modified genetic material is not detectable in the food with records verifying that the food has been subjected to a refinement process "validated" to render modified genetic material undetectable. Process validation for the purposes of the NBFDS can be achieved through laboratory testing, as provided in § 66.9(b). Commenters stated that modified genetic material is undetectable when bioengineered crops are refined or processed under certain conditions. Commenters described the food refining and manufacturing process and explained the rigorous quality controls necessary to meet modern customer demands. Based on this information, AMS believes that once a refiner's process has been validated by testing to render modified genetic material undetectable, foods subjected to the same process in a defined, controlled, documented, and repeated way will also have no detectable modified genetic material. Regulated entities that produce or use refined foods may rely on processing records alone to prove the absence of detectable modified genetic material. In other words, foods subjected to the validated refining process would not require additional laboratory testing to prove the lack of modified genetic material.

To comply with NBFDS requirements, regulated entities can maintain records to verify the foods they use have been subjected to refining processes that have been validated to render modified genetic material undetectable. Such records may include customary processing records

maintained in the normal course of business, as well as copies of the most recent analytical testing results used to validate the refining process. Section 66.9(c) provides standards of performance for analytical testing to validate that foods subjected to specific refining processes contain no detectable modified genetic material.

Third, as provided in § 66.9(a)(3), regulated entities can demonstrate that modified genetic material is not detectable by maintaining certificates of analysis or other testing records appropriate to the specific food tested which confirm the absence of modified genetic material. As mentioned above and provided in § 66.9(c), AMS established performance standards related to detectability analyses for the purposes of the NBFDS.

AMS recognizes that some regulated entities may wish to disclose that their processed food is derived from a bioengineered source even when modified genetic material is not detectable in the food. In addition to the authority to establish the mandatory disclosure Standard, the amended Act at 7 U.S.C. 1639b(a)(2) grants the Secretary the authority to establish other requirements that are necessary to carry out the Standard. AMS has determined, based on numerous comments, that it is necessary for the Standard to include the ability for regulated entities to disclose voluntarily that their processed food was made with ingredients derived from a bioengineered source to provide a mechanism for regulated entities to provide information to consumers. This provision is discussed in more detail Section III.I. – Voluntary Disclosure, below.

## *2. Conventional Breeding*

AMS did not include a proposed definition of “conventional breeding,” a component term of the definition of “bioengineering.” The NPRM solicited comments on whether such a definition should be included in the NBFDS, and if so, what it should be.

Many commenters recommended that AMS define “conventional breeding” within the NBFDS final rule, to better define the scope of NBFDS for regulated entities and consumers. Several commenters suggested various definitions, including adopting the definition used by FDA or from the Codex Alimentarius. Several commenters stated that the term “conventional breeding” is commonly understood in the industry and, therefore, does not need to be defined. Some of those commenters who did not support defining the term argued that any such attempts would be inherently confusing or misleading to consumers.

AMS finds no compelling reason to adopt a definition of “conventional breeding” at this time and agrees with commenters who advised not defining the term. AMS finds that “conventional breeding” is a commonly understood term within industry and does not need to be defined. As techniques and technology evolve, any definition today could become unworkable or obsolete because it does not and could not anticipate those advancements. Foregoing defining the term allows AMS to respond to those challenges in real time.

### *3. Found in Nature*

AMS did not include a proposed definition of “found in nature,” another component term of the definition of “bioengineering.” The NPRM solicited comments on whether such a definition should be included in the NBFDS, and if so, what it should be. The NPRM specifically requested comments on whether protections under intellectual property law might be considered when determining whether a genetic modification could be found in nature. Comments were also sought on other possible methods for determining whether a genetic modification could be “found in nature.”

Commenters generally did not support defining or including the term “found in nature” within the NBFDS. Many of those in opposition believed the term “found in nature” itself was

nebulous, misleading, and not adequately defined by science. Others argued that agriculture is inherently separate from nature. Of those that did request the term be defined, two common suggestions were “spontaneously occurs in nature, such as natural biological evolution, and does not overcome natural physiological reproductive or combination barriers,” or “the kinds of genetic modifications which can occur in nature within the genome of an organism, without human intervention.”

One commenter was concerned that if definitions are deemed necessary, the definitions avoid setting precedents in other regulatory areas, and be kept as simple and as clear as possible. Another group of commenters stated that “this should be done through a supplemental proposed rule that provides the public with an additional opportunity to provide public comments.”

Commenters mostly rejected the idea of using intellectual property law as a method of determination. Some of the objections were that it would add more complexity to the NBFDS without any additional clarity; could create unintended disincentives towards development of non-BE foods; or is outside the scope of the NBFDS. One commenter supported the consideration of intellectual property law “when appropriate, as one non-dispositive factor among others in making a determination.” Another stated that the absence of a patent should not be a factor in determining if a modification can be found in nature, since it is not required to seek patents on BE food.

AMS finds it unnecessary to define the term “found in nature.” AMS received no compelling arguments to define the term and believes that attempting to do so may cause confusion in light of the rapid pace of innovation. In addition, there was little support for relying on intellectual property law to inform decisions about whether specific modifications “could not otherwise be found in nature.” In order to incorporate technological changes in industry into this

mandatory labeling standard, AMS believes it needs to retain maximum flexibility. That will not be accomplished by narrowly defining “found in nature.”

#### *D. List of Bioengineered Foods*

AMS has developed the List of Bioengineered Foods (List) to identify the crops or foods that are available in a bioengineered form, and to aid regulated entities considering whether they may need to make a BE disclosure. The List is provided in § 66.6 of the Standard. As will be discussed later in Section III – Disclosure, a regulated entity’s records will determine whether disclosure for that food is required under the NBFDS. The List includes bioengineered foods for human consumption that may be produced anywhere in the world. But the List should not be considered exhaustive, as new BE products continue to be developed. Even if a food is not on the List, regulated entities that have actual knowledge that a food they are selling is bioengineered, as defined in § 66.1, must make appropriate disclosure of that food. The List will be maintained and updated as described later in this section.

The List of Bioengineered Foods replaces the two lists of commercially available bioengineered foods in the United States that AMS proposed in the NPRM. AMS proposed in the NPRM maintaining lists of “highly adopted” and “non-highly adopted” BE foods based on U.S. planted crop acreage.

While some commenters agreed that the lists might simplify compliance with the NBFDS, many recommended consolidating the two lists into one and expanding the consolidated list to include bioengineered foods produced in other countries to provide a more complete picture of the variety of foods produced through bioengineering. Commenters argued against equating U.S. planted acreage with human food production and commercial availability in the United States, explaining that a large percentage of highly adopted bioengineered crops are used

for animal feed, and that U.S. planted acreage does not necessarily reflect the prevalence of bioengineered foods available on the market. Commenters further argued that commercial availability should not be a basis for regulation, because that attribute is not specified in the definition of BE food, and because commercial availability can vary from country to country, depending on how foods are approved for use.

For simplicity, AMS consolidated the two lists into one and expanded the consolidated List to include bioengineered crops and foods that may be produced in other countries. The List makes no presumptions about market share represented by bioengineered versions of those crops and foods in the United States. It merely provides information about what bioengineered crops and foods (including ingredients made from such foods), that meet the definition of “bioengineered food”, could be offered for retail sale in the United States, based on information available to AMS. A crop or food may be included on the List, but not require disclosure under the NBFDS. For instance, not all apple varieties are bioengineered. Non-bioengineered apples would not require disclosure. As noted elsewhere, the amended Act requires each person subject to mandatory BE food disclosure under the NBFDS 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). The List establishes the need for recordkeeping by regulated entities who are using or selling the crops and foods on the List. Further, the List will aid regulated entities in deciding whether they may need to make a BE disclosure. Options for disclosure related to a regulated entity’s records about foods on the List are described in Section III.A.5 and IV.A of this document.

To compile the lists that were proposed in the NPRM, AMS considered data published by the International Service for the Acquisition of Agri-biotech Applications (ISAAA),<sup>2</sup> FDA's list of Biotechnology Consultations on Food from GE Plant Varieties (Consultations), and information published by USDA's Economic Research Service (ERS).<sup>3</sup> AMS also considered input from industry stakeholders and consumers about which foods should be considered bioengineered and require disclosure labeling. Some commenters in response to the NPRM recommended that ISAAA be the sole source for information on international BE foods and the modifications that have been made to them. Some commenters said that foods should be added to the list as soon as any one of FDA's consultation processes are completed for that food. Other commenters suggested that additional sources of data on BE foods, such as *Statistics Canada*,<sup>4</sup> should be considered, given the frequent exchange of foods between Canada and the U.S.

Each of the recommended sources assists in the development and maintenance of the List; the List should represent a composite of information gathered from many sources. However, to be consistent in determining what crops or foods should be on the List, AMS has determined that the foods included on the initial List of Bioengineered Foods must meet the following criteria: (1) they are authorized for commercial production somewhere in the world, and (2) they are reported to be in legal commercial production for human food somewhere in the world. AMS relied on resources such as USDA reports and databases, and ISAAA reports and databases,<sup>5</sup> to determine what crops and foods currently meet those criteria. The List attempts to

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<sup>2</sup> ISAAA (2016), Global Status of Commercialized Biotech/GM Crops: 2016. *ISAAA Brief No. 52*. ISAAA: Ithaca, NY. <http://www.isaaa.org/resources/publications/briefs/52/default.asp>, accessed February 5, 2018.

<sup>3</sup> Economic Research Service (2017), Genetically engineered varieties of corn, upland cotton, and soybeans, by state and for the United States, 2000-17, *Adoption of Genetically Engineered Crops in the U.S.*, <https://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us.aspx>, accessed February 5, 2018.

<sup>4</sup> Statistics Canada, <https://www.statcan.gc.ca/eng/start>, accessed July 26, 2018.

<sup>5</sup> ISAAA GM Approval Database: <http://www.isaaa.org/gmapprovaldatabase/>. Accessed August 10, 2018.

capture any BE crops or foods that meet the statutory definition of “bioengineering,” based on existing technology, and that could potentially be offered for sale in the United States. AMS recognizes that there are other bioengineered foods that meet one of the criteria for list inclusion, but not both. For example, bioengineered rice has been authorized for production and use as food in several countries, but AMS finds no evidence that it is currently in legal commercial production anywhere. Foods such as BE rice could be added to the List through the update process described below when available information suggests that it would be appropriate to do so.

The considerations described above and the NBFDS definition for “bioengineered food” will be used to determine what foods would be added to or removed from the List moving forward. (See the Treatment of Technologies section, below.)

Section 66.1 of the NBFDS defines the List of Bioengineered Foods as a list maintained and updated by AMS of foods for which bioengineered versions have been developed. In the NPRM, AMS proposed to describe the initial List in the preamble to the final rule and to update the List by notice in the **Federal Register** with the opportunity for public comment. Given the impact of including foods on the List, we have determined that it is appropriate to incorporate the foods on the List in the final rule text to provide greater transparency. Further, AMS will update the List through rulemaking.

Information and data to support inclusion of each crop or food on the List come from a variety of reliable sources, including industry reports and academic and government sources. In some cases, the listed crop or food itself may not typically be considered human food, but it may be the source from which human food is made. For example, products made from field corn, such as grits, corn chips, corn tortillas, and corn cereal are human foods and may be subject to

disclosure if they meet the definition of bioengineered food. The following foods comprise the List of Bioengineered Foods: alfalfa, apple (Arctic™ varieties), canola, corn, cotton, eggplant (BARI Bt Begun varieties), papaya (ringspot virus-resistant varieties), pineapple (pink flesh), potato, salmon (AquAdvantage®), soybean, squash (summer), and sugarbeet.

Where practical, the List includes specific information about individual crops and foods, such as descriptions or trade names, to help distinguish bioengineered versions of those foods from their non-bioengineered counterparts, as requested by commenters. This specificity is intended to identify foods for which disclosure may be necessary, based on the regulated entities' records. For instance, although apples are on the List, most apple varieties are not known to be bioengineered. The List is narrowed by identifying the specific apples that are known to be bioengineered. As other BE versions of the listed foods are authorized and become legally available, AMS will revise such listings to be more generic during the annual update process.

Regulated entities may refer to the AMS website to obtain additional information regarding the associated bioengineered events for crops or foods they are sourcing and determine whether they need to make a disclosure. In some cases, trade names or other information may be provided to further simplify the identification and determination process for regulated entities. As well, information on the website may provide consumers additional details about traits (e.g., non-browning, pesticide resistance, virus resistance, enhanced growth, etc.) for which the foods have been bioengineered. Providing this detailed information is intended to help reduce burdens for regulated entities by narrowing the list of varieties of each food that may be bioengineered.

#### *1. List Maintenance and Revision*

AMS proposed in the NPRM that the List be subject to review and update on an annual basis, allowing for public input into the process. AMS also proposed an 18-month compliance

period following List updates to allow for food label revisions in response. Such a schedule was proposed to minimize the frequency with which regulated entities would be required to update food labels, if, for instance, new BE foods were added to the List. Some commenters urged AMS to revise the List more frequently to avoid delay providing current information to consumers. Others suggested updates should occur less frequently than proposed to minimize the impact on small businesses that might have to change labels accordingly. Some commenters asked that the compliance period for revising labels be shortened, and others asked that it be extended.

The NPRM described a process to update the List on an annual basis. The final rule adopts that process, except that AMS will also initiate rulemaking to amend the List as appropriate. As described in § 66.7(a), AMS will announce the annual review through the **Federal Register** and on the AMS website. Interested parties may submit recommendations about foods that could be added to or deleted from the List at any time, including in response to the request for recommendations that accompanies the review notice. Recommendations should include data or other information to support those recommendations. AMS will publish any recommendations, along with supporting information, on its website and request comments on the recommendations.

Following a review of available information, including consultation with Federal Government agencies that comprise the Coordinated Framework or any successor body, AMS will make a determination on whether to initiate rulemaking to amend the List. Section 66.7(b) provides an 18-month compliance period from the effective date of any revision to the List to allow regulated entities time to revise existing food labels if needed.

While the List of Bioengineered Foods identifies the foods for which regulated entities must maintain records and that may be required to bear a BE disclosure, the List and the records kept do not alleviate a regulated entity's responsibility for disclosure when the entity has actual knowledge that its food is a BE food. Under § 66.109, a regulated entity with actual knowledge that it is using BE food is responsible for disclosing BE foods, even if the food is not listed on the List of Bioengineered Foods. This section does not require regulated entities to seek out that information, but they also cannot ignore or be willfully blind to information that the food they are sourcing is in fact bioengineered.

## *2. Treatment of Technologies*

Technologies continue to evolve, and food produced through a specific technology may or may not meet the definition of BE food. Respondents to the 30 questions urged AMS to determine whether foods developed through certain emerging technologies would be within the scope of the definition of BE food. However, AMS proposed in the NPRM that the products of technology, rather than solely the technology itself, should be evaluated to determine whether a food meets the BE food definition and might require disclosure. AMS proposed to provide for the consideration of new technologies used to develop foods during the process of reviewing and revising the List pursuant to § 66.7(a). AMS proposed to do so through consultation with the U.S. Government agencies responsible for oversight of the products of biotechnology – USDA-APHIS, EPA, FDA, and appropriate members of the Coordinated Framework for the Regulation of Biotechnology. In that way, AMS could understand whether foods resulting from new technologies would meet the definition of “bioengineered food” and should be added to the List. Conversely, foods may be removed from the List if they are no longer produced from a

technology that meets the definition of “bioengineered food.” In other cases, some varieties may meet the definition, while others do not.

Comments in response to the NPRM ranged from those commenters who urged that the scope of the NBFDS should reflect the use of all current and emerging technologies to those who argued that some new genetic engineering techniques would fall outside the scope of the statutory definition. AMS continues to believe that determinations about what constitutes BE food for the purposes of the NBFDS should focus primarily on the characteristics of foods that have been produced using bioengineering as defined in the amended Act, and whether such foods meet the definition of “bioengineered food.” Thus, as proposed, the products of new technologies will be considered during reviews and updates of the List of Bioengineered Foods.

#### *E. Factors and Conditions*

As described in the proposed rule, 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.

Commenters were generally supportive of the proposed process for adopting factors or conditions under which a food is considered a BE food, and AMS is adopting the proposed process described in the NPRM. Subpart C describes 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 allows 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 § 66.200, the determination process begins 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 § 66.204. Section 66.204 describes the process for submitting a request or petition, including where to send the submission. The submission needs to include a description and analysis of the requested new factor or condition and any supporting documents or data. Section 66.204 describes how to properly mark confidential business information that may be included to support the request, to ensure its confidentiality. Finally, § 66.204 instructs that the submission must explain how the standards for consideration apply to the requested factor or condition.

Section 66.202 describes the standards for consideration by which the Secretary’s designee, the AMS Administrator, would evaluate the request or petition. Given the existing statutory definition of “bioengineering,” the first standard, in paragraph (a), requires 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 paragraph (b), requires the Administrator to evaluate the cost of implementation and compliance. In applying this second standard, the Administrator will evaluate the cost related to the factor or condition, the difficulty for affected regulated entities to implement the factor or condition, especially small businesses, and the difficulty AMS would have in monitoring compliance with the factor or condition. Paragraph (c) allows the

Administrator to consider other relevant information as part of the evaluation. Relevant information for a particular proposed factor or condition will include its compatibility with the food labeling requirements of other Federal agencies or foreign governments. In determining compatibility with other requirements, AMS will 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 will also consult with the United States Trade Representative (USTR) and the Department of State 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 will initiate rulemaking that seeks to amend the definition of “bioengineered food” in § 66.1 to include the factor or condition.

Some commenters asked AMS to clarify in the final rule the parameters for submitting petitions to adopt factors or conditions. A few commenters asked AMS to establish a specific time period within which the agency would respond to requests for adoption of factors or conditions, as well as a time period for regulated entities to attain compliance with adopted factors or conditions.

AMS has made no changes to the submission parameters in connection with requests or petition for factors and conditions, as we believe they are clear and transparent. AMS has not established a time period within which the agency will respond to requests for adoption of

factors or conditions because such responses will vary depending on agency resources, the complexity of the submitted request for adoption of factors or conditions, and the nature of implementing regulation. Similarly, AMS has not provided a time period for regulated entities to attain compliance with adopted factors and conditions in subpart C, as adopted factors and conditions act as carve outs from the statutory definition of bioengineering such that compliance with the adopted factor or condition should not be burdensome. To the extent that the adopted factors or conditions would be burdensome or require additional time for compliance, AMS would address any compliance period in future rulemakings considering the specific adopted factors and conditions.

In the NPRM, AMS proposed two submitted requests for 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 refined food may be detected. The impact of adopting these factors or conditions will be to limit the scope of the definition of “bioengineered food,” thus potentially excluding certain products from disclosure.

#### *1. 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’s 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 product may be used in another product as an incidental additive that is not required to be included in the ingredient list. Under this factor or condition, such an item will 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 falls 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 will 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 will simplify compliance and reduce labeling costs for regulated entities. Finally, AMS finds it relevant that adoption of this factor or condition would 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” is to exclude certain incidental additives from disclosure. Based on public comments on the 30 questions and the NPRM, 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. In the NPRM, AMS sought comment on whether, more generally, enzymes present in food should be considered “bioengineered food.”

AMS has made no changes to this factor and condition regarding incidental additives under which products can be excluded from disclosure. The amended Act provides the Secretary with authority to limit disclosure in certain circumstances. The factors and conditions process

offers a fair and rational method by which to consider various proposals. For the reasons mentioned, AMS believes that exempting incidental additives from BE disclosure that are not required to be labeled per FDCA regulations is sensible, in alignment with the labeling requirements of other trading partners and will limit the burden on regulated entities without unduly limiting disclosure for consumers.

Some commenters sought modifications to the text of this provision clarifying what “insignificant” means or clarifying the types of incidental additives that are not subject to disclosure. AMS does not believe such clarification is necessary. The provision references the FDA regulations that AMS relied upon in drafting the provision. That FDA regulation describes the circumstances in which incidental additives are not labeled as an ingredient. Title 21 CFR 101.100(a)(3) provides an exemption for incidental additives that are present in a food at insignificant levels and do not have any technical or functional effect in that food. For the purposes of §101.100(a)(3), incidental additives are:

- Substances that have no technical or functional effect but are present in a food by reason of having been incorporated into the food as an ingredient of another food, in which the substance did have a functional or technical effect.
- Processing aids, which are as follows:
  - Substances that are added to a food during the processing of such food but are removed in some manner from the food before it is packaged in its finished form.
  - Substances that are added to a food during processing, are converted into constituents normally present in the food, and do not significantly increase the amount of the constituents naturally found in the food.

- Substances that are added to a food for their technical or functional effect in the processing but are present in the finished food at insignificant levels and do not have any technical or functional effect in that food.
- Substances migrating to food from equipment or packaging or otherwise affecting food that are not food additives as defined in section 201(s) of the act; or if they are food additives as so defined, they are used in conformity with regulations established pursuant to section 409 of the act.

Section 101.100(a)(3)(i), (ii), and (iii) provide a list of incidental additives that are not required to be labeled under FDA regulations and by extension are not required to be disclosed as BE foods. AMS believes that the cross-reference to the FDA regulations is clear.

With respect to treatment of yeasts, enzymes, or any other microorganisms, AMS agrees that if they qualify as incidental additives that are not required to be labeled as ingredients on a food label, then they do not require disclosure as BE foods. However, bioengineered yeasts, enzymes, and other organisms that do not qualify as incidental additives that are not required to be labeled as ingredients may require disclosure as BE foods unless they meet the requirements of another provision (for instance, by establishing that their modified genetic material is not detectable). AMS cannot make a categorical exemption for microorganisms in this final rule; however, such an exemption is possible through the factors and conditions process in future rulemakings.

## *2. Undetectable Modified Genetic Material*

The NPRM also sought comment on another proposed factor and condition – excluding food from the disclosure standard where the modified genetic material in the food cannot be detected. As the NPRM noted, if AMS ultimately proceeded with Position 2 and presumed that

refined ingredients are bioengineered foods, this factor or condition, if adopted, would be a means to potentially exclude products where modified genetic material cannot be detected. As discussed above, AMS did not adopt Position 2, so this factor or condition is not incorporated into the final rule. The definition of “bioengineered food” in the final rule already excludes foods where modified genetic material is not detectable.

#### *F. Exemptions*

The amended Act includes two express exemptions to the disclosure requirement: for food served in a restaurant or similar retail food establishment and for very small food manufacturers. 7 U.S.C. 1639b(b)(2)(G). 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 well, the amended Act prohibits 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 specifies that the certification of food under USDA’s National Organic Program (7 CFR part 205) shall be considered sufficient to make claims about the absence of bioengineering in the food. 7 U.S.C. 6524. Section 66.5 incorporates each of these as regulatory exemptions in the NBFDS.

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

Section 66.5(a) exempts food served in a restaurant or similar retail food establishment from disclosure under the NBFDS. In the NPRM, § 66.1 defined “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 the retailer's premises. This definition is consistent with the definition of "food service establishment" included in other labeling programs authorized by 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.

The NPRM solicited comments on the scope of this definition. Some commenters stated that restaurants should not be exempt from the NBFDS because it would undermine the transparency and consistency important to consumers who want to know the origins of their food. Other commenters supported the exemption generally and AMS's proposed definition. Other commenters stated that AMS's proposed definition was too narrow and should include a list of places as examples, rather than an exclusive list, such as cafeteria, lunch room, food stand, food truck, saloon, tavern, bar, lounge, salad bar, delicatessen, entertainment venue, or other retail business establishment where meals or refreshments constituting food may be purchased. One commenter requested that transportation carriers be added to the list of places exempted from the NBFDS.

Another commenter stated that all foods prepared, processed, or packaged in the retail food establishment, including those utilizing "central kitchen" locations for certain prepared foods, should be exempt from the disclosure requirement and that the term "packaged" should conform to 21 CFR 1.20, FDA's general food labeling requirements.

Based on the comments received, AMS has modified the definition of "similar retail food establishment" to add additional examples, including food truck and transportation carrier. AMS considered including a list of places as examples, rather than an exhaustive list, but believes that the reference to "other similar establishment operated as an

enterprise engaged in the business of selling prepared food to the public” should capture any additional places that are not specifically listed. To clearly address a point of confusion observed in the comments received, AMS is clarifying that salads, soups, and other ready-to-eat items prepared by grocery stores are exempt from the disclosure requirements.

AMS has not modified the definition to state “where meals or refreshments constituting food may be purchased,” as we believe that with this insertion the exemption would be much broader than the plain meaning of the amended Act. AMS believes that the exemption is intended to cover ready-to-eat or prepared foods. To extend the exemption to all foods prepared, processed, or packaged in a retail food establishment, which would include bulk foods such as granola or apples in a bin, would conflict with the requirement that foods subject to FDCA’s labeling requirements are subject to disclosure. The modified definition provides clarity and flexibility to regulated entities and is in accordance with the plain language of the amended Act.

## *2. Very Small Food Manufacturers*

Section 66.5(b) exempts very small food manufacturers from the disclosure requirement of the NBFDS. Section 66.1 defines “very small food manufacturer” as a food manufacturer with annual receipts of less than \$2.5 million. To develop this definition, AMS considered FDA’s exemptions or special labeling requirements for certain food 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 101.36(h)(1)) and U.S. Census Bureau (USCB) regulations. AMS evaluated the impact of applying various definitions of “very small food manufacturer” by estimating the number of firms that would be exempted, the number of products that would likely be exempt, and the proportion of annual industry sales that would be exempt under each exemption level. The

NPRM included the following tables showing 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 USCB’s 2012 *Statistics of U.S. Businesses*).

### Food Manufacturers

<b>Establishment Receipts Threshold (in \$)</b>	<b>Cumulative Percent of Firms Exempt</b>	<b>Cumulative Percent of Products Exempt</b>	<b>Cumulative Percent of Sales Exempt</b>
<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

<b>Establishment Receipts Threshold (in \$)</b>	<b>Cumulative Percent of Firms Exempt</b>	<b>Cumulative Percent of Products Exempt</b>	<b>Cumulative Percent of Sales Exempt</b>
<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-	63.96%	4.41%	3.63%

9,999,999			
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Applying the FDA exemptions (annual sales of no more than \$500,000) at 21 CFR 101.9(j)(1)(i) and 101.36(h)(1) as described above would exempt 45 percent of firms, only one percent of products, and less than 0.5 percent of sales for food manufacturers, and only 17 percent of firms and about 0.1 percent of products and sales for dietary supplement manufacturers. In conducting the Initial Regulatory Impact Analysis, we estimated the impact of applying the USCB definition of very small enterprise (fewer than 20 employees), which falls somewhere between the \$2.5 million and \$5 million annual sales cutoffs. We found that both of these revenue cutoff levels for the definition of “very small food manufacturer” would offer significantly greater relief for those manufacturers, while still having a relatively minor impact on the amount of information available to consumers. Exempting manufacturers with annual receipts of less than \$2.5 million would provide regulatory relief to 74 percent of food manufacturers and 45 percent of dietary supplement manufacturers, while reducing the number of products covered by four percent (two percent for dietary supplements), and the number of purchases covered by only one percent for both food and dietary supplement manufacturers.

The NPRM solicited comments on alternative revenue cutoffs for the definition of “very small food manufacturer” of \$500,000 and \$5 million. Many commenters generally supported AMS’s proposal. Some stated that there should be no exemption for very small food manufacturers or to use a \$500,000 or \$1,000,000 revenue cutoff. Some commenters stated that number of employees was a more suitable criterion in determining the threshold for a very small food manufacturer. One commenter recommended the agency should revise the definition of “very small food manufacturer” in proposed 7 CFR 66.1 to read: “any food manufacturer with

either (1) annual receipts of less than \$2,500,000 or (2) 50 or fewer employees, measured as an annual daily average.”

Some commenters suggested that we should use food sales, rather than total receipts, to define small food manufacturers to avoid inclusion of firms that have multiple sources of income that could cause them to exceed the threshold. Some commenters stated that the exemption for very small food manufacturers be extended to small retailers.

AMS has made no changes to its proposal. In considering this definition, AMS must balance providing regulatory flexibility for regulated entities and providing information to consumers regarding the bioengineered status of their foods. AMS considered other revenue cutoffs, including those above and below \$2,500,000, and considered other definitions from various sources. Because food and dietary supplement manufacturers are in the manufacturing sector, they are both defined by number of employees for purposes of SBA size categorization. However, the firms defined as small or very small for purposes of the NBFDS all fall well below the SBA size categorizations, so we do not feel we need to be bound by that methodology.

In addition, the small food manufacturer definition was defined to be consistent with the FDA definition of small manufacturer under its nutrition labeling standards, which use annual receipts. AMS believes that the very small food manufacturer definition should be consistent with these other definitions.

AMS believes that annual receipts are a reasonable measure in determining the threshold for small businesses and specifically here, very small food manufacturers. Using total receipts is administratively simpler than tracking and demonstrating revenue by category for purposes of this rule. We do not expect that there are a significant number of firms for which this distinction

would make a difference, but it would increase recordkeeping burden for all firms that fall under this exemption if it was based on food sales rather than annual receipts.

The \$2.5 million threshold will provide relief to small businesses, but will not markedly decrease the number of products subject to disclosure. By defining “very small food manufacturers” as those with annual receipts below \$2,500,000, about 74 percent of food manufacturers are exempt from mandatory disclosure, but 96 percent of products will still be subject to disclosure. An increase in revenue cutoff would increase the number of exempt businesses, but would also increase the number of products exempt from disclosure. The definition of very small food manufacturer provides flexibility for small entities while providing information to consumers regarding the bioengineered status of their foods.

With respect to comments seeking that this exemption extend to small retailers, AMS states that this exemption is statutorily mandated and cannot be extended to small retailers. To the extent that a small retailer is also a very small food manufacturer, they may be able to take advantage of the exemption in that instance.

### *3. Threshold*

Section 66.5(c) establishes a threshold for the inadvertent or technically unavoidable presence of bioengineered substances of up to five percent (5%) for each ingredient, with no such allowance for any BE presence that is intentional. Section 66.1 defines “bioengineered substance” as substance that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (rDNA) techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature. This definition differs slightly from the definition in the NPRM. We replaced the word “matter” with “substance” to simplify discussions about threshold. Thus, food in which any single ingredient contains more

than 5% of a bioengineered substance, regardless of whether its presence is inadvertent or unintentional, is subject to disclosure. Food containing any amount of a bioengineered substance that is not inadvertent or unintentional is also subject to disclosure.

In proposing an appropriate threshold level, AMS considered responses to the 30 questions posted on its website. Respondents offered a number of concepts to consider, including different threshold levels for determining exemptions (0.9, 5, and 10 percent) and different ways of calculating the threshold (by ingredient or by total weight). The NPRM solicited comments on multiple proposed issues pertaining to threshold exemptions. These exemptions consisted of three alternative thresholds for bioengineered substances that would trigger disclosure.

The first proposed option (Alternative 1-A) 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, would not be subject to disclosure as a result of that one ingredient. The second proposed option (Alternative 1-B) 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. The third proposed option (Alternative 1-C) would allow regulated entities to use intentionally 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.

Some commenters supported threshold alternative 1-B, which would have exempted products where the bioengineered substance in an ingredient was inadvertent or technically unavoidable and less than 0.9 percent of each specific ingredient by weight. They suggested that

this alternative is the most transparent, aligns with consumer expectations, is more widely used in other countries, and is the most closely aligned with existing industry standards.

A small number of comments supported alternative 1-C, an exemption allowing for the intentional use of a bioengineered substance up to 5 percent of the total weight of the food, because it would allow for the de minimis use of BE ingredients. Many commenters generally opposed alternative 1-C.

AMS has adopted Alternative 1-A because we believe this approach appropriately balances providing disclosure to consumers with the realities of the food supply chain. A threshold amount of 5 percent allows BE and non-BE production systems to coexist, whereas a lower threshold, such as 0.9 percent, may increase the regulatory burden for producers and food processors. Any disruption or increased burden on the food supply chain may unnecessarily increase the cost of producing food, and that cost may ultimately be passed on to consumers. To the degree that some production systems and supply chains have already adopted a threshold lower than 5 percent for purposes of voluntary labeling, continued compliance with a lower threshold for the inadvertent or technically unavoidable presence of a BE substance would meet the requirements of the NBFDS.

AMS considered the threshold amounts used by other countries and acknowledges that there is no uniform or universal threshold amount. While some other countries have chosen lower amounts for their threshold, such as 0.9 percent, compliance with a lower threshold for a foreign country would still comply with the NBFDS. For example, a food produced and labeled for sale in a country with a threshold amount of 0.9 percent, would still comply with the 5 percent threshold AMS has chosen because 0.9 percent is lower than 5 percent. AMS believes this approach minimizes the potential burden on trade.

AMS did not choose alternative 1-C or allow for the intentional use of a BE substance without requiring disclosure because the agency believes that allowing entities to avoid disclosing despite the intentional presence of BE substances in food does not provide consumers with the information they desire. In addition, AMS believes that, to the degree regulated entities are currently tracking the use of BE and non-BE foods for voluntary disclosure, most customary records only indicate the presence or absence of a BE substance and not necessarily the amount. Requiring regulated entities to track the amount of a BE substance for purposes of disclosure would create an unnecessary burden on regulated entities and likely increase their compliance costs.

AMS reiterates that the threshold is intended to allow for coexistence among BE and non-BE crops, and nothing about the threshold amount is meant to convey anything related to health, safety, or environmental attributes of BE food as compared to non-BE alternatives. This rule is intended only to provide a mandatory uniform national standard to equip consumers with information for their personal use.

#### *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). Section 66.5(d) incorporates 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.

As most commenters noted, this exemption is mandated by the amended Act, and AMS does not have the authority to change this statutory mandate. Some commenters argued that the

rationale for excluding the products of animals fed bioengineered feed should also apply to yeasts, rennet, and enzymes produced by fermentation using a bioengineered substrate. The plain reading of the statutory language exempting the products of animals fed bioengineered feed does not provide authority for AMS to extend the exemption to yeast, rennet, or enzymes or to extend the definition of “animal” to include those substances. As discussed above, those substances may be exempted if they qualify as an incidental additive or if they do not contain detectable modified genetic material. Thus, the final rule adopts the proposed rule text without revisions.

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

Subtitle F states that “[i]n 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. The NPRM stated that 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 under the NOP. *See* 7 U.S.C. 1639b(f). The NPRM proposed that § 66.5(e) would exempt certified organic foods from BE disclosure.

Commenters generally supported this exemption and some commenters stated the need for a technical correction to accurately exempt all food certified under the NOP and to create consistency with both the language and the meaning in the amended Act. The prohibition on the use of excluded methods extends to all NOP certified label categories (“100% Organic,”

“Organic,” and “Made with Organic”) and all ingredients (organic and nonorganic) contained within each label category. Commenters stated that the inclusion of the phrase “...certified organic...” is problematic because it could imply that the exemption does not extend to products certified in the “made with organic (specified ingredients or food group(s))” labeling category and recommended that the exemption should be applied to foods certified under the NOP.

AMS agrees with commenters that a technical correction to this provision is required. This exemption is intended to cover all NOP certified label categories (“100% Organic,” “Organic,” and “Made with Organic”) because NOP regulations at 7 CFR 205.301(a) through (c) clearly require that no ingredient may be bioengineered. *See* 7 CFR 205.301(f)(1) and 205.105(e) and the definition of “excluded methods” in 7 CFR 205.2. Accordingly, § 66.5(e) is revised to read “Food certified under the National Organic Program.” This exemption, however, does not apply to “products with less than 70 percent organically produced ingredients” as described in 7 CFR 205.301(d) and 205.305 because those products may include bioengineered ingredients along with organic ingredients.

#### *G. Severability*

AMS has added a new § 66.11 on severability in subpart A. This is a standard provision in regulations. This section provides that if any provision of part 66 is found to be invalid, the remainder of the part shall not be affected.

### **III. Disclosure**

As statutorily required, the NBFDS, “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.” 7 U.S.C. 1639b(b)(3) The amended Act provides three disclosure options for all food subject to the mandatory BE food disclosure standard, 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 required the Secretary to conduct a study to identify potential technological challenges that may impact whether consumers 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 1639(b)(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).

Subpart B specifies: (1) who is responsible for the BE food disclosure in § 66.100; (2) the text disclosure in § 66.102; (3) the symbol disclosure in § 66.104; (4) the electronic or digital link disclosure in § 66.106; (5) the text message disclosure in § 66.108; (6) the disclosure options for small food manufacturers in § 66.110; (7) the disclosure options for small or very small packages in § 66.112; (8) the disclosure for food sold in bulk containers in § 66.114; (9) the voluntary disclosure in § 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 § 66.1, these definitions are consistent with those used in the NOP regulations, 7 CFR 205.2. In addition, the terms “regulated entity,” “marketing and promotional information,” “principal display panel,” “small package,” “very small package,” and “small food manufacturer,” are also discussed.

## *A. General*

### *1. Responsibility for Disclosure*

The amended Act requires bioengineered food and bioengineered food ingredients to be labeled or “disclosed” in accordance with regulations promulgated by the Secretary. 7 U.S.C. 1639b(b)(1). Section 66.100(a) identifies three categories of entities responsible for disclosure: food manufacturers, importers, and certain retailers. This final rule adopts these three categories of responsible entities as proposed. For purposes of clarity, a definition of “regulated entity” is incorporated in § 66.1 as “the food manufacturer, importer, or retailer that is responsible for making bioengineered food disclosures under § 66.100(a).” Accordingly, if a food is packaged prior to receipt by a retailer, either the food manufacturer or the importer is responsible for ensuring that the food label bears a BE food disclosure in accordance with this part. If a retailer packages a food or sells food in a bulk container and/or display, then the retailer is responsible for ensuring that the food bears a BE food disclosure in accordance with this part. Based on the input received from commenters, this approach will align responsibility for labeling with the requirements of other mandatory food labeling laws and regulations, including those administered by FDA and USDA FSIS.

### *2. International Impact*

Based on extensive input from commenters, we continue to find that importers should be subject to the same disclosure and compliance requirements as domestic entities. Importers of BE foods are subject to the requirements of the NBFDS and are required to make appropriate disclosures on the labels of BE foods imported and sold in the United States.

Based on comments, this rule finds that establishing mutual recognition arrangements with appropriate foreign government entities that have established labeling standards for BE food

may be appropriate in the future. No such recognition arrangements are currently in place or are established under this regulation. As no mutual recognition arrangements are currently in place, imports of products are subject to the disclosure and recordkeeping requirements of the NBFDS as described in this final rule. U.S. exports to non-partner countries will need to continue to meet that country's import requirements.

### *3. Appearance of Disclosure*

Requirements on how the disclosure must appear on food labels and packaging remain the same as proposed in the NPRM. As provided in § 66.100(c), the disclosure is required 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 will 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 decided 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 after considering comments, 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 requirements in § 66.100(c) will likely provide the BE food disclosure information to consumers in an accessible and transparent manner, while allowing regulated entities to have flexibility in implementing the requirements.

### *4. Placement of Disclosure*

As proposed, § 66.100(d) offered 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. Section 66.100(d) would not apply to bulk foods (see § 66.114). “Information panel” as defined in § 66.1 is consistent with the definitions found in the USDA 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 § 66.1, reflects the definition found in FDA’s food labeling regulations at 21 CFR 101.1. Based on input from commenters, if there is insufficient space on either the information panel or the principal display panel, the disclosure may be placed on an alternate panel likely to be seen by a consumer under ordinary shopping conditions.

Based on commenter feedback, this rule requires locating the disclosure on the information panel or the principal display panel because 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 will be effective because consumers will be able to see all the disclosures, statements, and marketing claims in one common place on the label.

The NBFDS will require placement of the disclosure adjacent to the manufacturer/distributor name and location statement. Such placement will avoid interference

with other required statements on the information panel. We think that the information panel will 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 permitting 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. Also, as a result of input from commenters, we are including additional flexibilities for food manufacturers; if there is insufficient space on the information panel or the principal display panel, the disclosure may be displayed in an alternate panel, provided the disclosure is available to the consumer under ordinary shopping conditions. In response to a received comment, AMS is clarifying the BE disclosure for multi-unit packages. For multi-unit packages where individual units are not labeled for retail sale and are enclosed within and not intended to be separated from the multi-unit package, AMS has determined that disclosure on the outer packaging in a manner consistent with the options provided in § 66.100(c) is sufficient to meet the requirements of the NBFDS. Any additional requirements regarding multi-unit packaging would be addressed in future rulemakings.

This subpart does not prevent, pursuant to § 66.118, regulated entities from making other claims regarding bioengineered foods, provided that such claims are consistent with applicable Federal law.

##### *5. How the List of Bioengineered Foods Relates to Disclosure*

The purpose of the List of Bioengineered Foods is to provide regulated entities with a tool to determine whether a food must bear a BE disclosure. If a food or food ingredient is on the List of Bioengineered Foods, and the regulated entity's records show that the food is a

bioengineered food or does not indicate whether or not the food is bioengineered, the food must bear a BE disclosure. While we acknowledge that this framework may result in regulated entities placing a BE disclosure on a food that they do not know with certainty is bioengineered, we believe that it is appropriate to err on the side of disclosure to provide consumers with the fullest information about food that could be bioengineered.

The List of Bioengineered Foods is alfalfa, apple (Arctic<sup>TM</sup> varieties), canola, corn, cotton, eggplant (BARI Bt Begun varieties), papaya (ringspot virus-resistant varieties), pineapple (pink flesh), potato, salmon (AquAdvantage®), soybean, squash (summer), and sugarbeet. These foods comprise most of the bioengineered crops or foods grown in the world and, therefore, most of the bioengineered food and food ingredients. As described in § 66.7, AMS will conduct annual reviews of the List. Through this process, AMS will request public input, including data and other information, to support any changes made. Any amendments (additions or deletions) to this List will be made through rulemaking. We recognize that for some items on this List, most varieties are not bioengineered. Because of this, AMS will maintain more detailed information on its website about each bioengineered crop or food to help regulated entities understand the associated bioengineered events for crops or foods they are sourcing and assist in determining whether disclosure is required. AMS will update information on its website as necessary.

If a regulated entity is using a food, including an ingredient produced from such food, not on the List of Bioengineered Foods, and the regulated entity has actual knowledge that the crop or ingredient is, in fact, bioengineered, the entity is still responsible for labeling the food in compliance with the NBFDS. If a regulated entity uses a food, including an ingredient produced from such food, on the List of Bioengineered Foods and its records demonstrate that the food is

not bioengineered (*e.g.*, modified genetic material is not detectable in accordance with § 66.9) or is exempt from disclosure under § 66.5, the food is not required to bear a BE disclosure.

*a. Disclosure Options*

Regulated entities have several disclosure 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 type of disclosure used, regulated entities can generally look to the List of Bioengineered Foods to determine if the food is required to have a BE disclosure.

*b. Use of the “May be” Option*

The NPRM specifically requested comments on whether the phrase “may be” could be used when making a disclosure under the NBFDS. As proposed, the phrase “may be” would have been able to be inserted prior to the word “bioengineered” in the various disclosure methods, including a “may be bioengineered” symbol. This proposal was primarily included in the NPRM to provide regulated entities with flexibility when using food ingredients on the “low adoption” list of bioengineered foods. Because the List of Bioengineered Foods adopted in this rule does not distinguish between low and high adoption bioengineered foods, the “may be” option is no longer appropriate. Additionally, commenters explained how the use of “may be” in the disclosure will lead to unnecessary confusion for regulated entities and for consumers. Commenters explained that when consumers see the words “may be bioengineered” on a food package, consumers may be unsure whether the food is bioengineered or whether certain ingredients are bioengineered. Many commenters suggested that the disclosure be an affirmative statement. They noted that many of the countries with mandatory disclosure requirements do not allow the use of a “may” statement. Comments from food companies also described confusion

around when the “may be” wording is appropriate. Commenters noted that because records must be maintained to substantiate claims of disclosure and non-disclosure, any such use of “may” claims would only serve to confuse consumers. For these reasons, disclosure under the NBFDS must be made with the term “bioengineered,” unless making a voluntary disclosure as described in § 66.116. The “may be bioengineered” disclosure cannot be used.

#### *B. Text Disclosure*

The amended Act allows for BE food to be labeled with a text disclosure. 7 U.S.C. 1639b(b)(2)(D). Regulated entities may utilize text to disclose the presence of bioengineered food or bioengineered food ingredients for foods in the List of Bioengineered Foods. For a food, including a food ingredient produced from that food, that is a raw agricultural commodity and for which records demonstrate that the food or food ingredient is bioengineered or does not indicate whether the food or food ingredient is bioengineered, the text disclosure is “bioengineered food.” This same disclosure is applicable to multi-ingredient food products in which all ingredients are on the List of Bioengineered Foods and are bioengineered or records do not indicate whether the ingredients are bioengineered. For a multi-ingredient food that contains ingredients that are and are not on the List of Bioengineered Foods and records demonstrate that at least one of the ingredients is bioengineered, or do not indicate whether any of the ingredients produced from one of the foods on the List of Bioengineered Foods are bioengineered, the text disclosure is “contains a bioengineered food ingredient.” We believe this approach provides flexibility to regulated entities, transparency to consumers, and recognizes that some foods are entirely a product of bioengineering and that some foods are a mix of BE and non-BE food ingredients.

For BE food that is distributed solely in a U.S. territory, § 66.102(b) requires that disclosure statements equivalent to those above be allowed in the predominant language of that

territory. AMS believes this approach will make the BE food disclosure more accessible in territories where the predominant language is something other than English. AMS also believes this allows regulated entities who only distribute food in a given territory to respond to consumer demand.

### *C. Symbol Disclosure*

A symbol is another form of BE food disclosure regulated entities may use as set forth in the amended Act, 7 U.S.C. 1639b(c)(4). Regulated entities can use this symbol to designate BE food or food that contains a BE food ingredient.

AMS proposed three alternative symbols with variations of those symbols and invited comment on each alternative and its variation. The three symbols were 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. Based on comments, we have decided to use a variation of option 2-A below. AMS requested comments on whether the word “bioengineered” should be incorporated into the design of the chosen disclosure symbol. Based on comments, we have decided to include the word “bioengineered” in the symbol. This will improve the understanding of the symbol, as many comments explained that they did not understand what the acronym “BE” stood for. Comments in response to the NPRM reported results of independent surveys conducted during the public comment period that suggested the greatest number of respondents believe the symbol with the word “bioengineered” provides the right amount of information when compared to the symbol with the letters “BE.”<sup>6 7</sup>

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<sup>6</sup> Public comment submitted by the International Food Information Council Foundation (IFIC) reports their May 2018 study regarding consumer attitudes and perceptions related to the NPRM. Comment may be accessed at <https://www.regulations.gov/document?D=AMS-TM-17-0050-8861>.

The adopted symbol is a circle with a green circumference, with the word “bioengineered” displayed at the top and the bottom of the outer ring. The bottom portion of the circle contains an arch, filled in green to the bottom of the circle. The arch contains two light green terrace lines, sloping downward from left to right. On the left side of the arch, near the left side of the circle, is a stem 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 leaves, is a portion of a yellow circle that resembles a sun. The remainder of the circle is filled in light blue, resembling the sky.

Commenters recognized that a multi-colored product label can increase printing costs and disrupt product design in other ways. Therefore, like the USDA Organic seal under the NOP, AMS will allow regulated entities to use a black and white version of the symbol. Regardless of colors, the symbol is required to meet the appearance and placement requirements in § 66.100. A supplemental document to this final rule contains the symbol in full color, as well as another variation of the symbol incorporating the words “derived from bioengineering” (for voluntary disclosure discussed below). The document may be viewed in the docket for this rulemaking at [regulations.gov](https://www.regulations.gov) and on the AMS website.

#### *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) and 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

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<sup>7</sup> Public comment submitted by the Rutgers School of Environmental and Biological Sciences reports their June-July 2018 survey regarding consumer perceptions related to the proposed disclosure options in the NPRM. Comment may be accessed at <https://www.regulations.gov/document?D=AMS-TM-17-0050-14011>.

here for more food information” or equivalent language that reflects technological changes. 7 U.S.C. 1639b(d)(1). This statutory requirement is incorporated in § 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 (QR) 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. These technologies may or may not include an embedded Uniform Resource Locator (URL). Consequently, AMS will allow for other alternative statements that can appear above or below an electronic or digital link to direct consumers to the link to the BE food disclosure. Examples of other statements include: “Scan anywhere on package for more food information,” or “Scan icon for more food information.” The statement will provide the shopper with clear instructions on how to utilize an electronic device to scan a food package to obtain information about the bioengineered content of the food.

Section 66.106(a)(2) incorporates the amended Act’s requirement that the electronic or digital disclosure be accompanied by a telephone number that a consumer can call to access the disclosure information. 7 U.S.C. 1639b(d)(4). If a regulated entity decides to utilize electronic or scannable technology to convey bioengineered food information, they must also provide options for the consumer to access the disclosure by calling a phone number. There must be clear instructions for the shopper to “Call [1-000-000-0000] for more food information.” Many commenters explained how certain consumers do not understand how to utilize certain scannable technology to access food disclosure information. AMS believes that requiring regulated entities

who are disclosing bioengineered food information through scannable means to offer the option to call a telephone number will best provide for accessible and understandable food information.

The telephone number must be available at all times of the day and must clearly provide bioengineered food information to the caller. Pre-recorded information is permitted. The telephone number and instruction must be located in close proximity to the electronic or digital link.

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 and promotional information. 7 U.S.C. 1639b(d)(2). Section 66.106(b) incorporates this requirement. “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.” This definition aligns with that in the NOP regulations at 7 CFR 205.2. If a regulated entity wants to provide additional information about BE food to consumers, the information should be provided outside of the landing page that includes the BE food disclosure.

Based on commenter suggestions to ensure reliable, consistent disclosure information to consumers, AMS is requiring that the disclosure on the product information page conform to the requirements of the text disclosure in § 66.102 or the symbol disclosure in § 66.104. AMS believes that using a uniform, consistent approach to the disclosure language and symbol will 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 will make compliance easier for entities responsible for disclosure, and ensure consistency in the communication of required disclosure information.

If the regulated entity chooses to use an electronic or digital link, the amended Act requires that 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 § 66.106(b)(4), if such information must be collected to fulfill the disclosure requirements, that information must be deleted immediately and not used for any other purpose. 7 U.S.C. 1639b(d)(3)(B).

*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>.

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).

Several commenters agreed that the challenges described in the study prevented consumers from accessing electronic or digital disclosures. Other commenters noted that smartphone usage and broadband access were increasing in the United States. After reviewing the study and comments submitted to the NPRM related to the study, the Secretary has determined that consumers would not have sufficient access to the bioengineering disclosure through electronic or digital means under ordinary shopping conditions at this time. While a large number of Americans have a smartphone and a large number of national and regional supermarkets provide Wi-Fi, most consumers in the study experienced technical challenges in accessing the bioengineered food disclosure on their phones.

The NPRM proposed text message as an additional disclosure option if the Secretary were to determine that shoppers would not have sufficient access to digital or electronic disclosure. Food manufacturers and retailers that commented on this option were generally supportive of this option. Thus, AMS is adopting the text message option in § 66.108. Regulated entities that choose this option are required to include a statement on the package that instructs consumers on how to receive a text message. Those instructions can be shared or centralized among regulated entities, if so desired. Industry is not prohibited from developing a standardized instruction or response if it is in compliance with the NBFDS regulations. A one-time automated response would immediately provide the disclosure using text in conformance with § 66.102. Similar to the electronic or digital disclosure, the text message is not allowed to contain marketing and promotional information. The regulated entity must not collect, analyze, or sell any personally identifiable information, unless necessary to complete the disclosure, or use any information related to the text message for marketing purposes. If the regulated entity must collect any personally identifiable information to complete the disclosure process, it must

immediately delete the information and not use it for any other purpose. Additionally, consumers must not be charged a fee by the regulated entity to access the disclosure information. However, consumers may be subject to a text messaging fee charged through their wireless telephone carrier.

#### *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 has made very minor changes to the definition of small food manufacturer. AMS defines “small food manufacturer” as “any food manufacturer with annual receipts of at least \$2,500,000 but less than \$10,000,000.” This definition is similar to FDA’s final rule to extend the compliance dates for manufacturers with less than \$10 million in annual food sales (*see* 83 FR 19619).

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

##### *2. Telephone Number*

Under § 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, a compliant text accompanying the

telephone number is “Call [1-000-000-0000] for more food information.” The telephone number should provide the BE food disclosure regardless of the time of day. Disclosure via telephone number must include a BE food disclosure information that is consistent with §66.102 in audio form and can be pre-recorded. While some commenters suggested that a telephone disclosure at any time of day would be burdensome and unreasonable, AMS believes that the requirement to provide the BE food disclosure at any time of day is 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 will increase the burden on small food manufacturers.

### *3. Internet Website*

Under § 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 must meet the requirements for a product information page in § 66.106(b). Disclosure via website must include a bioengineered food disclosure that is consistent with § 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 will 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, 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). Section 66.112 continues to provide certain flexibilities for food in small and very small packages: a modified version of the electronic or digital link disclosure in § 66.106; a modified version of the text message in § 66.108; and a modified version of the phone number disclosure in § 66.110. In addition, for very small packages, regulated entities may use a label’s preexisting Uniform Resource Locator or telephone number for disclosure.

For the modified version of the electronic or digital link, § 66.112(a) allows regulated entities to utilize the electronic or digital link in § 66.106, but replace the statement “Scan here for more food information” and the accompanying phone number and instructions required in paragraph (a) of that section with the statement “Scan for info.” AMS believes that shortening the statement 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, § 66.112(b) allows regulated entities to utilize the text message in § 66.108, but replace the statement “Text [number] for more bioengineered food information” with “Text [number] 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 is small enough to fit on small and very small packages. Section 66.112(c) requires the disclosure to meet the

requirements of § 66.110, but allows the statement “Call [1-000-000-0000] for more food information” to be replaced with “Call [1-000-000-0000] for info.”

AMS recognizes that very small packages have limited surface area on which to bear disclosures. Under § 66.112(d), for very small packages, if the label includes a preexisting 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 § 66.102 or § 66.104 in written or audio form, as applicable.

Stakeholders representing food manufacturers who use small and very small packages indicated that using the symbol under § 66.104 is a viable disclosure option. Accordingly, the symbol and other disclosure options available to all entities responsible for disclosure are also available to those who package foods in small and very small packages. AMS believes providing the additional options described above will provide needed flexibility for disclosure on small and very small food packages.

#### *H. Food 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 requires that retailers be held responsible for complying with the BE food disclosure of bulk food. AMS already requires bulk foods sold in grocery stores to comply with Country of Origin Labeling requirements and believes that retailers are already accustomed to ensuring that bulk food appears with appropriate signage.

As requested by several commenters, § 66.114(a) requires that the BE food disclosure on bulk foods appears using any of the options for on-package disclosure including: text, symbol,

electronic or digital link, or text message (if applicable). The disclosure is 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 will allow consumers to identify and understand the bioengineered status of the food and allow retailers to adapt to new technologies and consumer preference. Retailers who use an electronic or digital link will be required to place any sign or image to be scanned in a place readily accessible by consumers. For all other disclosure options, signs currently used on or near bulk items, when supplemented with the BE food disclosure, are sufficient to comply with the requirements of the amended Act.

### *I. Voluntary Disclosure*

AMS received significant input on the proposed NBFDS regarding the ability for regulated entities to voluntarily label foods not subject to mandatory BE disclosure requirements. Comments from food companies explained that consumers expect transparency and as much information as possible on the origin of food ingredients. Comments from consumers agreed. AMS acknowledges that voluntary disclosure provisions enable food manufacturers, retailers, and other entities to share more information with consumers, provided the information is truthful and not misleading and otherwise in compliance with all applicable Federal laws.

In designing the NBFDS, which is focused on positive disclosure claims, AMS has attempted to provide as much flexibility to the food and grocery industry as possible, along with the transparency to consumers that they expect and deserve. As such, the final rule provides for voluntary labeling (1) by entities that are otherwise exempt from the requirements of the NBFDS or (2) for certain foods that do not meet the definition of “bioengineered food” but are derived from bioengineered crops or food. Voluntary labeling is only permitted in these circumstances.

Entities that are exempt from the NBFDS are very small food manufacturers, and restaurants and similar retail food establishments. Under § 66.116(a) those entities may voluntarily include a bioengineered disclosure on their products in the same manner as those that are required to provide a BE disclosure.

Under § 66.116(b), regulated entities may voluntarily include a disclosure for foods or food ingredients derived from items on the List of Bioengineered Foods. A food that meets a factor or condition under paragraph (2) of the definition of “bioengineered food” in § 66.1 or is exempt from disclosure under §§ 66.5(c) – (e), is prohibited from voluntary disclosure under the NBFDS. For example, a soup that lists beef broth as the first ingredient on the ingredient list may not bear a voluntary disclosure regardless of the other ingredients in the soup. Voluntary labeling provisions are found in § 66.116.

As described earlier in this final rule, only products that contain ingredients with detectable modified genetic material, as demonstrated through records maintained by the regulated entity, must be disclosed. This means that many refined products originating from bioengineered crops do not constitute bioengineered foods. However, if a food manufacturer, retailer, or importer that would otherwise not be required to provide a disclosure wants to voluntarily disclose that a refined food originates from an item on the List of Bioengineered Foods, it is free to do so. For example, if a beverage company makes a carbonated soda containing corn syrup originating from BE corn, and the corn syrup does not have detectable modified genetic material, the corn syrup alone does not trigger mandatory disclosure. Under voluntary labeling provisions, because the corn syrup originates from BE corn, the beverage company may provide a disclosure explaining to the consumer that the ingredients in the soda

are “derived from bioengineering,” even though the ingredient is not for the purposes of this regulation considered to be “bioengineered.”

AMS believes that exempt entities should also be permitted to voluntarily disclose bioengineered foods. For instance, AMS believes that very small food manufacturers, who are entities with less than \$2.5 million in annual receipts and who are exempt from mandatory disclosure requirements, should also be able to voluntarily disclose the presence of bioengineered ingredients, or ingredients originating from bioengineered crops. If a very small food manufacturer is using items on the List of Bioengineered Foods that contain modified genetic material and the food would be subject to mandatory disclosure requirements but for the company size exemption, they may provide a disclosure as provided in § 66.116(a). If a very small food manufacturer is using ingredients that do not contain modified genetic material but are derived from items on the List of Bioengineered Foods, they also may utilize the voluntary disclosure rules explained in § 66.116(b).

It is important to note that when entities utilize the voluntary disclosure provisions in § 66.116, they are required to comply with the disclosure requirements (size, location on package, etc.) for text, symbol, digital or electronic link, or text message disclosure, as applicable.

#### **IV. Administrative Provisions**

##### *A. Recordkeeping Requirements*

The amended Act requires each person subject to mandatory BE food disclosure under the NBFDS 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 include food manufacturers, importers, and retailers who label bulk foods or package and label foods for retail sale. Section 66.302(a)(1) therefore

requires that regulated entities maintain customary or reasonable records to demonstrate compliance with the BE food disclosure requirements. So long as the records contain sufficient detail as to be readily understood and audited as set forth in § 66.302(a)(2), each entity subject to the disclosure requirement may decide for itself what records and records management protocols are appropriate, given the scope and complexity of individual businesses, as well as the food being produced. AMS notes that regulated entities, both domestic and foreign, will likely have customary or reasonable records in accordance with the NBFDS if they are maintaining records in compliance with other laws or regulations associated with the food sector.

In general, comments in response to the proposed recordkeeping requirements in the NPRM supported AMS's proposals. Commenters agreed that the recordkeeping requirements of the NBFDS should be consistent with those under other AMS marketing programs so as not to present an unreasonable burden to entities who must comply with the Standard. Commenters observed that the recordkeeping requirements as proposed would probably not impose additional costs or burdens to existing business practices. Commenters provided examples of typical records generated in the course of business that should satisfy the audit requirements under § 66.402 to verify compliance with disclosure requirements under the NBFDS. Commenters suggested that the regulation include examples of appropriate records an entity might maintain to meet the recordkeeping requirements. Commenters supported the proposed flexibility that would allow for record maintenance in the format preferred by the entity. Commenters also supported the proposed two-year record retention period, consistent with the recordkeeping requirements under other USDA and FDA regulations.

AMS agrees that recordkeeping and compliance requirements under the NBFDS should be consistent with those under other AMS programs, such as NOP and PACA, and has

incorporated elements from each of those programs into the NBFDS. Accordingly, § 66.302 does not specify the records regulated entities must maintain to demonstrate compliance with the disclosure regulations. Instead, as with other AMS programs, regulated entities are free to determine for themselves which of their customary business records will demonstrate compliance and should be maintained. Section 66.302(a)(4) includes a non-exhaustive list of records that could satisfy the recordkeeping requirements of the NBFDS. That list includes: supply chain records, bills of lading, invoices, supplier attestations, labels, contracts, brokers' statements, organic certifications, laboratory testing results, validated process verifications, and other records generated or maintained by the regulated entity in the normal course of business. If records demonstrate that a product originates from a country where BE food is not commercially grown, those records are sufficient to justify lack of disclosure and demonstrate compliance with the NBFDS. Section 66.302(a)(2) provides that records can be in paper or electronic format at the discretion of the regulated entity. Section 66.302(a)(3) requires that records be maintained for at least two years beyond the date the food or food product is sold or distributed for retail sale.

As noted above, the amended Act requires that each person subject to mandatory BE food disclosure under the NBFDS must maintain records. In this regard, as noted in section 66.302(b), the List of Bioengineered Foods identifies the foods for which regulated entities must maintain records and that may be required to bear a BE disclosure, based on what the records show. Consistent with the statutory requirement, where the regulated entity has actual knowledge that the food or food ingredient is bioengineered, the regulated entity must maintain records for that food or food ingredient, even if the food is not on the List of Bioengineered Foods.

Some comments in response to the NPRM opposed requiring entities who do not handle BE foods to maintain records to verify compliance with the regulation. Other comments supported AMS's proposal to do so, explaining that all regulated entities subject to the disclosure standard should be required to keep the same kind of records. AMS agrees that all food manufacturers, importers, and retailers who offer for retail sale foods on the List of Bioengineered Foods are considered regulated entities for purposes of the NBFDS insofar as they may be required to make BE food disclosures. Their customary business records should be able to satisfy an audit to determine whether they are in compliance with the disclosure requirements of the NBFDS.

The amended Act requires each person subject to the disclosure requirements of the NBFDS to give the Secretary access to records to establish compliance with the disclosure requirements upon request. Accordingly, § 66.304 sets forth the provisions for AMS's access to records.

AMS proposed in the NPRM that entities would have five business days to provide records to AMS upon request, unless AMS extends the deadline. AMS also proposed to provide prior notice of at least three business days if we need to access the records at the entity's place of business. Finally, AMS proposed that it would examine the records during normal business hours and that entities should make their records available during those times.

Commenters generally supported the proposed five- and three-day timeframes for the production of records and access to records at the entity's place of business, respectively. Some commenters suggested that because the NBFDS is a marketing standard rather than a food safety regulation, longer timeframes for records production would be appropriate. AMS believes that the timelines for records production and access are appropriate for enforcing compliance with the

NBFDS and notes that flexibility is provided in the regulation to extend deadlines if necessary. Commenters requested that regulated entities be allowed to maintain records at locations most convenient for each business. AMS agrees that entities can maintain records at the location that best serves the entity's business needs.

Accordingly, § 66.304(a) provides that the entity must provide records to AMS within five business days of AMS's request, unless AMS extends the deadline. Section 66.304(b) provides that AMS will give at least three business days' notice if it needs access to records at the entity's place of business. As well, AMS will examine records during normal business hours, and records should be made available during those times. Finally, entities must provide AMS access to facilities necessary for records examinations. As proposed in the NPRM, § 66.304(c) specifies that if an entity fails to give AMS access to records as required, the result of the examination or audit will be that the entity did not comply with the requirement to provide access to records and that AMS could not confirm whether the entity is in compliance with the disclosure standard of the NBFDS.

#### *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). Section 66.400 of the NBFDS captures this prohibition. The amended Act authorizes AMS to enforce compliance with the standard only through records audits and examinations, hearings, and public disclosure of the summary of the results of audits, examinations, and similar activities. *See* 7 U.S.C. 1639b(g)(3). The amended Act further 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." *See* 7 U.S.C. 1639b(g)(4).

AMS considered responses to the 30 questions when developing the proposed enforcement provisions of the NBFDS, and many suggestions were incorporated into the proposal. Accordingly, the NPRM outlined a process for receiving complaints about possible violations of the disclosure standard and set forth a records audit procedure. As provided in the amended Act, AMS proposed to review the records of regulated entities during audits and examinations to verify compliance with the NBFDS's disclosure requirements. Provisions for making findings and allowing for appeals hearings in response to the findings were proposed. Finally, provision was made for publicizing the results of audits, examinations, and hearings.

As with responses to the 30 questions, comments on the proposed NBFDS enforcement provisions reflected a range of opinions about how AMS should enforce compliance with the NBFDS. Many suggested that AMS conduct regularly scheduled or unannounced records audits. Others supported conducting audits and examinations in response to complaints. Some commenters called for the imposition of heavy fines or other penalties for non-compliance, while others agreed that publicizing the results of audits and hearings would be adequate enforcement for this marketing regulation. Several commenters requested that records related to product formulations and formulas remain confidential.

As pointed out in the NPRM, the amended Act does not authorize civil penalties for violations of the NBFDS, and AMS believes some of the other enforcement suggestions to be impractical. Therefore, the enforcement provisions of the NBFDS reflect those proposed in the NPRM, with one exception. Comments in response to the NPRM suggested that AMS provide greater clarity about the process for filing complaints about potential violations of the disclosure standard. Paragraph (a) of § 66.402 is revised to include greater specificity about the complaint process. The remainder of § 66.402 continues to describe the process for initiating records audits

or examinations, including providing notice of such activities, making the audit or examination findings available to the regulated entity, and providing for appeals to object to the findings. Section 66.404 provides that within 30 days of receiving the results of an audit or examination of its records, the regulated entity that objects to the findings may request a hearing by filing a request and submitting a response to the findings, along with any supporting documents, to AMS. AMS may allow the entity to make an oral presentation, after which the AMS Administrator may revise the findings of the audit or examination. Section 66.406 provides that AMS will make public the summary of the final results of the audit, examination, or similar activity, and that such final results constitute final agency action for purposes of judicial review of the matter. AMS agrees that the confidential business records, including product formulations and recipes, should not be disclosed.

### *C. Effective, Implementation, and Compliance Dates*

Because this rule is a major rule, the effective date will be [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**] to comply with the Congressional Review Act. The proposed rule included an initial compliance date of January 1, 2020, and a delayed compliance date of January 1, 2021, for small food manufacturers, as mandated by the amended Act. AMS received several comments on the compliance date, some of which supported the proposed dates, while others sought earlier or later dates.

After considering input from commenters and other available information, AMS recognized that regulated entities should have sufficient time to transition their recordkeeping and labeling processes and procedures to implement the BE disclosure requirements and that the transition should be completed in phases. Section 66.13 sets forth the implementation and compliance dates for the NBFDS. The final rule establishes implementation dates of January 1,

2020, for regulated entities other than small food manufacturers and January 1, 2021, for small food manufacturers. Regulated entities should begin implementing the NBFDS no later than those dates by identifying the foods that will need to bear a BE disclosure, the records necessary to meet the recordkeeping requirements, and the type of BE disclosure they will use on their products.

Following the implementation dates, the final rule establishes a mandatory compliance date and a voluntary compliance period. Mandatory compliance begins on January 1, 2022, and all regulated entities must comply with the requirements of the NBFDS beginning on that date. For regulated entities that can and would like to do so, the final rule provides for a voluntary compliance period that ends on December 31, 2021. We believe this phased approach balances the needs of consumers to have access to information about bioengineered foods they may purchase with the cost and burdens to regulated entities in complying with the NBFDS requirements.

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

In an effort to reduce costs and burdens, AMS proposed in the NPRM to allow regulated entities to use up food labels that are printed by the initial compliance date, regardless of whether the existing labels comply with the NBFDS, until the remaining label inventories are exhausted or until January 1, 2022, whichever comes first. Comments in response to the NPRM generally reflected two viewpoints. Consumers and consumer groups claimed that manufacturers could theoretically continue printing and using non-compliant labels for up to six years after the Act was amended to require mandatory BE food disclosure. Those commenters urged AMS to allow a shorter compliance period for label use-up. Food manufacturer comments generally supported the proposed label use-up provision, but they asked that the final rule provide a two-year

compliance period after the compliance date, rather than specifying a hard date, to allow for regulatory delays. Manufacturer commenters also urged AMS to allow the use of labels compliant with the preempted State GMO labeling laws during the compliance period. Some commenters recommended that AMS allow entities to apply stickers or ink stamp disclosures to existing labels to reduce waste. Others suggested that AMS incorrectly assumes manufacturers maintain large label inventories, asserting that manufacturers order labels in the smallest batches economically practical.

As discussed above, AMS is providing a period of voluntary compliance until December 31, 2021, with mandatory compliance to begin on January 1, 2022. With this voluntary compliance period, it is not necessary to provide for regulated entities to be able to use its existing label inventories. Thus AMS is not adopting this component of the proposed rule. However, in response to comments regarding this proposal, regulated entities may use labels that are compliant with preempted State labeling laws during the voluntary compliance period. They may also apply stickers or ink stamp disclosures to existing labels. The sticker or printing cannot cover any other mandatory labeling, such as nutrition facts.

## **V. Comments on the NPRM**

AMS received approximately 14,000 comments in response to the NPRM. We received comments from individuals, consumer groups, companies, and organizations that represent different segments of the food industry. We review and respond to the comments below.

### *1. Definition of “food”*

In the NPRM, AMS described how it would implement the statutory definition of “food” in the amended Act and how the disclosure requirements would intersect with the FDCA, the FMIA, the PPIA, and the EPIA.

*Comment:* Many commenters supported the proposed definition of “food.” Some commenters disagreed with how predominance was determined for meat, poultry, and egg products for purposes of BE food disclosure. Some commenters stated that the final rule should adopt the labeling approach used by FSIS and determine the ingredient predominance based on weight of ingredients so as not to confuse companies and consumers. Other commenters noted that FDA permits composite and component labeling in ingredient declaration statements.

*AMS Response:* AMS notes that FDA and FSIS use the same method for determining predominance of ingredients by weight. Thus, we agree that the predominance determination for meat, poultry, and egg products should be based on weight. As FDA permits both composite and component labeling, AMS also will permit such ingredient declaration labeling.

*Comment:* Several commenters pointed out that because most seafood products are subject to the FDCA, BE seafood would be subject to disclosure. However, catfish and related species would not require disclosure because they fall under the FMIA. Commenters stated that this will cause consumer confusion and the rule should be reworded to require all seafood products that contain BE ingredients to be labeled.

*AMS Response:* AMS acknowledges that there may be consumer confusion if the industry develops a BE catfish and it may not be subject to disclosure, depending on its predominance on the ingredient list, while other BE seafood would be. However, the amended Act clearly sets forth how food subject to the FMIA are to be disclosed and AMS does not have the statutory authority to expand disclosure beyond what those statutory provisions provide.

*Comment:* Several commenters opposed limiting the definition of “food” to food for human consumption and sought to include food for animal consumption to be included.

*AMS Response:* We appreciate that several commenters would like to extend the BE disclosure to food for animals. The amended Act, however, clearly limits the mandatory disclosure requirements to food for human consumption and AMS does not have the statutory authority to require BE disclosure for food for animal consumption on a mandatory or voluntary basis.

## 2. Definition of “bioengineered food”

AMS requested public comments on the definition of “bioengineered food.” The statutory definition of bioengineering describes food that “contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques.” In the NPRM, we proposed two interpretations of this definition; Position 1 proposed that highly refined products do not contain genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (rDNA) techniques and therefore are not bioengineered food, while Position 2 proposed that all foods produced from bioengineering, including refined and highly refined products, are bioengineered food.

*Comment:* Several commenters supported Position 1. Those commenters concluded that, in general, highly refined foods and ingredients do not meet the statutory definition of “bioengineering,” and thus, are not subject to the labeling requirements because they lack rDNA. Many of those commenters cited several scientific studies they viewed as demonstrating an absence of genetic material in such foods. Some commenters also noted that the proposed regulation governs the food product, not the source plant from which the food was produced.

*AMS Response:* Because some countries previously established BE food labeling requirements, the industry recognized the need for standardized methods for the detection of rDNA. Technical Committee 34 (TC 34) “Food Products” of the International Organization for

Standardization (ISO) developed numerous validated sampling and detection methods to detect rDNA in food products.<sup>8</sup> Subcommittee 16 (SC 16) established the “Horizontal methods for molecular biomarker analysis” in 2008. ISO/TC 34/SC 16 published 19 ISO standards and has 17 additional standards under development. The established detection methods are generally carried out in accordance with the ISO/ICE 17025:2017 standard and validated according to Codex Alimentarius guidelines.

These methods are crop and event specific and most rely on quantitative Polymerase Chain Reaction (PCR). In general, the detection methods are most effective when applied to raw agricultural commodities because the DNA remains relatively intact; many types of food processing (*e.g.* heating) serve to degrade and eliminate DNA.

Screening of raw agricultural commodities (*e.g.* seeds, leaves and roots) for rDNA is routinely conducted by the global grain and food industries in order to maintain identity preserved supply chains. After testing at the commodity level, identity is generally preserved through records rather than through additional testing after processing. This is practical since methodology for detection of rDNA at the commodity level is well established; applying these same methods to refined ingredients and processed foods can be much more challenging.

The Pauli study attempted to extract DNA from 55 common foodstuffs derived from soybean, corn, potato, rice, sugar beet, tomato and wheat.<sup>9</sup> They were able to extract some DNA from most of the foodstuffs, but were not able to extract any DNA from refined sugar and oil.<sup>10</sup> Whether rDNA can be detected in processed foods will depend on the specific processing

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<sup>8</sup> ISO (2018) <https://www.iso.org/committee/560239.html>.

<sup>9</sup> Pauli *et al.* (2000) Extraction and amplification of DNA from 55 foodstuffs. *Mitteilungen aus Lebensmitteluntersuchung und Hygiene*. 91:491-501 (Pauli study).

<sup>10</sup> In this study, the scientists were simply extracting total DNA, and any rDNA, if present, would be a minute fraction of the total DNA extracted.

conditions for each food ingredient. The Greiner study analyzed 100 foods derived from BE corn and 100 foods derived from BE soybean; they were able to detect rDNA in 13% of the soy products and 8% of the maize products.<sup>11</sup> The Orlandi study evaluated 63 products derived from BE corn, but only detected rDNA in four of the products, all of which were taco shells.<sup>12</sup> The Arun study found that detectability of rDNA in cookies varied with cooking time and cooking temperature.<sup>13</sup>

When refining food ingredients from agricultural inputs, the objective is often to produce ingredients with a high degree of purity. Therefore, it is not surprising that the industrial processes developed for the refining of sugars and oils effectively eliminate the majority of undesired substances, including DNA and protein. Several published studies have demonstrated that genetic material is not detectable in refined beet sugar or refined cane sugar.<sup>14</sup> One study reported detection of rDNA in raw cane sugar, but not in refined cane sugar;<sup>15</sup> however, the Cheavegatti-Gianotto study did not detect rDNA in raw sugar. One commenter noted that raw cane sugar is not intended for human consumption; rather it is intended as a feedstock for refining white cane sugar. Therefore, all five published studies referred to above reached the same conclusion, that DNA could not be detected in refined sugar.

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<sup>11</sup> Greiner *et al.* (2005) Qualitative and quantitative detection of genetically modified maize and soy in processed foods sold commercially in Brazil by PCR-based methods. *Food Control* 16: 753-759 (Greiner study).

<sup>12</sup> Orlandi *et al.* (2002) Analysis of Flour and Food Samples for cry9C from Bioengineered Corn. *J Food Protection* 65:426-431 (Orlandi study).

<sup>13</sup> Arun *et al.* (2016) The effect of heat processing on PCR detection of genetically modified soy in bakery products. *J Health and Food Sci.* 2:130-139 (Arun study).

<sup>14</sup> See Cheavegatti-Gianotto *et al.* (2018) Lack of Detection of Bt Sugarcane Cry1Ab and NptII DNA and Proteins in Sugarcane Processing Products Including Raw Sugar. *Front Bioeng Biotechnology.* 27:24 (Cheavegatti-Gianotto study); Joyce *et al.* (2013) Sugar from genetically modified sugarcane: Tracking transgenes, transgene products and compositional analysis. *International Sugar Journal.* pp. 861-863; Klein *et al.* (1998) Nucleic acid and protein elimination during the sugar manufacturing process of conventional and transgenic sugar beets. *J Biotech* 60, 145-153; Oguchi *et al.* (2008) Investigation of Residual DNAs in Sugar from Sugar Beet (*Beta vulgaris* L.). *J. Food Hyg. Soc. Japan.* 50:41-46.

<sup>15</sup> Cullis *et al.* (2014) DNA and Protein Analysis throughout the Industrial Refining Process of Sugar Cane. *Science Target* 3:1-15.

The sugar refining process from sugar beet or sugarcane juice that has been extracted by pressing or diffusion, then clarified and evaporated, results in sucrose of 99.9% purity. Several of these refining steps involve heating which serves to degrade DNA. Additionally, prior to crystallization, lime is used to remove the impurities remaining in the sugar juice; DNA and protein are effectively removed at this step in the sugar refining process. Based on the available scientific evidence, several countries (*e.g.* Australia, Brazil, Japan, Israel, New Zealand and South Korea) have exempted refined sugar from their respective BE food labeling requirements.

Food grade vegetable oils can be derived from a variety of BE crop sources (*e.g.* corn, soybean, and canola) and can be refined with a variety of methods (*e.g.* chemical vs. physical refining). The detectability of rDNA may vary by crop and by refining method. Substances present in raw vegetable oil are removed by steps such as degumming, neutralizing, bleaching, deodorizing, and dewaxing.

The Pauli study was unable to extract DNA from refined oil. Another study was unable to detect rDNA in refined soybean oil; they observed degradation of DNA during degumming and concluded that degumming was the most important step in removing DNA when refining soybean oil.<sup>16</sup> However, one study was able to detect rDNA in refined soybean oil.<sup>17</sup> These variable results may be due to differences in refining processes; some oil refining processes may effectively eliminate all DNA, while others, such as cold pressing, are unlikely to eliminate all DNA. Similar to refined sugar, several countries (*e.g.* Australia, Brazil, Japan, Israel, New Zealand and South Korea) have exempted refined vegetable oils from their respective BE food labeling requirements.

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<sup>16</sup> Gryson *et al.* (2002) Detection of DNA during the refining of soybean oil. *JAOCS*, Vol. 79, 171-174.

<sup>17</sup> Costa *et al.* (2010) Monitoring GM soybean along the industrial soybean oil extraction and refining processes by PCR techniques. *Food Research Intl* 43:301-306.

The studies cited above, as well as similar studies provided by some commenters demonstrate for many refined food products and ingredients, the refining process removes the genetic material so that it can no longer be detected. If the genetic material is not detected, then it is not possible to conclude that the food product or ingredient contains modified genetic material. Thus, based on the available scientific evidence, refined beet and cane sugar, high fructose corn syrup, degummed refined vegetable oils and various other refined ingredients are unlikely to require BE food disclosure because the conditions of processing serve effectively to degrade or eliminate the DNA that was initially present in the raw agricultural commodity.

*Comment:* Many commenters supported the labeling of all foods produced through bioengineering including refined oils, sugars and starches. They believed processed foods originating from BE raw agricultural commodities should be considered bioengineered food, regardless of whether modified genetic material remains detectable in the final product. Some commenters did not believe disclosure should rely only on the detection of genetic material in a food, or food ingredient, or solely on specific test methods like PCR. Commenters noted that scientific methods may advance to where today's "undetectable" genetic material may be detectable using future technologies. In support of this position, commenters cited several studies documenting the evolution of our ability to detect previously undetectable bioengineered products.

*AMS Response:* AMS appreciates commenters' position on disclosing foods produced through bioengineering. AMS has adopted the statutory definition of "bioengineering," which makes clear that food must "contain genetic material that has been modified through in vitro rDNA techniques. . ." to be labeled as a "bioengineered food." Highly refined products have undergone processes that removed genetic material such that it cannot be detected using common

testing methods. As such, the NBFDS will not require disclosure for refined products that do not contain modified genetic material. Regulated entities who do not disclose such products would maintain records that substantiate their claim that the products do not contain modified genetic material. As described in the Preamble and in § 66.9, regulated entities can demonstrate that their food products do not contain modified genetic material in multiple ways.

AMS maintains that the products of technology, rather than the technology itself, should determine whether a food meets the BE food definition and requires disclosure unless exempted from disclosure pursuant to § 66.5. We also recognize that emerging technologies could impact the list of foods requiring disclosure. As such, AMS provides for the consideration of new technologies used to develop foods during the process of reviewing and revising the List of Bioengineered Foods.

We recognize that testing methodology may evolve so that a future test may detect modified genetic material in a food ingredient that current tests do not. The definition of “bioengineered food” accounts for this possible evolution. If the modified genetic material in that food ingredient becomes detectable under § 66.9 in the future, the food ingredient would be subject to BE disclosure.

*Comment:* Some commenters supported the inclusion of highly refined ingredients and foods, such as oils and sugars derived from bioengineered crops, in the mandatory disclosure standard (Position 2). Some commenters who supported Position 2 viewed it as being consistent with the FDA’s guidance to manufacturers entitled, “Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants.” Commenters considered detection of genetic material in the food immaterial to its exemption from the Standard. Instead, they justified their position based on consumer interest and popular

understanding of how common BE agricultural crops are grown, not whether the food or ingredient contains modified genetic material. These commenters proposed that a narrow focus on the presence of genetic material creates a differentiation based on rDNA that some could use to imply a safety issue with the rDNA. Commenters further suggest such implied issues could lead consumers to believe foods and food ingredients containing genetic material are different in a way that necessitates informing consumers.

*AMS Response:* AMS appreciates commenters' interest in the new Standard and their efforts to be transparent and build consumer trust. As stated in the previous comment response, AMS has adopted the statutory definition of bioengineering. That definition focuses on the products of technology, rather than the technology itself. For this rule, the presence or absence of detectable modified genetic material in a final food product determines in part whether a food meets the BE food definition and might require disclosure. AMS reiterates that nothing in the disclosure requirements set out in this final rule conveys information about the health, safety, or environmental attributes of BE food as compared to non-BE counterparts. The regulatory oversight by USDA and other Federal government agencies ensures that food, including that produced through bioengineering, meets all relevant Federal health, safety, and environmental standards.

AMS values transparency and consumer interests. AMS recognizes that some regulated entities may wish to disclose that their refined foods (that do not contain modified genetic material and thus are not bioengineered foods) are derived from bioengineering. Accordingly, AMS has provided for voluntary disclosure of such foods.

*Comment:* One commenter supported Position 2 suggesting that non-BE, identity-preserved, or certified organic crops and products can offer a price premium and new or

additional market access – domestic and international – to producers. These commenters maintain that disclosing all BE foods would improve these farmers’ market transparency, while exemption will require added costs for coexistence, segregation and detectability testing.

*AMS Response:* AMS agrees that it is possible that some marketing claims may offer a price premium or new market access. AMS has adopted Position 1 with some modifications. For further details on our rationale for adopting this position, see Section II.C.1 of this rule. With the adoption of Position 1, foods with undetectable modified genetic material are not bioengineered foods. Accordingly, regulated entities need not disclose such foods as bioengineered foods. AMS has determined that regulated entities can establish that their foods do not contain detectable rDNA through their records of the foods on the List of Bioengineered Foods.

*Comment:* Some commenters suggested a broad interpretation of the BE definition and scope accounting for existing technologies like CRISPR and TALENS, as well as for future developments. The interest of these commenters was to prevent confusion among consumers and in the international marketplace if the NBFDS failed to harmonize the law with existing standards – FDA, Codex Alimentarius, and USDA Certified Organic, all of which include gene editing and gene silencing techniques (e.g. sequence-specific nucleases, meganucleases, zinc finger nuclease, CRISPR-Cas system, TALENs, oligonucleotide directed mutagenesis RNAi, RNAi pesticides, and RNA-dependent DNA methylation). Commenters cited USDA’s General Counsel Jeffrey M. Prieto, who stated that it is well within USDA’s authority under Pub. L. 114-216 to mandate a broad interpretation. Another commenter was concerned that a failure to further define bioengineering could lead to state preemption concerns. The commenter stated that preemption, as intended by the BE Food Disclosure Act, Sec. 295, was not intended to be

limited to the smaller subset of foods now defined as “bioengineered,” which, as proposed, excludes highly refined ingredients and products of gene editing.

*AMS Response:* AMS appreciates commenters’ concerns and acknowledges the range of feedback provided. AMS has adopted a modified version of Position 1 and believes that the definition of “bioengineering” sets forth the scope of the mandatory disclosure. Although the Jeffrey Prieto letter seemingly advocated an expansive interpretation of the statutory definition of bioengineering along the lines of Position 2, AMS maintains that with the full range of information before it, including additional interpretation of the amended Act and responses to both the 30 questions and the NPRM, Position 1 is more closely aligned with the amended Act’s definition of bioengineering. AMS will adopt Position 1 and is incorporating the statutory definition of bioengineering into the regulatory definition of “bioengineered food.”

AMS does not find it necessary to further define bioengineering. AMS also disagrees with commenters’ concerns that failing to further define bioengineering would result in limiting preemption. Subtitle F of the amended Act addresses Federal preemption of State and local genetic engineering labeling requirements. 7 U.S.C. 1639i. The preemption provisions extend beyond bioengineering labeling and include genetic engineering labeling requirements.

Also, as stated earlier, this definition of bioengineered food focuses primarily on the products of technology, not the technology itself. AMS is not making a blanket statement regarding the scope of technologies that are covered by the NBFDS. Finally, AMS agrees the NBFDS should align with some elements of existing standards to the extent possible. In Sections II through IV of this rule, AMS outlines its efforts to align the NBFDS with existing laws.

*Comment:* Several commenters supporting Position 2 also recommended adopting the Codex Alimentarius definition for Modern Biotechnology: (i) in vitro nucleic acid techniques,

including rDNA and direct injection of nucleic acid into cells or organelles, or (ii) fusion of cells beyond the taxonomic family, that overcomes natural, physiological reproductive or recombination barriers, and that are not techniques used in traditional breeding and selection. These commenters state that the Codex Alimentarius definition of bioengineering is internationally recognized by the World Trade Organization as the standard for settling trade disputes, and therefore should serve as a guidepost for the USDA. Additionally, several commenters expressed concern that adopting Position 1 could negatively impact trade. According to these commenters, most countries with BE disclosure standards require that highly refined products be disclosed. They contend that adopting Position 1 and not aligning the NBFDS with existing international standards would create confusion among consumers and in the international marketplace.

*AMS Response:* In drafting the proposed rule and in finalizing the rule, AMS has reviewed and considered various foreign labeling regimes. To the extent possible, AMS has tried to align the NBFDS with existing domestic and international regimes to reduce burdens on regulated entities, promote consistency for consumers, and limit trade impacts. AMS is bound by the plain language of the amended Act. As described above, based on the language of the amended Act, AMS is incorporating the statutory definition of bioengineering into the regulatory definition of “bioengineered food.” As such, if a food does not contain detectable modified genetic material, it is not a bioengineered food and does not require disclosure.

*Comment:* Some commenters also cited evidence that the amended Act did not propose the adoption of any “other factors and conditions under which a food is considered a bioengineered food” as part of the final rule. These commenters state that this rulemaking may

only provide a process to allow any person to petition AMS and request the adoption of specified “other factors and conditions.”

*AMS Response:* AMS disagrees with commenters who assert that the amended Act did not provide for factors and conditions under which a food is considered a bioengineered food. The amended Act clearly provides the Secretary with this authority. 7 U.S.C. 1639b(b)(2)(C). AMS has interpreted this statutory provision as one that limits the scope of the definition of “bioengineered food,” thus potentially excluding certain products from disclosure. The factors and conditions process, as proposed in the NPRM and adopted in this rule, offers a fair and rational method by which interested persons can petition AMS to consider various proposals. See Section II.E of this rule for details of the process.

Additionally, nothing in the amended Act precludes AMS from considering requests for a factor and condition that were submitted as part of responses to the 30 questions as petitions contemplated by 7 U.S.C. 1639b(b)(2)(C) and applying the process in this final rule to consider those petitions. Because the process is a rulemaking process, we believe that it is appropriate and efficient to consider certain petitions that meet the standards for consideration in § 66.202 as part of this rulemaking.

*Comment:* One commenter stated that because there is no difference chemically between refined and highly refined products and their non-BE counterparts, these products should not be treated differently. Instead, commenters believe refined and highly refined products should be exempt from BE labeling similar to their non-BE counterparts. Several commenters expressed concern that treating these chemically identical products differently could negatively impact the market appeal of highly refined products. Commenters also point out that enzymes produced

from bioengineering as sourced from bioengineered crops are not themselves BE food, because enzymes are proteins and do not contain DNA.

*AMS Response:* AMS recognizes that highly refined foods produced from BE crops are generally chemically identical to the same foods produced from non-BE sources. Under the NBFDS, neither product would be subject to disclosure unless another ingredient triggers the disclosure requirement. However, regulated entities do have the option to voluntarily disclose information about highly refined foods derived from BE sources.

AMS notes that enzymes may be used in a manner that requires them to be labeled on the ingredient statement. Enzymes sometimes qualify as incidental additives that are not required to be labeled as ingredients on a food label. In those instances, they do not require disclosure as BE foods. However, bioengineered enzymes that do not qualify as incidental additives may require disclosure as BE foods, unless they do not have detectable modified genetic material.

*Comment:* Some commenters feel that mandating disclosure for refined products would disparage biotechnology. They also felt that labeling BE products would impose a burden on them that was not levied upon the non-BE counterpart.

*AMS Response:* AMS appreciates commenters' concerns about mandatory disclosure and explains the NBFDS seeks to minimize the food industry's implementation and compliance costs while providing a mandatory, uniform disclosure standard for BE food. As noted, AMS has adopted Position 1, in which products that do not contain modified genetic material are not bioengineered foods and are not subject to mandatory disclosure. Such products could be voluntarily disclosed.

*Comment:* Some commenters provided an economic argument that the number of BE foods covered would not change if refined and highly refined foods where no rDNA is detectable

are not covered by the NBFDS. In addition these commenters cite the inconsistency of requested exemptions for (1) incidental additives, processing aids, secondary direct additives; (2) food derived from insects or microorganisms that grow or feed on a bioengineered substrate, such as a bioengineered crop or other substance; (3) enzymes; (4) ingredients derived via fermentation regardless of whether the microorganisms used in the fermentation are derived using rDNA technology, and (5) food products with medicinal or supplementary applications to be excluded from the definition of a BE Food. They stated that exemptions for refined and highly refined products would be no different.

*AMS Response:* AMS acknowledges the range of comments citing substances that may or may not be subject to disclosure. In establishing this rule, AMS relied on the statutory language in the amended Act in adopting Position 1. Foods with no modified genetic material are not bioengineered food and therefore are not subject to BE disclosure. As stated in the RIA, because AMS has adopted this position, there would be a reduction in the number of products that are labeled BE. Because those foods are not bioengineered food subject to mandatory disclosure under the amended Act, AMS does not have the authority to require BE disclosure for those foods regardless of the number of food products that may be affected.

In addition, AMS sought to align the disclosure requirements of the NBFDS with the ingredient declaration requirements under applicable FDA regulations to simplify compliance and reduce labeling costs for regulated entities. Section II.E.1 of this rule details AMS's position on disclosure of incidental additives, including enzymes and microorganisms used in fermentation. AMS further discusses its position for some of these substances in Section II.E.4 of this rule.

AMS sought to limit inconsistencies to the extent possible and where it had the authority to do so. To the extent that interested persons think that other products should be subject to disclosure, they may submit a petition or request seeking to adopt a factor or condition to potentially modify the definition of “bioengineered food” in a future rulemaking.

*Comment:* Commenters pointed out that the NBFDS is a marketing standard, not a safety standard. Consequently, they feel AMS should aim to determine whether its new labeling system would confuse consumers. These commenters were concerned that consumers who expect food containing raw BE ingredients to be labeled as such may feel misled if AMS adopts Position 1 for the NBFDS. Other commenters suggested that the NBFDS clarify the definition of bioengineering to state that it is synonymous with “genetic engineering” or “GMO.” These commenters are concerned that the public, which commonly refers to BE products as GMOs, may be confused when using the term bioengineering and that the terminology may be inconsistent with other labeling systems.

Several commenters cited the option in the proposed rule to later petition AMS to include specific factors or conditions not otherwise provided for in the definition of “bioengineered food” and provide stakeholders with the freedom to disclose voluntarily additional ingredients/products if they are truthful and consistent with the NBFDS.

*AMS Response:* AMS acknowledges commenters’ concern for potential consumer confusion regarding the new labeling system. As explained in earlier comments, AMS has adopted Position 1 and has incorporated the statutory definition of bioengineering into the regulatory definition of “bioengineered food.” We believe this definition of “bioengineering” clearly sets forth the scope of the mandatory disclosure. AMS does not believe that the definition of bioengineered food will create consumer confusion. However, AMS does

understand that some regulated entities are interested in disclosing that certain products such as refined products are derived from bioengineering; accordingly, regulated entities may voluntarily disclose such products.

AMS considered similar terms to bioengineering as permitted by the amended Act but ultimately determined that bioengineering and bioengineered food accurately reflected the scope of disclosure and the products and potential technology at issue. AMS believes that using other terms such as genetic engineering or genetically modified organisms may create inconsistencies with the preemption provisions or muddy the scope of disclosure.

*Comment:* Several commenters cited the option in the proposed rule to later petition AMS to include specific factors or conditions not otherwise provided for in the definition of “bioengineered food” and provide stakeholders with the freedom to voluntarily disclose additional ingredients/products if it is truthful and consistent with the NBFDS. Many commenters saw this as a basis to exempt refined and highly refined foods from the NBFDS as proposed in Position 1.

Some commenters were concerned with the economic impacts of labeling refined foods as bioengineered and leading consumers to improperly believe refined products contain bioengineered ingredients. A related concern by one commenter maintains that Position 2 contradicts FDA’s requirement that labeling be accurate. As an example, the commenter suggested that labeling a package of sugar, a refined food product, with one of the NBFDS disclosure options would falsely imply the product contains modified DNA, and such a claim would not comply with FDA’s labeling requirement.

*AMS Response:* AMS has adopted Position 1 based on the plain language of the amended Act. In addition, we agree that entities can opt to voluntarily disclose information about highly refined foods made from BE sources in accordance with § 66.116.

*Comment:* Some commenters contend consumer expectations for BE disclosure are driven, in part, by voluntary marketing claims like Non-GMO Project Verified and True North. These voluntary programs label highly refined products derived from bioengineering as GMO's. Commenters suggest using an alternative approach to labeling these products would cause consumer confusion and disrupt the industry. Several commenters expressed concern this potential confusion could impact them personally, as many have experienced health-related issues after consuming products made with GMO ingredients. Others expressed concerns about products made using bioengineered products.

*AMS Response:* AMS acknowledges that entities may participate in voluntary labeling initiatives such as the non-GMO Project so long as they are in compliance with all applicable Federal regulations. To the degree possible, USDA has tried to minimize the impact the NBFDS will have on these voluntary absence claims. AMS acknowledges that some elements of the NBFDS may differ from requirements of some existing voluntary marketing claims. As explained in earlier comment responses, AMS has adopted the statutory definition of "bioengineering," thereby exempting from disclosure labeling foods such as refined products that have undergone processes to remove modified genetic material.

In establishing this rule, AMS has considered the interest of consumers and seeks to minimize the food industry's implementation and compliance costs --- costs that could be passed on to the consumers. That said, as we have stated previously, nothing in this disclosure standard conveys information about the health, safety, or environmental attributes of BE food compared

to non-BE counterparts. The NBFDS provides a mandatory, uniform disclosure standard for BE food -- as defined in this rule, by which uniform information is provided to consumers.

### *3. Conventional breeding*

AMS solicited comments on whether to define “conventional breeding” and suggestions for what that definition should be.

*Comment:* Many commenters requested that AMS define conventional breeding within the NBFDS final rule, to better define the scope of NBFDS for regulated entities and consumers. Several commenters stated that conventional breeding should be narrowly defined, opining that the purpose of the NBFDS was to require labeling of bioengineered food. This was in contrast to another commenter who desired a broad definition of the term, stating that the final rule “should recognize that because a process accelerates what could be accomplished through other, slower processes to achieve the same result, it should not preclude the accelerated process from being deemed “conventional.”

A few commenters accepted one of the sample definitions included by AMS in the proposed rule, but there were many additional proposed definitions. Some commenters suggested conventional breeding be defined as “referring to a wide range of modifications obtained through methods that use an organism's potential genetic variability within its gene pool.” One commenter suggested modifying one of AMS’s sample definitions for conventional breeding to state “protoplast fusion” rather than “protoplast,” “cell selection” rather than “cell” and “embryo rescue” rather than “embryo fusion.” Other commenters suggested adopting bioengineered food definitions from the USDA National Organic Standard (see 7 U.S.C. 1639b(f)(2)), by the Food and Drug Administration, or from the Codex Alimentarius. One such

commenter believed that doing so would make clear that the techniques of modern biotechnology, such as gene editing and gene silencing, were not conventional breeding.

A few groups of commenters requested the term be defined but did not propose a specific definition. Many of them stated that they disapproved of the use of any definition that includes a list, as breeding techniques are continually evolving. One commenter argued that the definition should be fashioned in such a way that the only products subject to labeling are the “products that were developed by transferring genetic material between non-sexually compatible species.” A few other commenters desired that clarity would be achieved by providing a definition and identifying, through examples, those modifications that could be obtained through conventional breeding. Another group of commenters stated that “this should be done through a supplemental proposed rule that provides the public with an additional opportunity to provide public comments.”

There were, however, several commenters who believed that there was no reason to define conventional breeding. Some stated that the term was commonly understood and therefore unnecessary to define. Others argued that the term was difficult to precisely define and therefore would only sow confusion amongst the regulated if there was any attempt to do so. One commenter worried that a definition would likely not stand the test of time due to the pace of new technology and therefore would not cover newly established processes.

*AMS Response:* AMS appreciates the wide range of comments received related to defining “conventional breeding.” AMS finds “conventional breeding” is a commonly understood term within the industry which does not require a definition. Additionally, any “conventional breeding” definition could become unworkable or obsolete as technology and

techniques evolves. Forgoing defining the term would allow AMS to respond to those challenges in real time.

*Comment:* Several commenters stated that conventional breeding is a common term which is well understood, therefore the term does not need to be defined. Some of those that did not wish the term to be defined argued that any such attempts would be inherently confusing or misleading to consumers.

*AMS Response:* AMS agrees that “conventional breeding” is a commonly understood term within the industry that does not require definition.

#### 4. *Found in nature*

AMS requested comments on whether the term “found in nature” should be defined, and if so, what that definition should be. AMS specifically sought comment on whether intellectual property law should be considered as one method for determination.

*Comment:* Commenters generally did not support defining or including the term “found in nature” within the NBFDS. Many of those in opposition believed the term “found in nature” itself was nebulous, misleading, and not adequately defined by science. Others argued that agriculture is inherently separate from nature.

Of those that did request the term be defined, two common suggestions were “spontaneously occurs in nature, such as natural biological evolution, and does not overcome natural physiological reproductive or combination barriers,” or “the kinds of genetic modifications which can occur in nature within the genome of an organism, without human intervention.”

One commenter suggested that should definitions be deemed necessary, the definitions avoid setting precedents in other regulatory areas, and be kept as simple and as clear as possible.

Another group of commenters stated that “this should be done through a supplemental proposed rule that provides the public with an additional opportunity to provide public comments.”

*AMS Response:* AMS finds it unnecessary to define the term “found in nature.” AMS received no compelling arguments to define the term and believes that attempting to do so may cause confusion in light of the rapid pace of innovation. In order to incorporate technological changes in industry into this mandatory labeling standard, AMS believes it needs to retain maximum flexibility. That will not be accomplished by narrowly defining found in nature.

##### *5. List of Bioengineered Foods*

AMS solicited comments on the option of utilizing a list of foods in an attempt to make it easier for regulated entities to identify what products require disclosure. AMS proposed two lists: one composed of highly adopted foods commercially available in the United States and another of non-highly adopted foods commercially available in the United States. AMS requested comments on maintenance of and revisions to the lists, the threshold for “highly adopted,” and list composition. AMS also requested comments on using list maintenance to evaluate whether a particular crop meets the definition of “bioengineering” in light of emerging technologies; on whether enzymes, yeasts, and other foods produced in a controlled environment should be included on the lists; and on the treatment of foods produced in other countries.

*Comment:* While some commenters suggested that a list should not be used as a tool to help identify potential BE foods, most commenters generally supported the use of a list method to identify foods subject to disclosure, noting a readily available list of such foods would make compliance less costly. A few commenters acknowledged the usefulness of the proposed lists as a reference tool but recommended that the presence of BE ingredients in a food trigger the disclosure requirement even if those foods do not appear on the lists.

*AMS Response:* AMS agrees that the List of Bioengineered Foods is an important part of the rule that will facilitate compliance with the NBFDS. AMS also agrees that foods should be subject to disclosure to the extent regulated entities have actual knowledge such foods are bioengineered. Disclosure decisions are based on entities' records. Nevertheless, entities that have actual knowledge that a food is bioengineered must make appropriate disclosure of that food, even if that food does not appear on the List. AMS believes, however, that it would be unduly burdensome to hold regulated entities responsible for failing to make BE disclosures for foods that do not appear on the List and for which regulated entities have no actual knowledge of bioengineered status. Disclosure and recordkeeping for unlisted foods is therefore required only when regulated entities have actual knowledge of the bioengineered status of the food in question. AMS notes that it intends its List to be as complete as possible, aiming to capture any BE foods that meet the definition of bioengineered food and that could potentially be offered for sale in the United States.

*Comment:* While some commenters supported the use of separate lists for highly adopted and non-highly adopted BE foods, many suggested that using two lists with different labeling requirements would be confusing and burdensome, and recommended the final rule call for the use of a single list. A few commenters noted that using a single list could make enforcement and list revision less burdensome for AMS. Others recommended using a single list because the adoption rates forming the basis of the two-list approach do not necessarily correspond to the rates at which the listed crops are used in foods commercially available for human consumption in the United States. Several commenters recommended the single list be comprised of all commercially available crops, while a few industry commenters asked that the single list include only crops with a high (85%) BE adoption rate.

*AMS Response:* In the interest of simplifying compliance with the NBFDS, AMS has consolidated the two lists proposed in the NPRM into one List of Bioengineered Foods and has expanded that List to include foods that may be produced internationally.

AMS has also determined that the purposes of the NBFDS are best served by maintaining a list that, to the extent possible, captures all foods meeting the regulatory definition of a “bioengineered food” that could potentially be offered for sale in the United States, regardless of U.S. adoption rate. AMS has therefore expanded the List beyond foods that are commercially available domestically. The initial List, in § 66.6, is comprised of foods that, to the best of AMS’s knowledge, are authorized for production somewhere in the world and are currently in commercial production somewhere in the world. AMS has considered information and data from several sources, including, but not limited to USDA reports and databases, ISAAA reports and databases, and reports and databases produced by other Federal government agencies. Foods that AMS believes are not currently in commercial production do not appear on the initial List, even if such foods are authorized for production in the U.S. or elsewhere. AMS may add those foods to the List through the process prescribed for list maintenance and revision when available information suggests it would be appropriate to do so. In any event, even if a food is not on the List, regulated entities knowingly using a bioengineered product are required to make disclosures for that food.

*Comment:* Several commenters recommended using an ingredients-based list rather than a crops-based list. A few commenters stated that presuming BE material is present in food derived from crops on the list would frequently be unwarranted, as many such foods derive from listed crops only because they contain certain highly refined ingredients that lack BE material; these commenters explained that using an ingredients-based list (such as a modified version of

the lists in Exhibit 2 or Table 5 from the Regulatory Impact Analysis) instead would avoid creating that misleading presumption. Other commenters stated that an ingredients-based list would make compliance easier for regulated entities, which are often unsure which crops a food's ingredients derive from. Some commenters, however, thought a crops-based list would be easier for regulated entities to use and noted that a crops list, unlike an ingredients list, could be updated and verified using adoption rates and field data. A few commenters also expressed a need for a list containing BE microorganisms or other BE species, such as BE salmon.

*AMS Response:* AMS believes that regulated entities are in the best position to know the source, origin, and type of food products they are procuring, sourcing, refining, and potentially labeling. AMS developed the List of Bioengineered Foods to reduce potential recordkeeping burden of regulated entities while also providing information about the scope of potentially available bioengineered foods. The List has been expanded to include bioengineered foods that may not be produced in the United States and non-crop bioengineered foods, for example salmon. AMS acknowledges that the List may not be complete and may require periodic updates. The rule provides for annual review of the List and provides a mechanism for public input into list population, including rulemaking as necessary, as well as consultation with other government agencies.

AMS anticipates that maintaining an ingredients-based list would be resource-intensive, difficult to maintain, and would likely become obsolete in short order. As stated, AMS believes that regulated entities have more knowledge than AMS regarding the ingredients they are sourcing. Entities who knowingly use bioengineered foods are responsible for making appropriate disclosures, even if the food is not on the List.

*Comment:* A few commenters requested that AMS establish a list of Excluded Ingredients identifying ingredients or substances AMS ultimately deems not to trigger the disclosure requirement. These commenters noted that such a list could reduce compliance and recordkeeping costs for regulated entities and suggested AMS could periodically amend the list as appropriate without going through formal notice and comment rulemaking. These commenters requested that AMS set forth the process for creating and updating a list of Excluded Ingredients in the final rule.

*AMS Response:* As explained in the Preamble, AMS cannot at this time establish and maintain a list of ingredients excluded from the scope of the disclosure requirement. Regulated entities are in the best position to know whether disclosure is not required for the ingredients in their products, including, for example, because records verify the products are sourced from non-bioengineered crops or other sources, the ingredients have been subjected to refinement processes validated to remove genetic material, or analytical testing results demonstrate the absence of modified genetic material.

*Comment:* Several commenters supported the proposed rule's exclusion of enzymes, yeasts, and other non-crop foods created in controlled environments from the proposed lists on the grounds that such foods contain no genetic material and thus should not trigger the BE disclosure requirement. Some commenters, however, recommended the lists be expanded to include those products and all other BE-derived substances in commercially available foods. Several of these commenters explained that such substances, if ultimately deemed to meet the NBFDS definition of BE food, should be included in the final lists to facilitate compliance with the disclosure rule.

*AMS Response:* AMS notes that if regulated entities have actual knowledge that enzymes, yeasts, and other similar foods produced in controlled environments are bioengineered foods, then regulated entities are obligated to disclose accordingly. AMS has decided not to include on the List of Bioengineered Foods enzymes, yeasts, and other similar foods produced in controlled environments. AMS believes that such substances often do not meet the definition of a “bioengineered food” because they may be incidental additives with no technical or functional effect in the food under § 66.1 and 21 CFR 101.100(a)(3) (see Section E.1 of the Preamble, adopting the “incidental additive” factor or condition). Similarly, in many instances, a regulated entity may be able to demonstrate that such foods do not contain modified genetic material, such that they are not bioengineered foods. AMS believes categorical inclusion of such substances on the List of Bioengineered Foods would create confusion and complicate regulated entities’ efforts to comply with the NBFDS’s disclosure requirement. Regulated entities must determine whether recordkeeping and, ultimately, disclosure of those substances are required on a case-by-case basis.

*Comment:* Some commenters supported the proposed approach of listing crops or foods generally by type rather than creating a more cumbersome list identifying specific derivatives or varieties of listed crops. Other commenters recommended that the final lists refer to crops with greater specificity than the lists proposed – such as by specific cultivars for each crop, brand name, variety, or narrowly-defined product characteristic – to avoid burdening too many producers of non-BE crops with the NBFDS recordkeeping requirement. For example, one comment suggested listing “Arctic® apple” instead of “Apple, Non-browning cultivars,” since the only commercially available version of BE apples uses the Arctic® brand name. A few

commenters also requested clarification on which types of corn constitute “sweet corn” and which types constitute “field corn.”

*AMS Response:* AMS recognizes that listing foods broadly by type, rather than by bioengineered derivatives or varieties of particular foods, may impose disclosure or recordkeeping burdens on overbroad segments of producers or sellers of non-bioengineered foods. To address that concern while maintaining a list of bioengineered foods that is not overly cumbersome, AMS has decided to list foods broadly by type while providing more details regarding specific varieties and characteristics, where possible. With respect to apples, AMS understands that most apple varieties are not known to be bioengineered. AMS has modified the List to identify the specific apples that are known to be bioengineered. As other BE versions of foods that are listed by variety are approved and become legally available, AMS will revise such listings to be more generic during the annual update process.

Additional information will be provided on AMS’s website about specific varieties of foods that have been bioengineered, where that information is available to AMS. To the extent possible, the AMS website will also provide additional information about the traits for which the foods have been bioengineered. The information on the AMS website should aid regulated entities in determining which foods must bear a BE disclosure. As part of the annual review process, AMS will solicit information from the public to ensure that the List and the additional information maintained on the AMS website are complete, accurate, and as detailed, as possible.

*Comment:* Some commenters asked AMS to expand the proposed lists of BE products to include any BE foods that have undergone an FDA pre-market consultation, noting that such foods would be free to enter the market in the United States. However, other commenters pointed out that FDA pre-market consultation is not necessarily a reliable indicator that

commercial availability is imminent, and they supported limiting the lists to products that are commercially available. Some commenters also requested clarification in the final rule on the definition of commercial availability, with a few commenters suggesting a market threshold of 10% for deeming a product commercially available.

*AMS Response:* As previously discussed, AMS has replaced the two lists of commercially available bioengineered foods proposed in the NPRM with a consolidated List of Bioengineered Foods that includes, to the best of AMS's knowledge, all foods that may meet the regulatory definition of a "bioengineered food" that could potentially be offered for retail sale in the United States. The consolidated List, which can be found in § 66.6, is comprised of foods that meet the following criteria: (1) they are authorized for production somewhere in the world and (2) they are believed to be in legal commercial production somewhere in the world. AMS believes this approach is consistent with the regulatory definition of "bioengineered food" and avoids potential confusion on the meaning of or threshold for the term "commercial availability," that was proposed in the NPRM.

*Comment:* Many commenters supported expanding the lists to encompass BE crops grown in and imported from other countries, as large quantities of foods containing or derived from such crops are commercially available in the United States. Several commenters acknowledged that assembling international food lists and ensuring NBFDS compliance by foreign suppliers may be complicated, but that AMS might accomplish those ends by, for example, collaborating with international trade partners, using data published by organizations like the ISAAA and setting forth specific recordkeeping and/or testing requirements for foods imported from other countries.

*AMS Response:* Because bioengineered foods produced abroad are imported and offered for sale (or incorporated into products offered for sale) in the United States, AMS has decided to expand the list to include bioengineered foods that are in commercial production internationally. AMS has assembled that list by gathering information from several sources, including data published by ISAAA, FDA's list of completed voluntary premarket biotechnology consultations, and information published by ERS. AMS believes ongoing maintenance of the list may appropriately involve consideration of information from these and similar sources, as well as information supplied by the United States' trade partners. During the annual process to review and update the lists, AMS will consider information from interested parties, including importers and trade partners.

*Comment:* Several commenters agreed that if a food contains an ingredient appearing on the List, the entity should make a BE disclosure unless it keeps records verifying it is not a BE food and does not contain BE ingredients. Other comments criticized basing the disclosure requirement on whether foods were among the listed crops, explaining that the presumption created by a food's inclusion on the lists would place the rule's recordkeeping burden primarily on those who use non-BE commodity varieties in their foods – a result these comments viewed as at odds with congressional intent. Similarly, another commenter suggested that AMS should be tasked with keeping track of records supporting disclosure, allowing entities to challenge their appearance on the list directly to USDA.

*AMS Response:* AMS has determined that all food manufacturers, importers, and retailers offering for retail sale foods on the List of Bioengineered Foods are regulated entities and must maintain records related to those foods. The records can be used to verify disclosure or non-disclosure decisions. AMS does not believe this approach places an undue recordkeeping

burden on entities that do not handle bioengineered foods; the NBFDS requires all regulated entities to maintain customary business records on foods they handle that appear on the List of Bioengineered Foods, and AMS anticipates those customary business records will be sufficient to demonstrate whether or not a food is bioengineered or contains bioengineered ingredients.

It would be expensive and very difficult, if not impossible, for AMS to keep track of records that support disclosure. AMS believes that regulated entities are in the best position to know the foods they are sourcing, distributing, using, and labeling, and the amended Act requires them to maintain usual and customary records. Because regulated entities must provide AMS with access to those records, it would be unnecessary to keep track of those records.

*Comment:* While some commenters favored annual review and revision of the lists, others found annual updates too infrequent to keep consumers effectively apprised of the BE status of their foods, and asked AMS to update the lists on a quarterly, monthly, or continuous basis instead. Some commenters, by contrast, suggested annual updates would be too frequent and unduly burdensome to AMS, particularly in light of the delay potentially associated with seeking public input before list revision, as proposed in the NPRM.

Commenters nevertheless generally approved of employing an open, clear, and transparent revision process. A few commenters warned against overreliance on the views of interested stakeholders in the proposed revision process, encouraging AMS to rely primarily on evidence-based criteria for list updates. Some commenters also requested that AMS disclose the potential environmental impact of the BE products recommended for inclusion on the lists.

*AMS Response:* AMS recognizes the brisk rate at which bioengineering technology is advancing and new bioengineered food products are entering the marketplace. Accordingly, and because of the role of the List of Bioengineered Foods in determining whether specific foods

require BE disclosure, AMS believes the List should be reviewed and updated on a regular basis. At the same time, AMS is mindful of the need to ensure the process for updating the list is transparent and allows for careful consideration of all relevant information on the appropriateness of proposed revisions. AMS has determined that updating the list on an annual basis through the notice process strikes the most appropriate balance among these considerations.

The Preamble and § 66.7(a) of the NBFDS describe the process by which AMS will seek recommendations and conduct an annual notice process through the Federal Register to review proposals regarding updates to the List of Bioengineered Foods. If indicated, AMS will conduct rulemaking to address proposed changes to the List. AMS believes this process will supply it with a wide range of pertinent information, including but not limited to scientific evidence, to allow the agency to make an informed decision whether certain foods should be added to or deleted from the list. The list review and update process will include consultation with other U.S. Federal government agencies with oversight of the use of bioengineered foods, including on the environmental impacts of using bioengineered foods. AMS, however, does not plan to attempt disclosure of potential environmental impacts as part of the list maintenance and revision process, as the NBFDS is not intended to convey information about the environmental attributes of BE food. AMS will instead revise the list based on whether a food meets the definition of a “bioengineered food.”

*Comment:* Many of those who commented requested that the lists reflect the use of new and emerging technologies such as CRISPR, Synbio, and Talens. Those commenters recommended the lists remain consistent with the standards set forth in other Federal regulations, as well as the Codex Alimentarius, in order to facilitate compliance with applicable requirements and avoid conflicts with trade partners. Other commenters maintained that some existing or

future genetic engineering techniques may not produce foods falling within the statutory definition of BE food and that such products should not appear on the proposed lists.

*AMS Response:* As previously noted, AMS believes that the characteristics of the biotechnology product itself, rather than the particular technological process by which the product was created, should determine whether a product is included on the List of Bioengineered Foods. AMS considers this approach more compatible with the text of the amended Act and Congressional intent. As part of the process for list maintenance and revision, AMS will, in consultation with the U.S. Government agencies responsible for the oversight of biotechnology products, consider new and emerging technologies and whether foods resulting from those technologies meet the definition of “bioengineered food.”

*Comment:* Comments reflected a wide range of opinion on the appropriate timeframe for regulated entities to attain compliance after the BE food lists are revised. Many commenters supported the proposed 18-month compliance period. Others, concerned that the proposed period would allow new BE products to remain undisclosed to consumers for too long, recommended a 12-month period instead. Several industry commenters recommended a 24-month period, explaining that labeling costs rise and packaging waste results each time relabeling and repackaging are required, so those processes should occur as infrequently as reasonably possible. A few commenters suggested taking a more flexible approach, which would allow interested parties to submit comments on an appropriate time period as part of the list revision process. These commenters stated that a more contracted or extended compliance period might be appropriate, depending on the foods proposed to be added to the lists and impacts of the proposed changes on supply chains.

*AMS Response:* AMS acknowledges the burden frequent relabeling and repackaging would place on regulated entities. We believe the proposed 18-month compliance period allows regulated entities sufficient time to exhaust existing supplies and make necessary revisions to labels, and strikes the most appropriate balance with the countervailing need for consumer-facing labels to reflect accurate and updated BE information. In addition, AMS believes using a fixed 18-month compliance period for all changes to the list will prove more workable than setting applicable compliance periods on an ad hoc basis as part of the annual notice process for list revision.

#### *6. Factors and Conditions*

AMS solicited comments on whether one or both of the following should constitute factors or conditions under which a food is considered a BE food: (1) whether incidental additives should be considered a BE food and labeled accordingly; and (2) whether the modified genetic material in a highly refined food may be detected. The proposed definition of BE food in the NPRM included the first factor or condition (incidental additives) but did not include the second (detection). AMS sought comment on whether the final rule should incorporate one or both of those factors or conditions into the definition. The proposed rule also sought comment on the process for seeking a determination on the adoption of other factors or conditions.

*Comment:* Commenters were generally supportive of the proposed process for adopting factors or conditions under which a food is considered a BE food. Some commenters, however, requested AMS to clarify in the final rule the parameters for submitting petitions to adopt factors or conditions. A few commenters asked AMS to establish a specific time period within which the agency would respond to requests for adoption of factors or conditions, as well as a time period for regulated entities to attain compliance with adopted factors or conditions. Other

commenters asked AMS to allow the adoption of factors or conditions under which food produced through new technologies falls within the definition of BE food.

*AMS Response:* As noted above, AMS has determined to adopt the process proposed in the NPRM for adopting factors and conditions under which a food is considered a BE food. AMS believes that process as outlined in the NPRM and this final rule is clear and transparent, and the agency has thus declined to alter the proposed submission parameters for petitions to adopt factors and conditions. AMS has also declined to establish a time period within which the agency must respond to requests for adoption of factors and conditions, as the time necessary for responding to such requests will vary depending on available agency resources, the complexity of the requests, and the nature of rulemaking. Similarly, AMS has not established a fixed compliance period within which regulated entities must attain compliance with adopted factors and conditions. To the extent necessary, AMS will address any compliance period in particular rulemakings considering factors or conditions to be adopted. It is the view of AMS, however, that because adopted factors and conditions operate only to carve out foods from the definition of “bioengineered food,” compliance with adopted factors and conditions will not ordinarily be burdensome.

AMS also notes that the text of the amended Act authorizes the Secretary to establish a process for making determinations regarding “other factors and conditions under which a food is considered a bioengineered food.” 7 U.S.C. 1639b(b)(2)(C). Although AMS may consider particular technologies as part of the factors and conditions process (as well as in revising and updating the List of Bioengineered Foods), in accordance with the language in the amended Act, AMS believes determinations whether to adopt a proposed factor or condition will primarily focus on the characteristics of the final food products, rather than on the particular technologies

used to create the food products. In deciding whether to adopt proposed factors or conditions, AMS will consult with U.S. government agencies responsible for oversight of biotechnology products and consider relevant information that may allow AMS to align the NBFDS with the standards of other Federal agencies or foreign governments.

*Comment:* A few commenters opposed the adoption of the factors or conditions on which AMS solicited comments on the grounds that all foods derived in any part from BE substances, including incidental additives or foods with no detectable modified genetic material, should be disclosed in the interests of transparency. The commenters added that consumers want to know not only whether the final product contains BE genetic material, but also whether BE substances were used to make the final product.

*AMS Response:* As explained in the Preamble to this final rule, a food does not fall within the definition of a “bioengineered food” simply because a BE substance was used in the process of making the food – to be a “bioengineered food,” the food must contain modified genetic material. For that reason, AMS cannot decline to adopt a proposed factor or condition – which, under this final rule, could serve only to exclude foods from the scope of the “bioengineered food” definition – solely on the basis that the factor or condition would exclude from disclosure a food derived in part from the use of a BE substance.

*Comment:* Many commenters agreed that incidental additives should not be subject to disclosure when FDA regulations exempt them from inclusion in the ingredient statement on a food label. These commenters stated that aligning the NBFDS with FDA ingredient labeling requirements would simplify compliance and reduce labeling costs for regulated entities, and would also avoid creating consumer confusion. A few commenters added that excluding incidental additives from disclosure would align the NBFDS with the regulations of international

trading partners. Several commenters further noted that incidental additives are present in food at an insignificant level and do not have any technical or functional effect in the final food product.

*AMS Response:* AMS agrees with the above comments. Exempting incidental additives that are not required to be labeled under FDCA regulations is sensible, aligns the NBFDS with practices of trading partners, avoids consumer confusion that could otherwise result if a substance not appearing on a food label triggered the NBFDS disclosure requirement, and limits the burden on regulated entities without unduly limiting disclosure for consumers. For these reasons, AMS has adopted the proposed factor and condition regarding incidental additives.

*Comment:* A few commenters recommended that enzymes be excluded from the disclosure requirement even if FDA regulations require their inclusion in the ingredient statement on a food label. These commenters stated this approach would be consistent with how state laws on BE disclosure treated enzymes. Some commenters noted, however, that certain yeasts (unlike enzymes) must be disclosed because they contain DNA and remain active and functional in finished food. One commenter added that if a 5% threshold is selected, it is unlikely that the presence of yeast would trigger disclosure.

*AMS Response:* AMS anticipates that enzymes, yeasts, and similar organisms will frequently be excluded from the disclosure requirement, either because they will meet the requirements of the incidental additive factor or condition or because they meet some other NBFDS provision permitting nondisclosure (such as §§ 66.1 and 66.9 regarding foods with no detectable genetic material). For organisms present in food that do not meet the requirements of any such provision, however, AMS cannot provide a categorical exclusion from the disclosure requirement. To the extent that interested parties seek a categorical exemption for

microorganisms, they may submit a request for such a factor and condition to modify the definition of bioengineered food in a future rulemaking.

*Comment:* Some commenters in favor of excluding incidental additives from disclosure requested the proposed factor or condition to be modified to expressly include within the meaning of “incidental additives” processing aids, secondary direct additives, and substances migrating to food from equipment or packaging. A few commenters further requested AMS to clarify that BE microorganisms (such as those used in fermentation) constitute incidental additives where those microorganisms do not remain active and have no technical or functional effect in the finished food product. One commenter requested that AMS clarify what it considers to be an “insignificant” level of an incidental additive present in food, and recommended AMS adopt a meaning of “insignificant” consistent with that set forth in the FDA’s regulations on labeling ingredients in food.

*AMS Response:* AMS does not believe the requested modifications or clarifications are necessary. The factor and condition regarding incidental additives is designed to align the NBFDS with the FDA’s regulations on labeling food ingredients. Section 66.1’s incorporation of the incidental additives factor and condition into the NBFDS thus references the FDA labeling requirement at 21 CFR 101.100(a)(3), which, among other things, outlines the circumstances in which incidental additives need not be labeled as ingredients and describes the types of substances constituting “incidental additives.” To the extent that secondary direct additives do not constitute incidental additives not subject to FDCA labeling requirements, then such additives would be subject to BE disclosure. AMS notes that 21 CFR 101.100(a)(4) defines “insignificant” levels of additives for certain applications of 21 CFR 101.100(a)(3). As § 66.1 thus incorporates the FDA labeling regulations’ conception of “incidental additives” into the

NBFDS, AMS believes further clarification or modification on the meaning of, or circumstances under which a substance may qualify as, an “incidental additive” would be redundant or risk creating the appearance of a conflict between the NBFDS’s incidental additives provision and the FDA’s labeling requirements.

*Comment:* Many commenters opposed the factor or condition excluding highly refined foods from disclosure where no modified genetic material can be detected. These commenters suggested that consumers deserve to make informed purchasing decisions and expect BE disclosure where food or ingredients are derived from BE crops, regardless of whether modified genetic material can be detected in the finished food. Some commenters objected to this factor or condition because it would result in fewer products being subject to disclosure, which in their view would be inconsistent with consumer expectations. Other commenters stated that testing for trace amounts of modified genetic material would be difficult to enforce, impose burdensome compliance and recordkeeping costs on the industry that would then be passed to consumers, and present barriers for international trade as several trade partners do not require testing before permitting nondisclosure for highly refined ingredients. Many regulated entities, these commenters added, would choose to make a BE disclosure rather than undergo testing, resulting in different labeling for similar food products. Some commenters also voiced concerns about the ability of current testing methods and technology to accurately or consistently capture the presence or absence of modified genetic material.

*AMS Response:* The NPRM sought comment on a second proposed factor and condition, excluding food from the disclosure requirement where modified genetic material in the food cannot be detected. Because this proposed factor and condition would serve a purpose in the NBFDS only if foods without detectable modified genetic material were included within the

general definition of “bioengineered food,” the NPRM explained that AMS would consider this factor and condition only if AMS decided to proceed with Position 2 on the scope of the regulatory definition of “bioengineered food.” As AMS declined to adopt Position 2 for the reasons stated in Section C.1, above, this factor and condition will not be incorporated into the NBFDS.

*Comment:* One commenter generally supported the exclusion of highly refined foods from the definition of BE food but opposed the undetectable modified genetic material factor or condition as proposed, on the ground that requiring regulated entities to provide the BE disclosure unless they first disprove the presence of modified genetic material by testing is an unconstitutional impingement on those entities’ First Amendment rights.

*AMS Response:* AMS has adopted Position 1. The statutory definition of bioengineering states that food must “contain[] genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques. . .”, to be labeled as a “bioengineered food.” AMS is not compelling regulated entities to label refined foods as “bioengineered food.” If the food product at issue is not a bioengineered food, AMS does not require that it be mandatorily labeled.

*Comment:* Many commenters supported the factor or condition excluding highly refined foods with no detectable modified genetic material from the disclosure requirement, pointing to several scientific studies they viewed as demonstrating an absence of genetic material in such foods. These comments explained that disclosure under the amended Act is triggered by the presence of modified genetic material and that, if no modified genetic material is detectable, Congress did not intend the food to be disclosed as BE. A few commenters also stated that treating highly refined ingredients derived from BE crops differently than their non-BE

counterparts would create harmful marketplace impacts with no meaningful benefit to consumers.

*AMS Response:* As discussed in Section II.C.1, above, AMS agrees that highly refined foods with no detectable modified genetic material should not trigger the disclosure requirement. AMS, however, has decided to permit nondisclosure for such foods by adopting Position 1 on the scope of the regulatory definition of “bioengineered food,” and will therefore not incorporate this proposed factor or condition into the NBFDS.

*Comment:* Some parties in favor of the undetectable modified genetic material factor or condition offered comments on the testing methods and standards to be used to determine the presence or absence of detectable rDNA. One commenter recommended AMS accept a “de minimis” level of modified genetic material at or below which ingredients are not subject to mandatory disclosure and set that de minimis level of detection at 0.1% modified genetic material to total DNA. That commenter added that if AMS decides a de minimis detection level is not appropriate, detectability should be defined in accordance with ISO/ICE standards and using a methodology validated by Codex Alimentarius guidelines. A few commenters asked AMS to establish minimal standards regarding the analytical tools used for detecting, identifying, and quantifying modified genetic material. Some commenters also urged AMS to update the NBFDS as scientific detection methods evolve, with a few further recommending that AMS maintain publicly available guidance documents or lists of scientifically validated genetic testing methods to ensure testing consistency in the marketplace.

*AMS Response:* As mentioned, because AMS has adopted Position 1 on the scope of the regulatory definition of “bioengineered food,” the proposed factor or condition regarding undetectable rDNA will not be incorporated into the NBFDS. The methods by which regulated

entities may demonstrate that particular foods contain no detectable modified general material, and thus are not bioengineered foods, are discussed in Section II.C.1, above. As stated in the Preamble, AMS will provide instructions to the industry to explain how they can ensure acceptable validation of refining processes in accordance with AMS standards. AMS will also provide instructions regarding acceptable testing methodology used to satisfy that a food does not contain detectable modified genetic material.

*Comment:* Several commenters requested AMS to establish a list of Excluded Ingredients, identifying ingredients excluded from the scope of the disclosure requirement under the undetectable rDNA factor or condition. Those commenters noted that AMS could periodically amend that list as appropriate without going through formal notice and comment rulemaking, helping to ensure the list is kept current. Those commenters requested AMS to set forth the process for creating and updating a list of Excluded Ingredients in the final rule.

*AMS Response:* AMS has not adopted the second proposed factor or condition. As discussed in Section II.C.1, above, AMS cannot at this time establish and maintain a list of ingredients excluded from the scope of the disclosure requirement. Regulated entities are in the best position to know the products they are sourcing and the refinement processes those products have undergone. AMS has determined that regulated entities can demonstrate that modified genetic material is not detectable by maintaining records verifying that a food is sourced from a non-bioengineered crop or source, showing that a food has been subjected to a refinement process validated to remove modified genetic material, or maintaining records of analytical testing results demonstrating the absence of modified genetic material.

*Comment:* Commenters also requested AMS to adopt additional factors or conditions excluding the following substances from triggering the disclosure requirement: microorganisms

derived through fermentation; ingredients derived from animals fed with or treated with pharmaceuticals produced from BE substances; ingredients produced through the chemical transformation of BE foods or ingredients into substantially new ingredients with no present or readily traceable BE source; and dietary supplements and/or food products with medicinal or supplementary applications.

*AMS Response:* AMS solicited comments only on the two factors and conditions proposed in the NPRM and cannot adopt additional factors and conditions in this final rule. It is possible, however, that some or all of the foregoing factors and conditions may appropriately be adopted through the factors and conditions process in future rulemakings. The process for requesting adoption of factors and conditions is discussed in the Preamble to this final rule and outlined in subpart C of the NBFDS.

## 7. Exemptions

### *a. Animals fed bioengineered feed*

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). Section 66.5(d) incorporates this statutory exemption and exempts products produced from animals fed bioengineered feed from displaying any form of disclosure regarding the presence of bioengineered ingredients or substances.

*Comment:* Commenters generally support the idea that animals fed with bioengineered feed and their products, including milk and eggs, should be exempt from the NBFDS. Many commenters understood that this provision was statutorily mandated. One commenter suggested that this provision should be framed as an exclusion rather than an exemption. Some commenters stressed that the NBFDS should state that products exempt from disclosure as

bioengineered, such as products from animals fed bioengineered animal food, cannot by default qualify for an absence claim.

*AMS Response:* As commenters recognized, the amended Act prohibits a food derived from an animal from being considered a bioengineered food solely because the animal consumed animal feed produced from, containing, or consisting of a bioengineered substance. 7 U.S.C. 1639b(b)(2)(A). Section 66.5(d) incorporates 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.

AMS has made no changes to this statutory mandate. Although this provision could be framed as an exclusion, AMS believes that it is permissible to frame it as an exemption. Moreover, the regulatory text makes clear that 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.

AMS agrees that food derived from an animal that consumed feed produced from, containing, or consisting of a bioengineered substance does not automatically qualify for absence claims. *See* 7 U.S.C. 1639c(c). AMS declines to insert this in the regulatory text because the amended Act in this respect is self-executing. In addition, the focus of the NBFDS is on BE claims and not on absence claims. AMS notes that FDA (and FSIS depending on the food at issue) retain authority over absence claims. Entities seeking to use absence claims should ensure that they are in compliance with all pertinent Federal regulations and that such claims are truthful and not misleading.

*Comment:* Some commenters suggested that AMS should work to align "Non-GMO" text claim mandates with the NBFDS disclosure requirements, and that the exemption should

also apply to products derived from animals or birds treated with drugs or pharmaceuticals produced through bioengineering.

*AMS Response:* AMS does not believe the amended Act provides authority to establish or align the NBFDS with a “non-GMO” label. Statutory provisions clearly instructed the Secretary to establish a national mandatory bioengineered food disclosure standard with respect to any “bioengineered food” and any food that may be “bioengineered.” As it pertains to other food labeling programs, the amended Act only acknowledges food certified under the NOP as sufficient to make a claim regarding the absence of bioengineering in the food, such as “not bioengineered,” “non-GMO,” or another similar claim. As noted above, AMS recognizes that FDA and FSIS retain authority over absence claims. Entities seeking to use absence claims should ensure that such claims comply with all applicable Federal laws and are otherwise truthful and not misleading. Regulated entities would need to ensure that their use of any other third-party standard that establishes and allows use of claims such as “non-GMO,” “non-Bioengineered,” or other similar claims does not put their product at risk of violating the NBFDS.

With respect to products derived from animals or birds treated with drugs or pharmaceuticals produced with bioengineering, AMS believes that such products, if they do not contain modified genetic material, would not meet the definition of “bioengineered food.”

*Comment:* Some commenters requested that AMS define the term “animal” to include any animal, fish, insect, or microorganism. One commenter specifically pointed out that bees consuming pollen from bioengineered crops should be included in the definition of animal, and that honey should be exempted from disclosure. Some commenters argued that food ingredients like yeast, rennet, and enzymes should be exempt from disclosure. They explained that because

yeast, rennet, and enzymes are typically produced or fed using bioengineered substrates, but may not be bioengineered themselves, they should be treated the same as products derived from animals that consumed bioengineered feed and exempted from the NBFDS. Many commenters agreed that the term “non-agricultural ingredients” is an appropriate description for such ingredients.

Another commenter went further to state that ingredients that are produced through the chemical transformation of a bioengineered food or ingredient and substantially transformed into a new ingredient, such as caramel flavoring and color, polydextrose, vitamin C, and sugar alcohols, should also be exempted. Commenters explained how for these kinds of ingredients that undergo significant processing, modified genetic material is rendered undetectable. Alternatively, other commenters argued that these ingredients should be subject to disclosure if they are listed as ingredients on a label.

*AMS Response:* AMS did not define animal in the regulatory text. AMS’s understanding of an animal is based on the common understanding of an “animal”, which refers to any organism in the biological kingdom Animalia, and would include fish, birds, and insects. “Products derived from an animal” would include milk, eggs, honey, rennet and other enzymes derived from animals, and similar products. The common understanding of “animal” and “products derived from an animal” would not include yeast since yeast is a single celled organism in the Fungi kingdom, or microbial rennet. Exempting yeast, microbial rennet, and enzymes that are not derived from animals as an extension of the exemption for animal fed with bioengineered feed is beyond AMS’s statutory authority. As discussed above, those substances may not be subject to BE disclosure if they qualify as an incidental additive that is not required to be labeled or if the modified genetic material in those products is undetectable.

Similarly, ingredients produced through the chemical transformation of a bioengineered food or ingredient and substantially transformed into a new ingredient, such as caramel flavoring and color, polydextrose, vitamin C, and sugar alcohols are subject to the NBFDS. They are not automatically exempt from disclosure. Based on AMS's understanding, these products would not qualify as products derived from animals that consumed bioengineered feed. However, they may not be subject to disclosure if they qualify as an incidental additive that is not required to be labeled or if the modified genetic material in those products is undetectable.

*Comment:* One commenter requested that AMS exempt foods produced from conventionally bred plants grafted to bioengineered rootstocks – provided that the plants producing such food have not otherwise been bioengineered. Such an exemption should cover the food and the plant that produced the food, including its bioengineered rootstock.

*AMS Response:* AMS cannot exempt foods produced from conventionally bred plants grafted to bioengineered rootstocks in this rulemaking. To the extent that these plants produce foods that have otherwise not been bioengineered, the resulting foods would not be bioengineered because they do not contain modified genetic material or for other reasons.

*b. Food served in a restaurant or similar retail food establishment*

As required by the amended Act, AMS proposed that food served in restaurants or similar retail food establishments should be exempt from the NBFDS. *See* 7 U.S.C. 1639b(b)(2)(G)(i). We received several comments on this exemption and what food establishments should qualify for the exemption.

*Comments:* Commenters generally supported exempting restaurants and similar retail food establishments from the NBFDS. Commenters explained how if these kinds of establishments were subject to the NBFDS, they would be unnecessarily burdened with

maintaining product lists of bioengineered food and ingredients sold on a daily basis. Other comments suggested that the proposed definition was too narrow and should include a list of places as examples, rather than an exclusive list, such as cafeteria, lunch room, food stand, food truck, saloon, tavern, bar, lounge, salad bar, delicatessen, entertainment venue, or other retail business establishment where meals or refreshments constituting food may be purchased. One commenter requested that transportation carriers be added to the list of places exempted from the NBFDS.

Comments were also received that opposed the exemption for restaurants and similar retail prepared food establishments. These comments explained how consumers deserve to know when the food they are buying is bioengineered, regardless of whether it was purchased in a restaurant or in a grocery store.

Another commenter explained how all foods prepared, processed, or packaged in a retail food establishment, including those utilizing “central kitchen” locations for certain prepared foods, should also be exempt from the disclosure requirements of the NBFDS.

Others suggested that AMS should consider exempting foods sold by manufacturers to restaurants and similar establishments, and foods marked as “for institutional use” or “not for resale.”

*AMS Response:* This final rule continues to exempt food served in a restaurant or similar retail food establishment from disclosure under the NBFDS. Based on the comments received, AMS has now modified the definition of “similar retail food establishment” to add additional examples, including food truck and transportation carrier: “Similar retail food establishment means a cafeteria, lunch room, food stand, food truck, transportation carrier (such as a train or airplane), saloon, tavern, bar, lounge, other similar establishment operated as an enterprise

engaged in the business of selling prepared food to the public, or salad bars, delicatessens, and other food enterprises located within retail establishments that provide ready-to-eat foods that are consumed either on or outside the retailer's premises." AMS considered including a list of places as examples, rather than an exclusive list, but believes that the reference to "other similar establishment operated as an enterprise engaged in the business of selling prepared food to the public" should capture any additional places that are not specifically listed.

AMS has not modified the definition to state "where meals or refreshments constituting food may be purchased" as we believe that with this insertion, the exemption would be much broader than the plain meaning of the amended Act. AMS believes that the exemption is intended to cover ready-to-eat or prepared foods. To extend the exemption to all foods prepared, processed, or packaged in a retail food establishment, which would include bulk foods such as granola or packaged apples in a bin, would conflict with the requirement that foods subject to FDCA's labeling requirements are subject to disclosure. AMS notes it does not have statutory authority to extend this exemption to foods sold by manufacturers to restaurants and similar retail food establishments, or to foods marked as "for institutional use" or "not for resale." However, AMS anticipates that some of these foods would fall under this exemption because the entities selling or providing such food meet the definition of a similar retail food establishment.

AMS believes that the modified definition provides clarity and flexibility to regulated entities and is in accordance with the plain language of the amended Act. AMS also notes that exempt entities such as restaurants and similar retail food establishments may voluntarily provide disclosures of "bioengineered food" in accordance with the NBFDS if they so choose.

*c. Very small food manufacturer*

As required by the amended Act, AMS proposed that very small food manufacturers be exempt from displaying any form of disclosure regarding the presence of bioengineered ingredients or substances in their products. *See* 7 U.S.C. 1639b(b)(2)(G)(ii).

*Comment:* Some commenters did not support a disclosure exemption for very small food manufacturers. These commenters stated that the NBFDS should apply equally to all companies regardless of size or revenue. These commenters stated that excluding small companies would undermine the transparency and consistency necessary for building consumer trust.

*AMS Response:* Section 66.5(b) exempts very small food manufacturers from the disclosure requirement of the NBFDS, as required by the amended Act. Section 66.1 defines “very small food manufacturer” as “any food manufacturer with annual receipts of less than \$2,500,000.” AMS has made no changes to its proposal. In considering this definition, AMS must balance between providing regulatory flexibility for regulated entities and providing information to consumers regarding the bioengineered status of their foods.

*Comment:* A few commenters stated that number of employees was an equally if not more suitable criterion than receipts for a small business. For instance, Congress has exempted small employers with 50 or fewer employees from some other Federal statutory provisions, such as the Affordable Care Act (42 U.S.C. 18024(b)(2)) and the Family and Medical Leave Act (29 U.S.C. 2601). A commenter recommended the agency should revise the definition of “very small food manufacturer” to include either those that have less than \$2.5 million in annual receipts or 50 or fewer employees.

Understanding that there is a statutory obligation to exclude very small companies from the disclosure requirement, some commenters suggested using the lowest reasonable financial

threshold of \$500,000 consistent with those exempted from labeling requirements under the FDCA (§ 66.3(b) or limited to only “cottage foods.”

A few commenters suggested revising the definition of “very small food manufacturer” to align with the Food Safety Modernization Act’s definition for a “very small business,” which is defined as “a business (including any subsidiaries and affiliates) averaging less than \$1,000,000.”

*AMS Response:* To develop this definition, AMS considered small business definitions under FDA (21 CFR 101.9(j)(1)(i) and 21 CFR 101.36(h)(1)) and U.S. Census Bureau (USCB) regulations. AMS evaluated the impact of applying various definitions of “very small food manufacturer” by estimating the number of firms that would be exempted, the number of products that would likely be exempt, and the proportion of annual industry sales that would be exempt under each exemption level. The NPRM and the final rule above included tables showing 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 USCB’s 2012 *Statistics of U.S. Businesses*).

Applying the FDA exemptions (annual sales of no more than \$500,000) at 21 CFR 101.9(j)(1)(i) and 21 CFR 101.36(h)(1) as described above would exempt 45 percent of firms, only one percent of products, and less than 0.5 percent of sales for food manufacturers, and only 17 percent of firms and about 0.1 percent of products and sales for dietary supplement manufacturers. In conducting the Regulatory Impact Analysis, we estimated the impact of applying the USCB definition of very small businesses (fewer than 20 employees), which falls somewhere between the \$2.5 million and \$5 million annual sales cutoffs. We found that both of these revenue cutoff levels for the definition of “very small food manufacturer” would offer

significantly greater relief for small manufacturers, while still having a relatively minor impact on the amount of information available to consumers. Exempting manufacturers with annual receipts of less than \$2.5 million would provide regulatory relief to 74 percent of food manufacturers and 45 percent of dietary supplement manufacturers, while reducing the number of products covered by four percent (two percent for dietary supplements), and the number of purchases covered by only one percent for both food and dietary supplement manufacturers.

AMS considered other revenue cutoffs, including those above and below \$2,500,000 and considered other definitions from various sources. AMS considered number of employees as a criterion by which to determine the threshold and ultimately determined that we do not need to be bound by that methodology. Because food and dietary supplement manufacturers are in the manufacturing sector, they are both defined by number of employees for purposes of SBA size categorization. However, the firms defined as small or very small for purposes of the NBFDS all fall well below the SBA, so we do not feel we need to be bound by that methodology.

In addition, the small food manufacturer definition was defined to be consistent with the FDA definition of small manufacturer under its nutrition labeling standards, which uses annual receipts. AMS believes that the very small food manufacturer definition should be consistent with these other definitions.

AMS believes that annual receipts is a reasonable measure in determining the threshold for small businesses and specifically here, very small food manufacturers. Using total receipts is administratively simpler than tracking and demonstrating revenue by category for purposes of this rule. We do not expect that there are a significant number of firms for which this distinction

would make a difference, but it would increase recordkeeping burden for all firms that fall under this exemption if it was based on food sales, rather than annual receipts.

The \$2.5 million threshold will provide relief to small businesses but will not markedly decrease the number of products subject to disclosure. By defining “very small food manufacturers” as those with annual receipts below \$2,500,000, about 74 percent of food manufacturers are exempt from mandatory disclosure, but 96 percent of products will still be subject to disclosure. An increase in revenue cutoff would increase the number of exempt businesses but would also increase the number of products exempt from disclosure. The definition of very small food manufacturer provides flexibility for small entities while providing information to consumers regarding the bioengineered status of their foods.

*Comment:* Some commenters expressed concern that exemptions did not extend to small retailers that display food for sale in bulk containers, including made-to-order products. Commenters explained how these products often have significant variation day-to-day depending on the ingredients available, and they can be difficult to trace. Several small entities stated that it is nearly impossible to change the labels on a daily basis, and that they would have to consider whether to continue to carry these items if required to label them under the rule. The Small Business Administration (SBA) Office of Advocacy recommended broadening the definition of “very small food manufacturer” to allow more small businesses an opportunity to take advantage of the exemption. Similarly, they advocated extending the exemption to small retailers to allow small or very small retailers to be exempt from the bulk container labeling requirement.

Another commenter suggested that these revenue limits should extend to dietary supplement manufacturers, and that AMS should consider exempting foods sold by manufacturers to restaurants and similar establishments, and foods marked as “for institutional

use” or “not for resale” because these foods are not consumer-facing and not required to carry consumer-directed information such as nutrition facts. In addition, medical foods, such as enteral foods, provided under a physician’s care should also be exempted from these disclosures.

*AMS response:* With respect to comments urging AMS to extend this exemption to small retailers, AMS states that this exemption is statutorily mandated and cannot be extended to small retailers. To the extent that a small retailer is also a very small food manufacturer, they may be able to take advantage of the exemption in that instance. Additionally, foreign very small food manufacturers shipping prepackaged food products intended for U.S. retail sale are exempt from regulation. Importers are ultimately responsible for verifying whether or not foreign food manufacturers are subject to the requirements of the NBFDS.

AMS acknowledges commenters’ concerns regarding labeling foods sold by manufacturers to restaurants and similar establishments, foods marked as “for institutional use” or “not for resale,” and medical foods. AMS notes that if such foods are subject to the labeling requirements of the FDCA, then they are subject to the NBFDS. Such foods may be exempt if they fall under statutory exemptions, but AMS does not have statutory authority to create exemptions for such foods in this rulemaking.

*d. Food Certified Under the National Organic Program*

AMS proposed that foods certified organic under the National Organic Program shall be exempt from disclosure.

*Comment:* Many commenters that weighed in on the exemption of foods certified under the National Organic Program (NOP) supported the exemption. Many commenters requested that AMS clarify that the NBFDS shall not: affect the definition of “excluded methods” or any other definition or practice under the NOP, circumvent the letter or intent of the organic standard, or

require any amendment to the organic standard, and that organic certification shall be sufficient to claim the absence of bioengineering in the food, such as “not bioengineered,” “not genetically engineered,” “non- GMO,” or another similar claim. A commenter recommended adding language to § 66.3 to state that a food or food ingredient that is not required to bear a BE disclosure does not necessarily mean that the food or food ingredient qualifies for an absence claim such as “non-GMO.” The commenter also suggested that food certified under the NOP may bear an absence claim.

Additionally, other commenters stated that food certified under other international organic product regulations with which the NOP has established either recognition or equivalency agreements would be exempt from this rule. These types of agreement are currently in place with nine countries or regional trading partners, including Canada, Mexico, and the European Union.

*AMS Response:* AMS has ensured that the final rule does not affect the NOP regulation or products certified as organic under the NOP. 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. The NPRM stated that implicit in the statutory provision is that certified organic foods are not subject to bioengineering 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). The NPRM proposed that § 66.5(e) would exempt certified organic foods from bioengineered 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.

The focus of the NBFDS is on establishing a disclosure standard with respect to any bioengineered food and any food that may be bioengineered. Although the amended Act mentions absence claims, the mandate of the NBFDS is not on absence claims. Therefore, AMS has reframed this provision as a statutory exemption and will not incorporate absence claims in the NBFDS. The amended Act's references to absence claims for foods certified under the NOP are self-executing.

AMS agrees with commenters that a technical correction to this provision is required. This exemption is intended to cover all NOP certified label categories ("100% Organic," "Organic," and "Made with Organic"). Accordingly, § 66.5(e) is revised to read "Food certified under the National Organic Program." In addition, AMS confirms that food certified under other international regulations with which the NOP has established recognition or equivalency agreements would be exempt from the NBFDS.

*Comment:* Other commenters requested that the NBFDS also exempt from disclosure foods certified/verified to the AMS Processed Verified Program (PVP); non-GMO certification programs or third-party verification programs such as the Non-GMO Project, NSF True North Protocol, or SGS Non-GMO Certification; and other credible schemes. In addition, commenters suggested that AMS should help consumers distinguish among these many claims and standards.

*AMS Response:* AMS only has authority to exempt food certified under NOP. However, to the extent that these third-party verified programs meet the standards under § 66.9 and/or recordkeeping requirements associated with non-disclosure, then regulated entities employing

these external frameworks may use associated paperwork to show that their products are not BE to the extent the scope of such programs align with that of this rule. As discussed previously, regulated entities seeking to use absence claims should ensure that such claims comply with all applicable Federal laws and are otherwise truthful and not misleading.

*Comment:* Another commenter stresses that the NOP has recognized that ingredients developed with the use of mutagenesis, such as docosahexaenoic acid (DHA) algal oil, may be used as an ingredient in organic foods. Under the NOP, bioengineering is considered an “excluded method” that cannot be used. The NBFDS needs to make clear that mutagenesis is excluded from the definition of bioengineering.

*AMS Response:* AMS agrees that NOP regulations require that no ingredient may be bioengineered. See 7 CFR 205.301(f)(1) and 205.105(e) and the definition of “excluded methods” in 7 CFR 205.2. In addition, AMS agrees that mutagenesis is a conventional breeding method.

#### 8. *Threshold*

The NPRM solicited comments on an array of issues pertaining to the threshold exemption. This proposed exemption consists of three alternative threshold options that would exempt products from disclosure depending on the amount of a bioengineered substance that they contain.

*a. Alternative 1-A: 5 percent of inadvertent or technically unavoidable*

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.

*Comment:* Many commenters generally agreed with Alternative 1-A. These commenters suggested that this threshold offered adequate disclosure, the most flexibility, and limited impacts on the food supply chain. They stated that many parties throughout the food supply chain use the same manufacturing processes and equipment for both BE and non-BE crops, so a 5 percent threshold would allow for the continued coexistence of existing supply chains without significantly increasing costs. They also noted that the standard is a marketing standard and not one based on health and safety.

*AMS Response:* AMS believes that Alternative 1-A provides the right balance between disclosing and minimizing the potential impact on the food supply chain. BE crops and non-BE crops are often grown in close proximity and, depending on the crop, cross-pollination may occur. Similarly, BE and non-BE crops are often harvested and processed using the same equipment, which means trace amounts of BE crops may unintentionally be mixed with non-BE crops. The proximity of bioengineered crops to non-bioengineered crops, and the use of the same production, transportation, and processing equipment allows for the coexistence of different production systems without unnecessarily increasing food production costs. Because the NBFDS is a marketing standard and not related to health or safety, any threshold amount must balance the benefits gained from disclosure with the costs to implement that disclosure. AMS believes Alternative 1-A appropriately identifies that balance.

*Comment:* Some commenters noted that countries such as Canada, Indonesia, and Japan, have incorporated a 5% threshold into their mandatory and voluntary disclosure regimes. The commenters state that it would be prudent to mirror that level to support regulatory certainty in the international food supply chain.

*AMS Response:* AMS acknowledges that some US trading partners have adopted a five percent threshold, either on a mandatory or voluntary basis, and that aligning our threshold amount with those countries will facilitate trade.

*Comment:* Some commenters proposed variations of Alternative 1-A, including hybrid schemes that would adopt Alternative 1-A for the inadvertent and unintentional presence of a bioengineered substance, and then an additional threshold for intentional use of bioengineered substances. These commenters believed such a hybrid method would give food manufacturers flexibility and allow them to intentionally use a de minimis amount of bioengineered ingredients without requiring disclosure.

*AMS Response:* AMS determined that food containing any amount of a bioengineered substance that is not inadvertent or unintentional is subject to disclosure. Therefore, whenever a regulated entity intentionally uses a food or food ingredient that contains a bioengineered substance, no matter the amount, that food would be subject to disclosure, so long as the food is not otherwise exempt. AMS believes that allowing for the intentional use of food and food ingredients that contain a bioengineered substance without requiring disclosure would undermine consumer trust and confidence in the NBFDS.

AMS also believes that any sort of hybrid or dual threshold scheme unnecessarily complicates compliance for regulated entities and increases the likelihood of confusion among consumers. The agency is not aware of customary or usual business records that would allow a regulated entity to accurately track the percentage of a bioengineered substance that is intentionally used in a food, and any such requirement to create new records unnecessarily increases the cost and complexity of complying with the NBFDS. Similarly, a marketing standard should be designed to clearly communicate information to consumers and a hybrid or

dual threshold would unnecessarily complicate the type and amount of information being communicated to consumers.

*Comment:* Some commenters stated that AMS should not measure the threshold by weight, but by other means, such as a percent of rDNA that is present in the food or food ingredient. They suggested that this approach is more consistent with the BE labeling regimes of other countries and existing industry standards.

*AMS Response:* AMS agrees that the phrase “by weight” should be removed from the threshold exemption. AMS understands that existing industry standards and the BE labeling requirements of other countries do not use weight to calculate the threshold, but typically calculate such threshold amounts as the BE content of an item or ingredient relative to the non-BE content of that same item or ingredient. AMS believes existing industry standards are sufficient.

*Comment:* A number of commenters suggested that AMS should adopt Alternative 1-A because the NOP allows for up to 5 percent of products that are not certified organic to be used in organic products.

*AMS Response:* While we recognize that the NOP regulations at 7 CFR 205.301(b) suggest that products labeled as organic may contain 5 percent of ingredients that are not organic, that would be an incomplete understanding of that regulation. That regulation also states that this 5 percent must be organic unless the organic form is not commercially available and must be nonagricultural substances or non-organically produced agricultural products produced consistent with the National List in 7 CFR part 205, subpart G. The NOP regulations further require that this 5 percent not be bioengineered. *See* 7 CFR 205.301(f)(1) and the

definition of “excluded methods” in 7 CFR 205.2. Thus, the NOP regulations are not an analogous situation that would be a rationale for adopting a 5 percent threshold.

*b. Alternative 1-B: 0.9 percent inadvertent or technically unavoidable*

*Comment:* Many commenters, including consumers, consumer groups, food manufacturers, and some industry trade groups were generally in favor of Alternative 1-B. Commenters noted that this threshold most closely aligns with consumer expectations, the threshold used by many trading partners, and existing domestic standards currently in use for voluntary BE and non-BE labeling programs. Additionally, a commenter stated that farmers, testing organizations, and food manufacturers have used 0.9% as the maximum threshold since 2003. The commenters argued that adopting the 0.9 % threshold would avoid confusion into the marketplace and would ease the process of negotiating and executing mutual recognition agreements which would help stimulate trade between countries.

*AMS Response:* AMS recognizes that uniformity and consistency promote efficiency and lessen confusion. We note, however, that there is not one consistent threshold used for all foods and inputs domestically or by all trading partners. When determining whether the absence or presence of a bioengineered food or substance requires disclosure, domestic voluntary standards and/or foreign governments use thresholds greater than 0.9%, including 5%, under specified circumstances. AMS, however, must balance the costs and benefits for regulated entities and consumers in the United States when establishing thresholds for the NBFDS. A threshold substantially lower than 5% per ingredient may not be practical or achievable in production systems across a range of commodity groups. Furthermore, the requirements to attempt to meet a 0.9% threshold would be overly burdensome in proportion to the goal of providing consumers with a suitable amount of information on the presence of bioengineered substances in food

products. AMS believes a threshold of 5% per ingredient does the best job in balancing the costs and benefits for regulated entities and consumers in the United States.

*Comment:* Consumer transparency is another reason commenters give for supporting Alternative 1-B. They suggest that the relatively wide use of Alternative 1-B internationally and domestically promotes consumer transparency, and that adopting Alternative 1-B would ensure that the greatest number of products are subject to disclosure while still allowing for co-existence of BE and non-BE foods. A food manufacturer states that consumers recognize the potential for inadvertent and technologically unavoidable commingling of BE substances and accept standards in use today that allow for the presence of a BE substance up to the 0.9% level, including companies that voluntarily disclose and voluntary standards established by third-party organizations for non-BE labels. Some commenters suggested that any higher threshold amount would negate the purpose of labeling and not match consumer expectations for transparency. Commenters also said that Alternative 1-B would promote good practices by companies because they would be able to segregate ingredient streams, while still allowing for some inadvertent or unavoidable introduction of BE material.

*AMS Response:* AMS understands that a lower threshold would likely result in a larger number of products being subject to disclosure. AMS also understands that if a threshold is set too low, regulated entities may have to label almost everything and the information may become less meaningful to consumers. Ensuring each ingredient stream remains below the threshold of 0.9% may not always be practical or achievable for all commodity groups, or the processes and equipment required to do so may increase food production costs. AMS believes a threshold of 5% per ingredient provides the best balance between reducing costs for regulated entities and maximizing information conveyed to consumers.

*Comment:* Several comments propose hybrid alternatives. A few commenters suggested combining the requirements of Alternative 1-A allowing for the inadvertent or technically unavoidable presence of a BE substance up to 5% in any ingredient with the requirements of Alternative 1-C to also allow for the intentional use of a bioengineered substance up to 0.9% in the finished product by weight. Another commenter suggested allowing a product to contain up to 0.9% total ingredients that had not been tested for BE substances, and requiring each such ingredient to comprise no more than 0.5% of the finished weight of the product, minus added water and salt. Other commenters were opposed to a hybrid approach. They argue that this would be more confusing and difficult to explain to consumers and would suggest a lack of transparency.

*AMS Response:* AMS understands the desire for flexibility that a hybrid approach might create. However, AMS believes the threshold is intended to recognize the complexities of the supply chain, not necessarily create a mechanism to avoid BE food disclosure. A simple, straightforward threshold that allows for the unintentional or technically unavoidable presence of a BE substance acknowledges the complexities of the supply chain while increasing transparency. A hybrid or dual threshold scheme would add an unnecessary degree of complexity that would confuse to consumers and increase the administrative burden on regulated entities. The additional sampling, testing, and recordkeeping requirements of a multi-pronged threshold scheme would likely go beyond the customary business records currently kept by regulated entities and AMS does not intend to unnecessarily increase the administrative burden of the rule on regulated entities.

*Comment:* A small number of commenters in response to Alternatives 1-A and 1-B suggested making two minor changes to clarify how the threshold would be applied and how it

would be calculated. The first recommendation was to change “an” to “any” to clarify that the threshold applied to all ingredients. The second recommendation was to remove “by weight” because some methods of testing for threshold amounts do not calculate by weight, but rather as a percent of DNA.

*AMS Response:* AMS has changed the language used to define the threshold to make it clear that it applies to all ingredients. AMS also removed the reference to “by weight” to clarify that existing industry standards for determining the amount of a BE substance that is present in a food or food ingredient would be appropriate for purposes of applying the threshold exemption.

*Comment:* A number of comments supported Alternative 1-B but called on AMS to establish very specific testing requirements to guarantee manufacturers applied 0.9% thresholds meaningfully. They state that the testing should be conducted using the real-time or digital polymerase chain reaction (PCR) method conducted by an ISO 17025 accredited laboratory, conducted on samples where laboratory controls indicate the DNA input is sufficiently intact to allow for valid quantitative analysis, and follow a meaningful sampling plan in accordance with industry standards. Regulated entities would be required to adhere to these testing standards.

A commenter who was a food manufacturer stated that many food manufacturers do not test food products for BE substances. They rely instead on certifications of food ingredients from suppliers. The commenter stated that food importers in Europe are not required to test imported products. They stated that checking certifications from suppliers in place of testing was reasonable because suppliers are more familiar with ingredients, they already test their products, and there is no requirement that food manufacturers conduct further testing.

*AMS Response:* AMS understands the desire for uniform application of the threshold and a regimented approach to ensure that regulated entities are complying with all aspects of the

NBFDS, including the threshold. However, AMS is aware that strict requirements on methodologies, processes, testing, and recordkeeping all increase the cost of compliance with the NBFDS. Because this is a marketing standard that provides additional food information to consumers, there is little benefit to highly prescriptive testing and recordkeeping requirements. AMS has the authority to enforce compliance with the NBFDS and believes the best way to ensure compliance is through the enforcement process described in the final rule, not through strict, burdensome regulations.

*Comment:* Those opposed to Alternative 1-B suggested that this alternative is overly restrictive, especially for a marketing standard. A few noted that Alternative 1-B would lead to over-disclosure because some companies would likely consider any commingled food as BE food. They said this could discourage consumers from purchasing products with BE labels. Others suggested that a 0.9% threshold would denigrate biotechnology and reduce choices for both farmers and consumers. Similarly, some commenters state that they believe Alternative 1-B treated BE substance as a contaminant. A few commenters believe that any threshold below 5% is not practical or achievable for many commodities. They state that traceability requirements would be overly burdensome in relation to the benefits derived from providing additional information to consumers. They believe that this would result in technology avoidance and a stifling of innovation. A few comments suggested that recordkeeping burdens would be costly at a 0.9% threshold because regulated entities would have to account for traces of BE substance down to a very small degree throughout the entire supply chain. Although food manufacturers keep records now, these commenters believe such records are usually on a finished product basis and not by ingredient.

*AMS Response:* AMS understands the concerns raised by these comments. AMS is aware that setting a threshold too low may have practical limitations on the supply chain and could increase costs as entities throughout the supply chain implement additional measures to maintain a lower threshold on the food and ingredients they produce. While AMS understands that some supply chains and some countries currently produce food and ingredients that contain a BE substance below 0.9 percent, AMS does not want to unnecessarily increase the regulatory burden and costs on supply chains that may not currently be meeting that threshold. Moreover, those who are currently meeting the threshold for 0.9 would still be in compliance with Alternative 1-A, because ingredients that contain an inadvertent or technically unavoidable BE substance below 0.9 percent are still below the 5 percent threshold in Alternative 1-A.

*Comment:* A few comments questioned how AMS would interpret Alternatives 1-A and 1-B with respect to what is inadvertent or technically unavoidable, and whether such a definition would require any intentional use of a BE substance to be disclosed.

*AMS Response:* AMS has clarified in the final rule that any intentional use of a BE substance requires disclosure.

*c. Alternative 1-C: 5 percent of intentional use*

One of the exemptions from food labeling proposed by AMS was Alternative 1-C. Alternative 1-C would exempt food from disclosure if the ingredient or ingredients in the food containing a BE substance accounted for no more than five percent (5%) of the total weight of the food in final form. AMS also sought comments on whether the specific threshold amount of 5% should be increased or decreased.

*Comment:* Comments in favor of Alternative 1-C suggest that this approach would allow for the de minimis use of BE food ingredients without requiring disclosure. They also indicate

that this approach would align with that used in some other countries. Supporters of this alternative also suggest that this approach is the most supportive of bioengineering. Some commenters also believe this alternative would have the least impact on domestic and international value chains and international trade. Similarly, they suggest this would also be the option most compatible with our North American trading partners, Mexico and Canada, neither of which mandate labeling.

*AMS Response:* AMS understands that for some commenters, Alternative 1-C would increase the amount of flexibility under the standard and allow for the de minimis use of a BE substance without requiring disclosure. Although Alternative 1-C could be used in other countries, AMS is aware that there is no universal threshold level and that any choice of threshold will have implications on trade. While some have suggested that Alternative 1-C could cost less to implement because fewer products are labeled, AMS believes that current industry practices track the presence of absence of BE substances in an ingredient and not necessarily the specific amount. Adding the requirement to track the amount of a BE substance in each ingredient, and subsequently the final product, could unnecessarily increase costs for regulated entities, even though the number of products subject to disclosure may ultimately be less.

*Comment:* Some commenters suggested that Alternative 1-C would reduce consumer confusion.

*AMS Response:* AMS does not agree with those suggesting that a 5% threshold as proposed in Alternative 1-C would reduce consumer confusion. AMS believes it will lead to the exemption of a wider array of foods from labeling and cause consumers to have less confidence and trust in the NBFDS. AMS believes that providing more information and not creating an

exemption for the intentional use of a BE substance is likely to provide more BE food information to consumers.

*Comment:* Several commenters suggested Alternative 1-C but with an amount lower than 5 percent—such as 0.9 percent. One commenter said that such an approach would exempt most fermentation/probiotic, viable enzymes, and defining/characterizing ingredients.

*AMS Response:* A threshold substantially lower than 5% per ingredient may not be practical or achievable in production systems across a range of commodity groups. Furthermore, the traceability requirements to attempt to meet a 0.9% threshold would be overly burdensome in proportion to the goal of providing consumers with a suitable amount of information on the presence of bioengineered substances in food products. AMS believes a threshold of 5% per ingredient does the best job in balancing the costs and benefits for regulated entities and consumers in the United States. AMS is allowing regulated entities to voluntarily disclose (§ 66.116) the presence of bioengineered substances even when not otherwise required to do so. This will help regulated entities to meet demands on their food products to conform to standards used in other programs. AMS will also work to develop mutual recognition arrangements so that countries might agree to recognize each other's standards as comparable.

AMS understands that some food products may include only a very small amount of a BE substance, such as enzymes or other products created in a controlled environment. Similarly, if there are other products that people believe should be exempted from disclosure, AMS has established a process to exclude them under factors and conditions. For reasons stated above, AMS believes that Alternative 1-A is the appropriate threshold and that any intentional use of a bioengineered substance should be disclosed.

*Comment:* One commenter supports the 5% threshold, but believes it should be measured using the percent based on volume of the BE substance in the ingredient, rather than ingredient weight. They state that other countries quantify the threshold by the volume of BE substance present in ingredients. They assert that a BE threshold defined by weight is not enforceable.

*AMS Response:* AMS has determined Alternative 1-A is the best approach, but has removed the phrase “by weight” from the regulatory text reflecting that option.

*Comment:* A majority of comments received regarding Alternative 1-C are opposed to this alternative. Many believe that this alternative is not transparent enough and that it would exempt wide amounts of food items from labeling. They suggest this would undermine consumer expectations, and possibly damage consumer confidence and trust in the labeling program. Commenters expressed the opinion that consumers wanting to avoid BE substances would not support Alternative 1-C because they would believe it was not low enough to be meaningful. A number of comments suggested that Alternative 1-C subverted the amended Act by allowing the intentional use of a BE substance into food products without requiring labeling.

Another large group of comments state that the 5% threshold amount will result in the rejection of our exports by countries with lower threshold amounts, damaging our ability to trade food products in foreign markets. A food exporter expressed concern with the lack of conformity between Alternative 1-C and disclosure requirements in other countries. The exporter said that this lack of conformity would add complexity to their efforts to export their products because they would have to make disclosure adjustments for each country with differing disclosure laws.

*AMS Response:* AMS understands the concerns raised by Alternative 1-C, AMS has not chosen this alternative. AMS will not allow an exemption from labeling when a regulated entity intentionally introduces a bioengineered substance into a food product.

AMS believes that exporters are already complying with the laws of the countries into which they import their products and to the degree possible, AMS has tried to minimize any potential impacts on international trade. If other countries have a BE labeling program, AMS is also working to develop mutual recognition agreements where the requirements of countries with similar labeling requirements may be recognized in the United States.

*Comment:* A commenter stated that the EU uses “accidental” and “technologically unavoidable” instead of inadvertent and technically unavoidable. The exporter states that the EU defines accidental to include BE adulteration occurring during cultivation, transportation, or processing. AMS interprets inadvertent or technologically unavoidable as “insignificant amounts of a BE substance in food that resulted from the coexistence of BE and non-BE foods in the supply chain” [83 FR 19869]. This commenter presses AMS to interpret inadvertent in a manner identical to EU’s “accidental,” or in a way that was consistent with the EU definition for “accidental.”

*AMS Response:* AMS is not in a position to interpret how the EU implements their BE labeling law, but does intend to interpret AMS regulations in a manner that minimizes the impact on international trade.

*Comment:* Several commenters questioned how AMS will treat ingredients that are not considered bioengineered foods, such as incidental additives, for purposes of determining whether a food is exempt from labeling under the threshold.

*AMS Response:* If an ingredient is not considered a bioengineered food under another section of the NBFDS, such as an incidental additive, a regulated entity does not need to apply the threshold exemption to that ingredient to determine whether a food is disclosed as BE. If an ingredient is otherwise not a bioengineered food, it will not trigger labeling due to the presence of a bioengineered substance.

*Comment:* A commenter suggested that for Alternative 1-A and 1-B, any intentional use of a BE substance would require labeling even if the threshold limit is not exceeded. They then pointed out that to avoid this, food manufacturers would have to establish records to show that any BE substance in the food came only from inadvertent and technically unavoidable sources. This may require the manufacturer to keep additional records than those currently generated.

*AMS Response:* AMS intends to require only customary business records. For purposes of ensuring compliance with the threshold, AMS will look to the records to determine whether a regulated entity intended to purchase non-BE ingredients and the documentation they have from their suppliers indicating as much.

*Comment:* A commenter suggested that AMS should not require the exclusion of water and salt from the threshold calculation. This commenter stated that the finished product should be in the same form as it would be when presented to the consumer and excluding the weight of the water and salt from the calculation of the amount of BE would add complexity. The manufacturers would have to adjust their calculations to account for only the amount of a BE substance in the dry ingredients in the absence of water or salt.

*AMS Response:* AMS did not choose Alternative 1-C and this comment is inapplicable to Alternative 1-A. Water and salt do not contain DNA and would therefore, as individual ingredients under Alternative 1-A, never trigger disclosure.

*Comment:* A few commenters stressed that testing for BE content should not be a requirement. They emphasized the use of proper documentation, supplier assurances, along with existing controls should suffice. One commenter stated that in some cases statistical and qualitative tests could be used to obtain qualitative results and provide adequate verification of BE content. The commenters suggest that testing, such as PCR testing, would drive up costs significantly, decrease efficiencies in the handling and distribution systems, introduce new market risks, and disrupt global trade.

*AMS Response:* AMS does not intend to prescribe specific tests or methodologies for verifying compliance with the threshold. AMS intends to rely on customary business records.

#### *9. Appearance and placement of disclosure*

The NPRM solicited comments on the size, legibility, appearance, and location under ordinary shopping conditions for the BE food disclosure. The NPRM also solicited comments on the placement of the BE disclosure. AMS received several comments on those topics.

*Comment:* Many commenters supported the NPRM goal of ensuring that the BE food disclosure was likely to be read and understood under ordinary shopping conditions. Commenters suggested that the disclosure be concise, large enough to read, easily located, and intelligible. One commenter recommended the BE food disclosure size be consistent with FDA regulations at 21 CFR 101.2(c) governing “customary conditions of purchase.”

*AMS Response:* AMS agrees that the BE food disclosure should appear prominently and conspicuously on the label, such that it can be read and understood under ordinary shopping conditions. This position aligns with other mandatory food labeling requirements, including the FDA regulations at 21 CFR 101.15.

*Comment:* Several commenters felt that the term BE was misleading and confusing to consumers. Commenters suggested that a disclosure using GMO would be simple, clear and suffice.

*AMS Response:* AMS understands and appreciates commenters request for clear, understandable disclosure language that references a familiar term like “genetically modified organism.” However, the amended Act clearly sets forth use of the term bioengineering. AMS acknowledges that the amended Act authorizes the Secretary to determine other terms that are similar to “bioengineering.” 7 U.S.C. 1639(1). But, for purposes of ensuring disclosure consistency and minimizing marketplace confusion, AMS has chosen not to adopt other similar terms and to require the use of the term “bioengineered.” AMS will engage in outreach and education to provide information about the new disclosure term.

*Comment:* Some commenters recommended AMS implement strong guidelines for the type size used for the BE disclosure. One commenter recommended that size requirements be defined with a minimum letter height and logo size. Another commenter requested that AMS provide uniform requirements for the disclosure location and size. Others suggested that the disclosure be similar in size of the product/brand name or at least 75 percent of the font size.

Several commenters requested flexibility in determining the disclosure’s size and placement. One stated that AMS should give regulated entities flexibility in selecting the size and placement options that provide the best proportions for displaying the disclosure while also complying with the requirement for maintaining high visibility. Commenters also proposed if AMS specifies a disclosure size that it should range from 0.5-1 inch in diameter.

*AMS Response:* AMS acknowledges that font and type size contribute significantly to the consumers’ ability to access information provided on food labels. As such, AMS considered

prescribing specific type sizes for different disclosure options. After considering comments, however, AMS 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. Therefore, AMS is allowing regulated entities responsible for the disclosure to have flexibility in implementing the disclosure requirements. The NBFDS requires that disclosure text “...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.”

*Comment:* Most commenters supported AMS’s proposal for placement of the BE disclosure. One commenter recommended that the disclosure had to be placed on the information panel if room allowed. The commenter recommended that the disclosure needed to be consistent, and not at the discretion of the manufacturer.

*AMS Response:* AMS acknowledges commenters’ support for the NPRM’s proposed placement of the BE disclosure. AMS also agrees that the information panel is an appropriate location for the BE disclosure because consumers who are interested in additional information on food products will generally look for it on the information panel. Section III.A.4 of this rule provides a more detailed rationale regarding AMS’s position on placement of the BE disclosure.

*Comment:* One commenter recommended that manufacturers be given greater flexibility in determining the disclosure placement and size. Another commenter also stated that there should be the option of placement and size of disclosure on the package. One commenter recommended that the disclosure be placed on any of the panels of the food package provided the disclosure is displayed prominently on the label and does not interfere with mandatory nutrition labeling requirements.

*AMS Response:* AMS agrees that manufacturers may need some flexibility when determining the size and placement of a BE disclosure. Based on its review of comments, AMS will allow manufacturers to include the disclosure on an alternate panel likely to be seen by a consumer under ordinary shopping conditions if there is insufficient space on either the principal display or information panels. Similarly, the NBFDS allows flexibility in the disclosure size. For a detailed explanation of AMS's position regarding the appearance and placement of the BE disclosure, refer to Section III.A.3 and Section III.A.4 of this rule, respectively.

#### *10. Text Disclosure*

AMS solicited comments on adoption of the text disclosures: "Bioengineered Food," "Contains Bioengineered Food Ingredients," "May Contain Bioengineered Food Ingredients," and "May Be Bioengineered."

*Comment:* Several commenters believe the phrases "may contain a bioengineered food ingredient" and "may be a bioengineered food" would lead to more confusion for consumers who want to know the exact nature of the ingredients being consumed by their families. Some comments noted that many of the countries with mandatory disclosure requirements do not allow the use of a "may" statement. Some commenters stated that a "may" claim should be permissible to describe foods that contain ingredients where the sourcing may change from a bioengineered to a non-bioengineered source. Other comments suggested that regulated entities know and have records to demonstrate the bioengineered status of their foods and should not be permitted to use "may" claims when they know with certainty that their foods are bioengineered.

Commenters suggested that a symbol, such as an asterisk, could be used to denote an ingredient that was BE. Commenters also suggested that the disclosure statement should provide a declarative statement designating the BE information.

*AMS Response:* AMS appreciates commenters' desire for USDA to implement clear standards for disclosing bioengineered food products using on-package text. We recognize that consumers want additional information about the food they eat and may see the use of the word "may" in the text disclosure as ambiguous. As a result, AMS has removed the "may" disclosure option and will only allow regulated entities to make affirmative BE food disclosures.

*Comment:* Commenters requested straightforward labeling that would not confuse consumers by using unfamiliar terms. Many commenters suggested allowing or mandating other phrases such as "genetically modified organism," "GMO" or "genetic engineering." Another commenter suggested using the phrase "includes" rather than "contains." Some commenters also requested clarification regarding whether regulated entities could provide additional statements regarding bioengineered foods as part of their disclosures.

*AMS Response:* AMS understands and appreciates the desire for clear, straightforward text disclosure language. The Secretary believes that the language used by Congress in the amended Act clearly and accurately describes the technology and provides consumers with the information they desire. AMS will engage in outreach and education to provide information about the new disclosure term. AMS also notes that, pursuant to § 66.118, nothing in the final rule prohibits regulated entities from providing additional statements or other claims regarding bioengineered foods and bioengineered food ingredients, so long as such statements are consistent with all other applicable laws and regulations.

*Comment:* Some commenters expressed concern about the disclosure options for foods contained on the proposed non-high adoption list of bioengineered foods. One commenter was concerned about the possibility that manufacturers could use loopholes to avoid having to say a food is bioengineered.

*AMS Response:* AMS acknowledges the concerns and notes that, as part of the NBFDS, AMS has developed a List of Bioengineered Foods for human consumption that may be produced anywhere in the world. This list establishes a presumption about what foods might require disclosure under the NBFDS, but does not absolve regulated entities from the requirement to disclose the bioengineered status of food and food ingredients produced with foods not on the list when the regulated entities have actual knowledge that such foods or food ingredients are bioengineered.

AMS also appreciates the concerns about regulated entities complying with the disclosure requirements. As such, subpart E of this rule outlines the enforcement regulations established to ensure compliance with the regulations.

*Comment:* Many commenters requested the use of the phrase “bioengineered ingredients used in this product,” regardless of the amount of bioengineered foods or ingredients contained in the product. Similarly, other commenters stated where trace amounts of bioengineered ingredients are identified, the entire food product should be labeled “contains BE ingredients.”

*AMS Response:* The amended Act directs the Secretary to determine the amount of a bioengineered substance that may be present in a food, as appropriate, in order for the food to be a bioengineered food. Requiring a label for food that includes a bioengineered substance that falls below this amount would contravene Congress’s intent.

## *11. Symbol Disclosure*

AMS solicited comments on three alternatives for disclosure symbols, each in full color and black and white. All three include some variation of the letters BE, short for “bioengineered.” AMS also sought comment on whether the symbol should include the word “bioengineered.”

*Comment:* Some comments suggested that none of the three symbols were acceptable. Many of these commenters suggested that the alternatives AMS provided promoted bioengineering or provided the BE food disclosure in a misleading or confusing manner. Some comments provided alternative symbols and others suggested general ideas that AMS should incorporate, such as more neutral colors or images.

*AMS Response:* AMS appreciates the comments and alternative symbol designs. AMS has chosen a modified version of Alternative 2-A. The modified version removed the letters “BE” and instead uses the word “Bioengineered,” which AMS believes will better inform consumers than just the letters “BE.” AMS believes the modified symbol is an appropriate, non-disparaging way to communicate the information required by the amended Act.

*Comment:* Some commenters believed adding the word “bioengineered” to the symbol was unnecessary and that other symbols used on food (e.g. the organic seal, irradiation symbol, and recycling symbol) do not use additional text to convey meaning. Other commenters, including some who conducted research on consumer response to the proposed symbols and text options, said the proposed symbols and text options did not provide clear information to consumers. Conversely, other commenters who also conducted research on consumer response to the proposed symbols and text options, believed adding the word “bioengineered” would provide consumers with more information than a symbol with the acronym “BE.”

*AMS Response:* AMS has chosen to add the word “bioengineered” to the symbol and believes that the combination of the symbol with the additional text will provide consumers with more information about their food. AMS understands that because the symbol has not yet been used in commerce, consumers and those who may have responded to surveys conducted during the comment period that examined the proposed disclosure options may not fully understand the

meaning of the symbol and accompanying text. As the NBFDS is implemented, AMS is committed to helping consumers understand the meaning of the new symbol and accompanying text.

*Comment:* Of those in favor of the proposed symbols, most favored Alternative 2-A. Commenters indicated that Alternative 2-A was the “best choice of the three provided.” They found it to be the “most simple,” “most professional,” and “most neutral” of the three proposed.

*AMS Response:* AMS agrees that Alternative 2-A is the most appropriate choice of the three proposed alternatives and has modified Alternative 2-A in the NPRM to address some of the concerns raised by other commenters, as described above.

*Comment:* Most commenters did not support the use of Alternatives 2-B or 2-C. Commenters believed the symbols and colors were misleading, not neutral, and that they resembled a smiley face. Conversely, several commenters liked the symbol because they believed they were the “friendliest” or “happy” option.

*AMS Response:* AMS appreciates commenters’ concerns regarding the use of Alternatives 2-B or 2-C. Based on comments received for all three alternatives and commenter sponsored studies on consumer perceptions of labeling (see footnotes 7 and 8), AMS has chosen a modified version of Alternative 2-A, as discussed above.

## *12. Electronic or Digital Link Disclosure*

AMS solicited comments on the option of an electronic or digital link disclosure including the use of current technology such as QR codes and digital watermark technology. In addition to the use of electronic or digital link technology, AMS solicited comments on language that must accompany the electronic or digital link such as, “Scan here for more food information” or equivalent language that reflects technological changes. The proposal would

also incorporate a requirement to include a telephone number that provides access to the BE food disclosure and would further require that 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 and state “Call for more food information.”

*Comment:* The majority of commenters did not support the use of electronic or digital link disclosure in lieu of on-package labeling. Many commenters cited the USDA study conducted by Deloitte Consulting LLP, *Study of Electronic or Digital Link Disclosure: A Third-Party Evaluation of Challenges Impacting Access to Bioengineered Food Disclosure* (July 2017), and listed concerns with electronic or digital link disclosures. Such commenters stated that reliance on electronic or digital link disclosure would discriminate against those without access to smartphones or other technology, such as reliable high-speed internet access, and would disproportionately have a negative impact on rural, low-income, minority, and elderly consumers. Commenters stated that many consumers are not aware of QR codes or how they work. Many of these commenters also stated that electronic or digital link disclosure should not replace on-package disclosure because even when consumers are aware of QR codes and attempt to access the information through their smartphones, the QR codes do not always work and are not easy for all consumers to use. Some of these commenters also stated that consumers associated digital link disclosures like QR codes with marketing, and would not be inclined to take steps to access the disclosure information. Most of these commenters stated that electronic or digital link disclosure would serve as a barrier between consumers and BE disclosure. Such barriers identified by commenters included additional costs for consumers, such as through increased data plans, and time spent scanning and obtaining information. Some commenters

noted that consumers with families or limited windows of time for shopping would find accessing electronic or digital link disclosures difficult and frustrating.

*AMS Response:* AMS acknowledges that most commenters do not support the use of electronic or digital link disclosure. However, AMS notes that electronic or digital link disclosure is mandated by the amended Act. AMS also notes that if a regulated entity decides to utilize electronic or digital link technology to convey bioengineered food information, that entity must also provide options for the consumer to access the disclosure by calling a phone number. AMS believes that requiring the option to call a telephone number will provide BE food information in an accessible and understandable manner. AMS also notes that such telephone number disclosure must be available regardless of the time of day.

*Comment:* Several commenters suggested that the use of electronic or digital disclosures would be acceptable only in conjunction with on-package text or symbol disclosures. Such commenters stated that on-package labeling provided shoppers a way to quickly and easily compare one product to another for BE ingredients and, at the same time, compare prices and nutritional content. These commenters identified many of the same issues as commenters opposed to electronic or digital disclosures. Some of these commenters noted that a store could install its own scanners to allow consumers to access electronic or digital link disclosures, but a subset of such commenters stated that such scanners would need to be installed within easy access to all shelves throughout the store, and not just near check-out counters, in order to be comparable to on-package labeling.

*AMS Response:* AMS notes that the amended Act mandates the electronic or digital link disclosure without requiring any separate on-package disclosure. AMS acknowledges that in-store scanners could allow consumers to access electronic or digital link disclosures. However,

AMS does not believe such a requirement is necessary because any electronic or digital link disclosure must also provide options for the consumer to access the disclosure by calling a phone number.

*Comment:* Many commenters stated that if digital disclosure is allowed, the rule should account for new developments in technology that would be subject to guidelines to improve readability and ease of access to information. Some commenters stated that AMS should adopt rules to make sure that such disclosures made using electronic or digital technology consistently scan every time, work in all conditions, are optimized for readability and accessibility, and are easily accessible for consumers who do not have smartphones. In addition, commenters stated the need for AMS to ensure that QR code design, packaging material and shape is included in its performance standards. Commenters also stated that AMS should not allow multiple QR codes on the same package to diminish the risk that consumers will not know where to obtain the BE disclosure. Some commenters stated that AMS should use language that alerts the consumers that scanning the QR code or calling the provided number would provide BE information. Other commenters stated that if digital disclosure is allowed, the rule should account for new developments in technology that would be subject to guidelines to improve readability and ease of access to information. They also stated that AMS should use URLs or shortened URLs rather than QR codes as a disclosure method.

*AMS Response:* AMS recognizes that electronic and digital links currently used on food products in the marketplace take different forms, and are accessible on different devices, which would make certain specific requirements impractical. The amended Act allows for equivalent statements that reflect technological changes. Consequently, AMS has allowed for other alternative statements to direct consumers to the link to the BE food disclosure. Examples of

other statements include: “Scan anywhere on package for more food information,” or “Scan icon for more food information.” AMS acknowledges that some consumers may experience difficulty accessing electronic or digital link disclosures. However, AMS does not believe additional rules mandating standards for QR codes are necessary because any electronic or digital link disclosure must also provide options for the consumer to access the disclosure by calling a phone number. Therefore, consumers experiencing difficulty with any electronic or digital link disclosure methods will have an alternative disclosure method available. AMS notes that the language to accompany any electronic or digital link disclosure is provided in the amended Act, which only allows for changes to the terminology based on technology, not a specific reference to bioengineering. AMS notes that while the amended Act does not allow for the use of URLs or shortened URLs for all manufacturers, website disclosure is allowed for small food manufacturers.

*Comment:* Many commenters urged that any electronic or digital link disclosure must remain free from any promotional or marketing information on the first product information page, or “landing page,” to which consumers are directed. These commenters urged that such disclosure must contain only BE information, as many of these commenters were concerned that QR codes would direct consumers to marketing information before bioengineering disclosure information. Some commenters disagreed with AMS’s proposal requiring that the electronic or digital link disclosure provide the bioengineering disclosure on the first product information page.

*AMS Response:* Based on the amended Act, AMS believes that the electronic or digital link disclosure requires that the bioengineering disclosure be on the first product information

page. *See* 7 U.S.C. 1639b(d)(2). AMS does not believe that consumers should have to navigate to other pages to locate the bioengineering disclosure.

AMS agrees that any electronic or digital link disclosure should remain distinct from any promotional or marketing information. While AMS acknowledges that some commenters have urged maximum flexibility in allowing disclosures alongside other information, AMS notes that 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 and promotional information. Therefore, if a regulated entity wants to provide additional information about BE food to consumers, the information should be provided outside of the landing page that includes the BE food disclosure.

*Comment:* Some commenters were concerned about the potential liability digital disclosure options could present if they were accessed by unauthorized individuals, such as hackers.

*AMS Response:* AMS agrees that unauthorized access to personal information is a grave concern to many consumers. AMS notes that the amended Act specifically states that any electronic or digital link disclosure may not collect, analyze, or sell any personally identifiable information about consumers or the devices of consumers and, to the extent that any such information must be collected for the purposes of disclosure, that information must be deleted immediately and not used for any other purpose.

*Comment:* Many commenters supporting the use of electronic or digital link disclosure also cited the Deloitte study, noting that a vast and growing majority of Americans own smart phones capable of accessing digital disclosures and that wireless internet access is nearly universal in retail establishments. However, several commenters who support the use of

electronic or digital link disclosure objected to the proposed requirement for an additional phone number and call to action statement (“Call for more food information”) in conjunction with the digital disclosure link and digital call to action statement (“Scan here for more food information”). Some commenters stated that such a requirement will be costly to implement and is unnecessary when the regulated entity chooses the digital disclosure option. From their perspective, because existing toll-free numbers already appear on many labels, the package will also bear a link to the digital disclosure, and consumers will have sufficient and growing access to digital disclosure methods. Some of these commenters suggested that when regulated entities choose the digital disclosure option, consumers could access bioengineered food disclosure information through existing phone numbers, with the same placement and call to action to which consumers are accustomed. Commenters stated that by not allowing such flexibility, consumers could face two competing phone numbers on a single package, which would cause confusion. In addition, commenters stated the proposed requirement that phone lines be staffed at all hours would be extremely costly to implement. These commenters request that AMS consider less costly alternatives, such as allowing existing consumer support phone lines to also provide disclosure and specify in the final regulation that phone lines must be available only during normal business hours.

*AMS Response:* AMS acknowledges that a large number of Americans have smartphones and most national and regional supermarkets provide wireless internet connections. However, as discussed in relation to the study identifying potential technology challenges impacting consumers, the Secretary has determined that many consumers do not have sufficient access to electronic or digital link disclosures under ordinary shopping conditions at this time. AMS notes that the amended Act requires that any electronic or digital link disclosure also includes a

telephone number that provides access to the bioengineering disclosure. While AMS acknowledges that a product may bear more than one phone number, AMS believes that any consumer confusion would be minimized because the bioengineering disclosure phone number must be in close proximity to the digital link. AMS believes that access to the disclosure regardless of the time of day is important to provide meaningful disclosure to consumers. AMS further believes that allowing pre-recorded information for such a disclosure lessens any burden on regulated entities.

### *13. Study on Electronic Disclosure*

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 to solicit comment on the study. AMS contracted with Deloitte Consulting LLP (Deloitte) to conduct the study and posted the resulting report, *Study of Electronic or Digital Link Disclosure: A Third-Party Evaluation of Challenges Impacting Access to Bioengineered Food Disclosure*, on its website in September 2017. As part of the NPRM, AMS sought comments on the study, as well as the proposed text message disclosure option, should the Secretary determine, after reviewing the study and comments, that consumers would not have sufficient access to the bioengineering disclosure through electronic or digital disclosure methods.

*Comment:* Many commenters cited the study in opposition to electronic or digital link disclosure, with several citing the study's finding that consumers may not have smartphones or access to internet speeds capable of downloading BE disclosure content. These commenters stated that this lack of access would disproportionately impact groups such as rural consumers and retailers. Commenters also cited the study's finding that consumers either do not know what

digital links are or, if they do recognize them, they typically associate digital links with marketing information and they may not know, or be inclined to use, such methods to obtain a BE disclosure. Commenters further cited the study to note that even when consumers are aware of digital links and attempt to use them, they often run into problems scanning and using such links.

*AMS Response:* AMS acknowledges that some consumers may lack access to technology required to utilize electronic or digital link disclosure. In fact, after reviewing the study and comments submitted to the NPRM related to the study, the Secretary has determined that consumers would not have sufficient access to the bioengineering disclosure through only electronic or digital means under ordinary shopping conditions at this time. Thus, AMS, in compliance with the amended Act, is adopting a text message disclosure option. *See* 7 U.S.C. 1639b(c)(4). The amended Act does not, however, vest AMS with authority to eliminate the electronic or digital disclosure option. *See id.* The amended Act is clear that it is the food manufacturer that selects the disclosure option that it wants to use to make the required disclosure. *See* 7 U.S.C. 1639b(b)(2)(D).

*Comment:* Some commenters noted additional disclosure technology cited in the study, such as in-store digital link scanners, and stated that digital disclosure would need to be paired with other such disclosure options to ensure access to all consumers.

*AMS Response:* AMS agrees that additional technology in the grocery stores may make electronic or digital disclosure more accessible. Grocery stores are welcome to have those technologies in place for consumers. However, the amended Act does not provide AMS with the authority to require grocery stores to make those technologies available to consumers.

*Comment:* Some commenters cited the study in support of digital disclosure. These commenters noted the study's findings that wireless internet and cellular networks are already widely available, and access to these technologies is increasing.

*AMS Response:* AMS acknowledges that a large number of Americans have smartphones and many national and regional supermarkets provide wireless internet connections. However, as noted above, the Secretary has determined that many consumers do not have sufficient access to electronic or digital link disclosures under ordinary shopping conditions at this time.

*Comment:* Numerous commenters, including those representing food manufacturers and retailers, supported the use of text message disclosure. Many of these commenters urged maximum flexibility in disclosure, including text messages. Some commenters supporting text message disclosure noted that it would provide for disclosure without access to a smartphone or the internet. These commenters stated that text message disclosure could serve a broader range of consumers than digital disclosure options, noting the availability of cellular phone coverage throughout the country.

*AMS Response:* AMS notes that the Deloitte study reported that approximately 5% of Americans do not own mobile phones based on the Pew Research Center's Mobile Fact Sheet. Because text messaging is not dependent on broadband or wireless internet access, it stands to reason that 95% of Americans can receive text messages. Thus, we agree that text message disclosure can serve a broad range of consumers. Additionally, the amended Act requires the Secretary to consult with food retailers and manufacturers in providing the additional and comparable option. *See* 7 U.S.C. 1639b(c)(4). AMS, therefore, gave significant weight to comments from this group that overwhelmingly supported the text message disclosure option.

*Comment:* Many commenters opposed the use of text message disclosure. Several argued that the additional need for a phone, even if it is not a smartphone, is a burden on consumers. Many of these commenters cited the study and noted that many consumers, especially rural consumers, do not have access to reliable cellular phone service, making text message disclosure difficult to use. Some of these commenters also noted that text messaging could result in additional charges to consumers who pay for individual text messages or have to pay for an upgraded phone plan. Other commenters stated that the need to text for a disclosure would be time consuming and ineffective, placing unnecessary barriers between consumers and BE disclosures. These commenters stated that text messaging was not comparable to on-package labeling and should not be adopted.

*AMS Response:* AMS acknowledges that text messaging might require an additional cost for some consumers depending on the consumer's cellular phone data plan. However, AMS notes that consumers must not be charged a fee by the regulated entity to access the disclosure information by text message. We also note that a text message disclosure request sent by a consumer must trigger an immediate response to the consumer's mobile device. Finally, we note that the amended Act requires a comparable option to access the BE disclosure, not that the option be comparable to on-package labeling. Therefore, we conclude that the text message disclosure meets the requirements of the amended Act.

*Comment:* Some commenters urged that if text message disclosure is allowed, the text message disclosure should not include any marketing information. Other commenters noted that the proposed rule would prohibit charging fees, data collection, and privacy invasions that could be associated with text message disclosure, but they stated that consumers may not know of these prohibitions.

*AMS Response:* AMS agrees that any text message disclosure must not contain marketing and promotional information and is adopting proposed § 66.108(c) in the final rule to prohibit that information in the text message option. AMS is also adopting § 66.108(d) to protect the privacy of consumers who access BE information through text message. AMS will inform consumers of the privacy protections for text message disclosures on its website and encourages food manufacturers and retailers and consumer advocacy groups to do the same.

#### *14. Disclosures for certain circumstances*

##### *a. Small Food Manufacturers*

AMS solicited comments on two 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. 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. AMS proposed 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.

*Comment:* Several commenters recognized a need to give small food manufacturers the flexibility to disclose in a way that is cost effective for a small business, while providing the same level of protection for consumers’ personally identifiable information. Several commenters recommended that the annual receipts threshold defining a small food manufacturer be changed to \$2,500,000 or less, while other commenters suggested the definition should be based on number of employees, such as 500 or 100, because the measure of annual receipts can become

outdated over time. Some commenters requested that the implementation date for small food manufacturers be delayed one additional year. Some commenters said no manufacturers should be exempt from disclosure based on size, with many of those commenters stating that the same reasons for disclosing apply regardless of the size of the manufacturer.

*AMS Response:* AMS believes that annual receipts are a reasonable measure in determining the threshold for small and very small food manufacturers, and that the definition of “small food manufacturer” provides flexibility for small entities while providing information to consumers regarding the bioengineered status of their foods. AMS notes that it considered other revenue cutoffs and other definitions. For instance, AMS considered the number of employees as a criterion, but found that it could be misleading and difficult to administer given the seasonal and part-time nature of some food manufacturing. AMS also believes that using total receipts is administratively simpler. In addition, AMS believes that the small food manufacturer definition should be consistent with the FDA’s definition under its nutrition labeling standards, which also uses annual receipts. AMS believes that delaying implementation for small food manufacturers for the statutorily-required 1-year period, but not longer, provides such manufacturers with enough time to ensure compliance. AMS understands the concern of commenters that any exemption will lead to some level of non-disclosure, but notes that the implementation delay for small food manufacturers and the very small food manufacturer exemption are statutorily required. AMS also notes that any electronic or digital link disclosure utilized by small food manufacturers must take the same steps as larger manufacturers to protect personally identifiable information about consumers.

*Comment:* Several commenters recommended that the text accompanying telephone numbers and websites be clarified to include a reference to bioengineered disclosure so

consumers know what type of information the text refers to. Some commenters recommended that companies should be able to use the same phone numbers and websites already on packaging to inform consumers because having a separate phone number or website link for bioengineered disclosure would be redundant.

*AMS Response:* AMS appreciates that some commenters requested a specific reference to bioengineering on small food manufacturer disclosures. However, AMS notes that the disclosure wording for small food manufacturers matches the statutorily-required on-package language required for electronic or digital link disclosures and any telephone number disclosures. AMS also acknowledges concerns commenters expressed regarding redundant phone numbers or website links. However, AMS believes that the rule provides small food manufacturers flexibility in disclosing bioengineered food information to consumers while ensuring that the manufacturer's chosen disclosure method is consistent with the disclosure required for larger manufacturers.

*b. Small and very small packages*

AMS solicited comments on three disclosure options for small and very small packages: (1) a modified version of the electronic or digital link disclosure ("scan for info"); (2) a modified version of the text ("text for info"); and (3) a modified version of the phone number ("call for info"). The definition of "small packages" and "very small packages" was taken from FDA labeling requirements.

*Comment:* Many commenters supported using the FDA labeling requirement definitions of "small packages" and "very small packages," with many of these commenters recognizing the need for flexibility for disclosure as small and very small packages have limited surface area for labels. Several commenters recommended that the disclosures be simplified to include a clear

reference to bioengineering. Some commenters recommended that even small packages should fully disclose BE with a symbol or distinct on-package marking, with many such commenters stating that consumers might not have access to technology to access links or QR codes.

*AMS Response:* AMS appreciates that some commenters requested a specific reference to bioengineering on small and very small packages. However, AMS notes that the disclosure wording for small and very small packages matches the statutorily-required on-package language required for other electronic or digital link disclosures and any telephone number disclosures, but in a shortened form. AMS acknowledges concerns some commenters expressed regarding on-package labeling, even for small packages, and concerns with access to electronic or digital disclosure. However, AMS believes that the disclosure options available to manufacturers utilizing small and very small packages, including electronic or digital disclosure, provides needed flexibility to such manufacturers while providing disclosure to consumers.

*c. Food sold in bulk containers*

AMS solicited comments on the AMS proposal that retailers would be responsible for complying with the BE food disclosure of bulk food, and that 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.

*Comment:* Several commenters supported the proposed disclosure requirements for food sold in bulk containers, stating that such disclosure is necessary to allow consumers to easily identify and understand the bioengineered status of the food. Such commenters stated that the proposal provided retailers flexibility in the form of disclosure. Some commenters expressed that bulk food should not be subject to disclosure. While some other commenters stated the proposed requirements were reasonable if disclosure was required. In some instances, commenters

emphasized that retailers should be given maximum disclosure flexibility. Some commenters requested that small and very small retailers and other businesses should be exempt from the bulk container disclosure because the availability and selection of bulk food, and therefore the presence of BE in such food, can change daily, making disclosure burdensome. Other commenters noted that the bulk food disclosure requirements may result in non-BE food being sold or commingled with, and disclosed as, BE food.

*AMS Response:* AMS agrees that labeling bulk containers is necessary to provide consumers with disclosure information. The final rule is meant to provide retailers with flexibility in choosing a disclosure method. With respect to comments seeking an exemption for small food retailers, such as the exemption for very small food manufacturers, AMS states that the very small food manufacturer exemption is statutorily mandated and cannot be extended to small retailers. To the extent that a small retailer is also a very small food manufacturer, it may be able to take advantage of the exemption in that instance. Although retailers will be required to correctly disclose BE food, AMS believes that retailers are already accustomed to ensuring that bulk food appears with appropriate signage because AMS already requires Country of Origin Labeling on bulk food. Additionally, commingled bulk foods should be disclosed in the same manner as commingled food or ingredients in packaged or processed food.

#### *15. Voluntary Disclosure*

AMS solicited comments on voluntary BE disclosure. Recognizing that some entities may want to provide a BE disclosure to consumers even though they are not required to do so, AMS proposed allowing voluntary disclosure for food that meets the definition of “bioengineering” in the amended Act to ensure that entities responsible for disclosure would have the option to disclose bioengineering information regarding foods not subject to mandatory

disclosure. AMS proposed that voluntary disclosure methods and requirements (for text, symbol, digital or electronic link, or text message disclosure) would be the same as for mandatory disclosure.

*Comment:* Most commenters agreed that the law allowed voluntary disclosure.

However, some commenters expressed concern that voluntary disclosures could potentially be false or misleading, while others stated that voluntary disclosures could lead to a fractured system where individual companies make different choices regarding the exact same ingredients and consumers would not know what such disclosure really means.

*AMS Response:* AMS agrees that voluntary disclosure is permissible under the amended Act. AMS acknowledges that regulated entities may make different decisions regarding voluntary disclosure. However, AMS has attempted to provide flexibility to the food industry, along with the transparency to consumers that they expect and deserve. Voluntary disclosure is available to exempt entities, as described in § 66.116(a), and to foods in which rDNA material is not detectable but are derived from bioengineered crops or foods, as described in § 66.116(b). AMS believes that the final voluntary disclosure provisions give food manufacturers, retailers, and other entities the ability to provide consumers with the information to make informed choices.

*Comment:* Some commenters agreed with AMS's proposal to permit voluntary disclosure for food that meets the regulatory definition of "bioengineered food" but is not subject to mandatory disclosure, so long as such disclosure is consistent with the Act. Some of these commenters agreed that voluntary text disclosure methods should be identical to mandatory disclosure rules to minimize consumer confusion and unfair competition, while others recommended that AMS offer companies additional flexibility in deciding what language to use

for voluntary disclosures. These commenters also stated that voluntary disclosure should not be permitted for a non-bioengineered food that was “derived from” or “sourced from” a bioengineered crop, and they opposed allowing voluntary disclosure for highly refined ingredients because consumers would find it challenging to make accurate comparisons between similar products where only one bears a voluntary disclosure. A subset of these commenters also requested that AMS prohibit voluntary disclosure terminology that suggests that food derived from animals fed bioengineered feed is therefore considered bioengineered. Other commenters stated that AMS should permit voluntary disclosure on food from animals consuming feed derived from BE crops. Several commenters stated that voluntary claims such as “non-bioengineered” should be prohibited for foods where there is no bioengineered alternative.

*AMS Response:* AMS agrees that any methods to voluntarily disclose bioengineered food should match the disclosure methods available to regulated entities to ensure consistent disclosure. AMS also notes that food companies and consumers generally agreed that consumers expect as much information as possible on the origin of food ingredients. For this reason, the final voluntary disclosure provisions allow for a food manufacturer, retailer, importer, or other entity to voluntarily disclose a food that originates from a bioengineered crop that they would otherwise not be required to disclose, using the distinct terminology “derived from bioengineering.” This terminology includes refined ingredients. As noted above, AMS acknowledges that regulated entities may make different decisions regarding voluntary disclosure. However, AMS believes that allowing voluntary disclosure of these ingredients allows food manufacturers, retailers, importers and other entities to provide the information that consumers expect in a consistent manner. AMS agrees with commenters that stated that voluntary BE disclosure is not permitted for foods derived from animals fed bioengineered feed.

Section 66.116 makes clear that voluntary BE disclosure is available in limited circumstances and does not apply to any foods that the amended Act excludes from the requirements for disclosure. AMS notes that the final rule does not prohibit regulated entities from making other claims regarding bioengineered foods. Entities seeking to use absence claims should ensure that such claims are in compliance with all applicable Federal laws and are otherwise truthful and not misleading.

*Comment:* Many commenters supported voluntary disclosure for products that do not meet the definition of “bioengineered food,” with some commenters noting that many manufacturers have already invested resources into systems of voluntary disclosure. Some of these commenters favored the ability to use terminology that is distinctly different from the mandatory disclosure language, provided the claims are truthful, not misleading, and otherwise consistent with applicable Federal law. Some of these commenters favored voluntary disclosure of foods that contain an ingredient “derived from” or “sourced from” a bioengineered crop, such as ingredients on the Bioengineered Source List. Some of these commenters favored voluntary disclosure of highly refined ingredients that are not required to be disclosed but were derived from a BE crop, especially if AMS excludes refined ingredients from the definition of “bioengineered food.” Some commenters recommended voluntary disclosures be standardized in a way that is rigorous but flexible, with some urging inclusion of a non-exclusive list of examples of permitted claims into the rule. A subset of these commenters stated that voluntary disclosure should be permitted below the threshold or amount of a bioengineered ingredient that triggers mandatory disclosure.

Some commenters favored voluntary disclosure of the amount of ingredients that meet the BE food definition, regardless of whether the finished food meets the definition. Some of

these commenters favored voluntary disclosure of a food made using genetic engineering, ingredients sourced from gene editing, or use of other technology that may fall outside the definition of bioengineering. Some also stated that AMS should allow voluntary disclosure with crops that do not meet the 85-percent acreage threshold because BE technology has not been widely adopted.

Some of these commenters requested that AMS allow entities to identify individual ingredients that meet the definition of BE food within the ingredient statement by using an asterisk or other symbol next to the ingredient in the ingredient list, regardless of whether the finished food meets the definition of BE food. Another subset of commenters favored voluntary disclosure permitting the use of an asterisk or other symbol to identify ingredients in the ingredient statement that fall outside the definition of “bioengineered food,” such as those derived from gene editing.

*AMS Response:* AMS agrees that voluntary disclosure should be allowed for foods that do not meet the “bioengineered food” definition because the rDNA is not detectable, and that such disclosure should utilize distinct terminology. As noted above, the final voluntary disclosure provisions allow a food manufacturer, retailer, importer, or other entity to voluntarily disclose a food that is derived from a bioengineered crop that they would otherwise not be required to disclose, using the statement “derived from bioengineering.” AMS has considered comments requesting additional disclosure options and understands that some entities may want to disclose bioengineered crops or ingredients with more specificity. Therefore, when an entity chooses to voluntarily disclose foods derived from bioengineering with the statement “ingredient(s) derived from a bioengineered source,” the word “ingredient(s)” may be replaced with the name of the specific crops or ingredients that are being disclosed. AMS acknowledges

that many entities have invested resources into alternative voluntary disclosure methods or labels, but AMS believes that voluntary disclosure should be consistent to avoid consumer confusion. Therefore, an entity utilizing the voluntary disclosure provisions must comply with the disclosure requirements for text, symbol, digital or electronic link, or text message disclosure, as applicable. Nonetheless, as noted above, the final rule does not prohibit regulated entities from making other claims regarding bioengineered foods, provided that such claims are consistent with applicable Federal law.

*Comment:* Some commenters favoring voluntary disclosure urged AMS not to limit voluntary claims. They stated that AMS should recognize that entities may want to provide additional information beyond what is required under the disclosure standard, including statements about the safety of bioengineering.

Many commenters stated that AMS's use of the single term "bioengineered" for mandatory disclosure should not preclude the use of different terms, including "genetically engineered" and "GMO," in additional voluntary statements and symbols about foods. However, these commenters disagreed about whether AMS should consider these terms synonymous and interchangeable with "bioengineered." In addition, one commenter suggested that AMS add a provision about absence claims that would clarify that claims such as "not bioengineered" or "non-GMO" are permitted on certified organic products by nature of their certification and that a food may not be considered "not bioengineered" solely because the food is exempt from mandatory disclosure.

*AMS Response:* As noted above, AMS acknowledge that entities may want to make additional claims regarding bioengineered foods. However, AMS believes that voluntary disclosure should generally be consistent to avoid consumer confusion. Therefore, an entity

utilizing the voluntary disclosure provisions must comply with the disclosure requirements for text, symbol, digital or electronic link, or text message disclosure, as applicable. Nonetheless, the final rule does not prohibit regulated entities from making other claims regarding bioengineered foods, provided that such claims are consistent with applicable Federal law. With respect to absence claims, NBFDS covers mandatory and voluntary bioengineered and BE-derived claims and 7 U.S.C. 1639b does not provide authority for AMS to establish an absence claims regime as part of the NBFDS. AMS notes that FDA (and FSIS depending on the food at issue) retain authority over absence claims. Entities seeking to use absence claims should ensure that such claims are in compliance with all applicable Federal laws and regulations and are otherwise truthful and not misleading. With respect to organic certification, AMS believes that the amended Act in this respect is self-executing.

#### *16. Recordkeeping*

AMS proposed recordkeeping requirements that aligned with the disclosure requirements. Commenters generally supported the proposal, and several commenters submitted suggestions for clarification.

*Comment:* Many commenters appreciated the flexibility provided to regulated entities by enabling the use of multiple documentation sources. Commenters agreed with the 12 categories of documentation identified as appropriate to verify that foods are not BE, though some asked that examples of appropriate records be incorporated into the final rule. Commenters noted that records should be in any format (hard copy or electronic), with records stored at any business location.

*AMS Response:* AMS agrees with these comments. Section 66.302(a) includes a non-exhaustive list of examples of customary or reasonable records that demonstrate compliance with

the NBFDS's disclosure requirements. That section also clearly states that the records may be maintained in electronic or paper format.

*Comment:* Many commenters noted that the reasonable or customary records already in use throughout the industry should suffice to comply with the Act and agreed that the recordkeeping requirements would not impose additional costs or burden to existing practices. One commenter, however, noted that implementation could result in significant changes to existing supply chain documentation practices, increasing complexity and cost throughout the value chain.

*AMS Response:* As the commenters stated, we do believe that many, if not most, regulated entities currently maintain the types of records that will satisfy the NBFDS's recordkeeping requirements. Regulated entities may make changes to their documentation practices for business reasons, but this final rule does not specifically require them to do so.

*Comment:* A commenter suggested that USDA should require companies to maintain records similar to those required by private certification entities such as the Non- GMO project (i.e. for a particular crop or ingredient, companies must have the DNA testing records, certifications by crop suppliers of GE/non- GE content, supply chain documents, purchase orders, bills of sale).

*AMS Response:* AMS believes that it is efficient to allow companies to determine the records that best fit their business needs while demonstrating compliance with the NBFDS. If a regulated entity maintains one type of records that does so, it serves no purpose to require that entity to maintain additional or redundant records.

*Comment:* A commenter encouraged AMS to coordinate with other Federal agencies to better understand what recordkeeping and records access is already required and enforced.

*AMS Response:* AMS agrees that recordkeeping and compliance requirements under the NBFDS should be consistent with those under other AMS programs, such as NOP and PACA, and has incorporated elements from each of those programs into the NBFDS. Accordingly, § 66.302 does not specify the records regulated entities must maintain to demonstrate compliance with the disclosure regulations. Instead, as with other AMS programs, regulated entities are free to determine for themselves which of their customary business records will demonstrate compliance and should be maintained.

*Comment:* A commenter suggested that bioengineering-specific records should be necessary only to support decisions that disclosure is not required. Manufacturers typically do not test for or maintain documentation on the presence of modified genetic material in food unless they are making a “non-GMO” claim. A commenter recommended a regulated entity should only be required to maintain records about foods on the List of Bioengineered Foods for which the regulated entity does not make a bioengineered disclosure, including records demonstrating that the food is below the 5 percent threshold. The commenter also suggested that acceptable records include documentation showing the identity preserved seed was produced and handled throughout the supply chain in a manner to mitigate the potential for cross-contact with BE substances in the supply chain.

*AMS Response:* To ensure that BE disclosures are consistent with the requirements of the NBFDS, AMS is requiring that customary or reasonable records be maintained when bioengineered food or food ingredients are used.

*Comment:* Several commenters suggested that requiring testing documentation would be burdensome. Commenters suggested adopting a recordkeeping approach based on traceability and segregation rather than analytical testing. A commenter sought clarification regarding

whether regulated entities may entirely rely on traceability records rather than testing results to establish compliance with the Act.

*AMS Response:* AMS believes that regulated entities should have the flexibility to determine what customary or reasonable records they should maintain to demonstrate compliance with the NBFDS, because each business is different. Section 66.302(a)(4) provides a non-exhaustive list of record types that might be used to verify that foods are or are not bioengineered. Further, § 66.9 provides that, in order to verify that refined foods do not contain modified genetic material, regulated entities can choose to rely on traceability or source records, validated process verifications, or analytical testing results.

*Comment:* A commenter suggested that if AMS exempts ingredients from disclosure that do not contain modified genetic material, AMS should maintain a list of these kind of ingredients. This list would eliminate the need for testing and maintaining documentation.

*AMS Response:* The final rule does not exempt any specific ingredient. Rather, if the regulated entity can demonstrate that no modified genetic material may be detected in the food or food ingredient, the regulated entity is not required to include a BE disclosure for that food or food ingredient. Consequently, AMS will not maintain a list of ingredients that do not include modified genetic material.

*Comment:* A commenter suggested that each BE food manufacturer has an independent duty to comply with the standard and its provisions, including record-keeping, regardless of whether and when USDA puts a food product on its lists. Other commenters argued that there should be no recordkeeping requirements for foods not on the list.

*AMS Response:* AMS believes that foods that bear a BE disclosure must have records to verify that disclosure. Regulated entities do not have to maintain records for foods that are not

on the List of Bioengineered Foods provided in § 66.6, unless a regulated entity has actual knowledge that a food or food ingredient is bioengineered. Regulated entities must make BE disclosures when their records show that foods or ingredients are bioengineered, regardless of whether those foods or ingredients are on the list. If regulated entities have actual knowledge that the foods or food ingredients are bioengineered § 66.109 requires those foods and food ingredients to bear a BE disclosure, and § 66.302(b)(2) requires regulated entities to maintain records for those foods.

*Comment:* A commenter agreed with AMS's proposed 5 days to produce records (except in the event USDA grants an extension). A commenter also suggested that USDA specify business days in its timelines. Several commenters disagreed with the proposed five business days' notice to produce records. As the NBFDS is intended as a marketing standard unrelated to food safety, commenters stated that it is more appropriate for record production requirements to be consistent with other marketing programs (*i.e.* the four to six week notice given to produce records establishing compliance with FDA menu labeling requirements).

*AMS Response:* AMS agrees that the final rule should specify that the timelines are business days and § 66.304 makes that clear. We also believe the timeframes in the final rule provide reasonable notice to regulated entities to produce records. If a regulated entity requires additional time to provide records, AMS may grant an extension. Additionally, the timelines to produce records are consistent with other marketing labels administered by AMS. *See e.g.* 7 CFR 60.400 (country of origin labeling for fish and shellfish).

*Comment:* Several commenters supported the timeline of at least three days' notice for an on-site visit, but requested that the final rule permit the entity to determine the location of the

audit at the regulated entity's discretion, including the option to conduct an audit at a company's corporate headquarters.

*AMS Response:* AMS agrees that entities may maintain records at the location that best serves the entity's business needs.

### *17. Compliance and enforcement*

Several commenters addressed the Enforcement section of the proposed rule, including the complaint process and audit and hearing procedures. Most of the comments broadly back the rule text while emphasizing that the rule should not authorize USDA to recall any food based on whether the food has a BE disclosure or impose civil penalties for violations.

*Comment:* Several commenters argued that accountability is a key aspect of a meaningful labeling claim, that label misuse must trigger consequences, and that USDA must prioritize and implement a more rigorous audit regimen and make the audit results available to the public. However, other commenters agreed with AMS that conducting unannounced audits or imposing steep fines for non-compliance issues are impractical, and supported the rule on the basis that AMS's enforcement authority remain limited as set forth in the amended Act.

*AMS Response:* AMS acknowledges various stakeholders' advocacy for more rigorous enforcement provisions. We note, however, that the amended Act prescribes an enforcement program based on records audits, and provides for publicizing the results of an audit after the opportunity for a hearing. The amended Act does not authorize civil penalties or other remedial or punitive measures. We believe that the enforcement process in the final rule that includes a complaint process, investigations, audits, hearings of limited scope, and resulting notifications to both regulated entity and the public sufficiently meets the amended Act's requirement for enforcement.

*Comment:* Some commenters requested that USDA more clearly state when an audit may occur, so producers are not erroneously subject to audit reviews due to baseless complaints. Several commenters asked that the rule specify what information is required when filing a complaint. One commenter asked that the rule incorporate deadlines for considering complaints.

*AMS Response:* In response to comments, § 66.402(a) was revised to include a description of the information that must be submitted with a complaint alleging violation of the NBFDS. To ensure that audits are not conducted needlessly, the rule provides that AMS will consider complaints about potential violations of the disclosure requirements and determine whether audits or other further investigations are merited. Complaints will be considered on a case-by-case basis, and depending on the complexity of the complaints, some may require more time than others to consider, so no deadlines for consideration were added. If the complaint merits further investigation, the regulated entity will be given notice regarding access to its records. It should be noted that the results of all investigations will be publicized, and if an audit or investigation finds that the regulated entity is in compliance with the disclosure requirement, such finding will be made public.

*Comment:* Comments regarding audit procedures suggested that while USDA's proposal is reasonable, if an audit finds a firm out of compliance, then a detailed summary of records should not be released to the public to protect confidential business information. Some input cites public access concerns to confidential business information of product formulations or recipes. Related comments requested the regulated entity set the location where the audit should occur. Some comments stated a labeling duty should arise only if AMS, while conducting audit procedures, determines producer testing is inadequate and/or its products really do contain modified genetic material.

*AMS Response:* AMS does not release confidential business information, consistent with other applicable Federal regulations. AMS agrees that entities may maintain records at the location that best serves the entity's business needs. Audits can be conducted at the regulated entity's place of business. Regulated entities subject to the NBFDS should make determinations about disclosures based on records. AMS does not intend to test final food products to determine compliance with the rule.

*Comment:* Several commenters favored notice of non-compliance to regulated entities with a 30-day window to object and request a hearing, then making results public if a hearing is not requested or the Administrator upholds the finding of non-compliance. In addition, when auditing a regulated entity to determine whether the entity is in compliance with the disclosure standard – either on its own initiative or in response to a complaint by a consumer, competitor, state regulator, or another party – some commenters suggested AMS should begin by contacting the regulated entity and providing a 4 to 6-week period for the entity to produce appropriate records. If the company can provide records demonstrating the food is not subject to disclosure, the entity would be deemed in compliance. Another comment addressing timeframes advocated that deadlines for providing records for review during audit or investigation be “business days.”

*AMS Response:* AMS deems the goals of disclosure and minimizing economic burden whenever feasible is best obtained by NBFDS flexibility on maintaining customary business records, while requiring compliance with the specified timeframes for furnishing data access to AMS. Since all regulated entities are required to maintain customary and usual business records to demonstrate compliance, the timeframes provided should give entities adequate time to produce appropriate records. Nevertheless, the rule provides for extending records access deadlines at AMS's discretion. It should also be noted that § 66.304 of the rule specifies records

production deadlines in terms of business days. Thus, the rule declines to impose the timeframes suggested by these comments, and provides for an audit process with the more immediate investigative and auditing elements specified.

*Comment:* Several comments acknowledged the statutory obligation to provide the results of an examination or audit, and further asserted the rule also needs to ensure any trade secrets or confidential commercial information is redacted before providing publicly those results, as required under the Freedom of Information Act (FOIA). One commenter recommended that results only be posted for six months, as afterwards this information has diminishing relevance, but can still be accessed via FOIA requests.

*AMS Response:* Proprietary business information, including product formulation and recipes, will be kept confidential by AMS, consistent with FOIA, 5 U.S.C. 552(b)(4). Section 66.406 does not specify how long hearing results will be posted. The duration of posting hearing results will be in accordance with relevant departmental policy and FOIA.

*Comment:* Several commenters suggested that regulated entities making “may contain” disclosures should be subject to periodic compliance audits in a separate mode from other regulated entities.

*AMS Response:* The final NBFDS does not provide for “may contain” disclosures.

*Comment:* Several commenters argued a deadline for agency responses to complaints should be set, and a standard for when and why further investigation is warranted should be established. These comments recommended USDA should audit or examine records of manufacturers and establish fines for non-compliance violations. In addition, comments suggested the audit and hearing process should be undertaken pursuant to deadlines to ensure timely resolution, and all results must be made public.

*AMS Response:* AMS notes the concern, but determines the optimal balance between expeditious enforcement and associated aspects, including complaints, audit, examination, investigation, hearing and appeal, and the disclosure rule's broad mandate to also facilitate commerce, is best met by the rule's mix of strict record access deadlines with further timeframes for hearing request and appeal. Other response deadlines are deemed impractical, as audits or investigations are case specific, require individual time to complete, and reflect various factors such as extensiveness of a case under review and AMS workload.

*Comment:* Many commenters recommended that AMS include limitations on recall authority in the final rule.

*AMS Response:* The amended Act does not authorize product recalls based on compliance with the disclosure requirements of the NBFDS. Thus, establishing limitations on recall authority is unnecessary.

#### *18. Compliance dates*

AMS proposed an initial compliance date of January 1, 2020, for all regulated entities other than small food manufacturers whose initial compliance date would be January 1, 2021. We also proposed allowing regulated entities until January 1, 2022, to use up labels that have been printed by the initial compliance date. We received many comments on this proposal.

*Comment:* Several commenters argued that manufacturers have had plenty of warning about the NBFDS and that consumers have waited a long time for mandatory bioengineered food labeling and should not have to wait longer. Other commenters suggested extending compliance deadlines for all manufacturers, explaining that label changes are costly and time consuming. Still other commenters agreed with the compliance dates as proposed, finding that they hit a balance between consumer desire for information and industry need for time to make label

changes. Other commenters advocated that the compliance dates for the NBFDS should align with the FDA deadlines related to the recently updated Nutrition Facts and Supplement Facts panel.

Several commenters claimed that manufacturers could theoretically continue printing and using non-compliant labels for up to six years after the Act was amended to require mandatory BE food disclosure. Those commenters urged AMS to allow a shorter compliance period for label use-up. Food manufacturer comments generally supported the proposed label use-up provision, but they asked that the final rule provide a two-year compliance period after the compliance date, rather than specifying a hard date, to allow for regulatory delays.

Commenters also urged AMS to allow the use of labels compliant with the preempted State GMO labeling laws during the compliance period. Some commenters recommended that AMS allow entities to apply stickers or ink stamp disclosures to existing labels to reduce waste. Others suggested that AMS incorrectly assumes manufacturers maintain large label inventories, asserting that manufacturers order labels in the smallest batches economically practical.

Several commenters requested additional time for regulated entities to meet the requirements of the NBFDS because complying with the regulatory requirements of the NBFDS will be complex. They explained how regulated entities will need time to determine how their specific business might be impacted by the labeling and recordkeeping requirements of the NBFDS, and the challenges in meeting the proposed January 1, 2020, deadline. Several commenters explained how labeling costs would not be costly as many companies print labels in minimally necessary quantity and print labels themselves using digital equipment. Under this view, the proposed January 1, 2020, compliance date would be more than enough time for affected entities to make necessary changes to achieve compliance.

Other comments supported the proposed compliance dates. Conversely, many commenters felt that the compliance dates and compliance periods proposed in the NPRM were too lenient, and that regulated entities should be required to immediately change their labels to denote the presence of bioengineered food and/or food ingredients. They explained that consumers have a right to know that the food they are buying is bioengineered and should have access to this information as soon as possible.

*AMS Response:* Because this rule is a major rule, the effective date will be [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**] to comply with the Congressional Review Act. After consideration of the comments, AMS has decided to adopt implementation dates, a compliance date, and a compliance period. The implementation dates are the same as the proposed compliance dates: January 1, 2020, for regulated entities other than small food manufacturers and January 1, 2021, for small food manufacturers.

As evaluated in the Regulatory Impact Analysis, AMS recognizes that this final rule will be complicated to implement, requiring regulated entities to modify their existing business practices, and thus, regulated entities will need adequate time to come into compliance. Requiring compliance on the rule's effective date or by January 1, 2020, would be overly burdensome because of the time and cost involved in determining which foods require disclosure, identifying the required records, modifying labels, and providing the appropriate disclosure on the labels. In establishing the compliance dates, AMS determined that regulated entities should have greater flexibility, beyond using existing label inventories, to transition to the mandatory BE disclosure and recordkeeping. Thus, the final rule includes a voluntary compliance period and the mandatory compliance date. As explained above, regulated entities

may voluntarily comply with the requirements of part 66 until December 31, 2021. Beginning on January 1, 2022, all regulated entities must comply with the requirements. Those periods are comparable to the extended compliance date of January 1, 2020, for FDA's Nutrition Facts and Supplement Facts Label and Serving Size final rules, which is approximately 3.5 years after FDA published the final rules. We note that many food manufacturers have complied with the FDA's final rules well ahead of the compliance date, and we anticipate the same for the NBFDS.

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

AMS recognizes that the new NBFDS will require regulated entities to make BE disclosures on their labels. The NPRM included a proposal to allow regulated entities a period of time to use their existing label inventories and AMS received several comments in support and in opposition to this proposal.

*Comment:* Many commenters supported continuing use of existing label inventories until the compliance deadline. They believed that ongoing use of existing inventories reflects the best economic, environmentally valid option to mitigate waste associated with letting existing label stock go unused if not depleted before the deadline. Such feedback sought an extension of the compliance deadline until existing stock had been exhausted or materially depleted. Several commenters were concerned that by providing a blanket exemption for unused label stock, AMS would be encouraging noncompliance. One commenter expressed concern that the rule has insufficient safeguards to prevent or discourage excess labels being printed merely to escape or unduly extend the compliance deadline.

*AMS Response:* As explained above, AMS is adopting a voluntary compliance period until December 31, 2021, to allow regulated entities more flexibility. Thus we are not adopting the proposal to allow regulated entities to use existing label inventories because it is unnecessary.

*Comment:* Commenters suggested an alternative website disclosure option be available until new labels can be printed.

*AMS Response:* The amended Act does not authorize AMS to require an independent website disclosure. Regulated entities, however, are free to include BE disclosures on their websites.

## 20. *Regulatory Flexibility Analysis*

The Agricultural Marketing Service sought public comment on several aspects of the proposed National Bioengineered Food Disclosure Standard rule to guide efforts in creating a final rule for implementation. Though the proposed rule was not predicted to have a significant adverse economic impact on substantial number of small entities, the Agricultural Marketing Service conducted an initial regulatory flexibility analysis and provided suggestions and analysis of measures to reduce the economic effect on small entities. For purposes of the regulatory flexibility analysis, AMS solicited comments regarding suggested standards to define “very small food manufacturer” based upon a range of annual receipts. Additionally, AMS sought comments on the defining a “small food manufacturer” based upon receipts or upon number of employees to determine what firms should receive additional time to comply with the disclosure requirements of the rule. Comment summaries below represent public input on suggested flexibility provisions in the proposed rule.

*Comment:* Commenters supported a range of definitions for a “very small food manufacturer.” Some commenters suggested that there be no exemption for food manufacturers of any size. Many commenters supported the alternative definition analyzed by AMS to narrow “very small food manufacturers” as those with less than \$500,000 in annual receipts. Several noted this number would comply with similar standards imposed by the FDA for nutrition

labeling requirements. Many of these commenters cited a desire for increased transparency by labeling more products. Some commenters supported the proposed definition of food manufacturers with \$2.5 million or less in annual receipts, citing the high costs of bringing their business into compliance with the rule. Several commenters also proposed an alternative definition of food manufacturers with less than \$1 million in annual receipts. These commenters cited the FDA's use of this number to define "very small businesses" in rules not related to food labeling.

*AMS Response:* AMS considered a range of definitions for a "very small food manufacturer" including the small business definitions under FDA and U.S. Census Bureau (USCB) regulations. AMS evaluated the impact of applying various definitions by estimating the number of firms that would be exempted, the number of products that would likely be exempt, and the proportion of annual industry sales that would exempt under each exemption level. Exempting manufacturers with annual receipts of less than \$2.5 million will provide regulatory relief to 74 percent of food manufacturers and 45 percent of dietary supplement manufacturers, while reducing the number of products covered by only one percent for both food and dietary supplement manufacturers.

*Comment:* To define "small food manufacturers," some commenters expressed interest in aligning the definition with Small Business Administration standards on number of employees rather than the proposed annual receipts definition to promote consistency. Many of these commenters supported the AMS alternative definition of businesses with fewer than 500 employees. Other commenters suggested defining "small food manufacturers" as those with less than \$2.5 million in annual receipts.

*AMS Response:* The Small Business Administration uses both the number of employees and annual receipts to describe business size categories. Because food and dietary supplement manufacturers are in the manufacturing sector, they are both defined by number of employees for purposes of SBA size categorization. However, the firms defined as small or very small for purposes of the NBFDS all fall well below the SBA definition of small, so we do not feel we need to be bound by that methodology. The FDA nutrition labeling definition of small is based on sales rather than number of employees, and it is important to remain consistent with that definition. We decided to extend the use of receipts to define very small food manufacturers because we believe it to be administratively simpler, as it does not require development of an averaging system to track employees over time (especially in firms that may have some degree of seasonality).

*Comment:* Some commenters specifically suggested that we define very small manufacturer as a manufacturer with annual receipts below \$2,500,000 or less than 50 employees.

*AMS Response:* While we do not have data on manufacturers with less than 50 employees (Census has data cutoffs at 20 employees and 100 employees), we do know that defining very small manufacturers as those with less than 20 employees would exempt the same 74 percent of firms as receipts less than \$2,500,000. So, the compound definition would result in significantly more exemptions. When Census uses the term very small enterprise, it refers to 20 employees. The fact that the results of estimating exemptions at 20 employees and \$2,500,000 annual receipts are so close gives us confidence that we are not outside of the reasonable norm in using this cutoff.

*Comment:* Several commenters also sought shorter compliance deadlines and no implementation extensions for small food manufacturers with more than \$2.5 million in annual receipts. Several commenters insisted no entities be exempted from the NBFDS, including those defined as very small and small food manufacturers.

*AMS Response:* AMS appreciates that several commenters insisted no entities be exempted from the NBFDS including those defined as very small and small food manufacturers, however, the very small food manufacturer exemption is a statutory requirement. Congress contemplated some level of undisclosed use of bioengineered foods to avoid undue burden on very small food manufacturers. Our goal is to find a reasonable balance between the number of small firms that are exempted and the number of products for which the consumer may not receive full disclosure of bioengineered content. By defining “very small food manufacturers” as those with annual receipts below \$2,500,000, about 74 percent of food manufacturers are exempt from mandatory disclosure, but 96 percent of products will still be covered.

*Comment:* Some comments further suggested the proposed exemption for very small food manufacturers be extended to very small food retailers using the standard in FDA’s Menu Labeling Rule applicable only to restaurants and similar retail food establishments that are part of a chain with 20 or more locations doing business under the same name and offering for sale substantially the same menu items.

*AMS Response:* The exemption for “very small food manufacturers” is provided for in the amended Act. The amended Act also provides an exemption for all restaurants and similar food establishments. The amended Act does not contain a similar exemption for retail establishments that are not manufacturers or restaurants. However, the portions of grocery stores and similar retail establishments that prepare food for immediate consumption (e.g. deli or

prepared food section) fall within the definition of restaurant and are exempt from the disclosure requirement. So unpackaged food in the produce section would be subject to disclosure if it meets the definition of bioengineered food, while the same product used as an ingredient in a sandwich in the deli would not.

## *21. Regulatory Impact Analysis*

AMS provided a Regulatory Impact Analysis (RIA) with the proposed rule that provided details on the expected costs and benefits of the rule, and solicited comments.

*Comment:* One commenter provided a detailed analysis of the costs and benefits of the NBFDS conducted by John Dunham and Associates (JDA) (National Bioengineered Food Disclosure Standard: A Review of the United States Department of Agriculture's Regulatory Impact Analysis (Brooklyn, NY: June 2018)). The JDA assessment estimated much higher costs than the AMS analysis, though since it also estimated much higher benefits, the JDA analysis concluded that the Federal disclosure standard would be the most cost-effective method to provide information and minimize inefficiencies caused by inconsistent State-level standards. JBA found cost savings of avoiding compliance with twenty separate state rules to be \$97.3 billion over twenty years and \$129.7 billion cost savings over the same period if all 51 states implemented different labeling provisions.

*AMS Response:* The JDA assessment provides valuable corroborating evidence of the net benefits of the NBFDS. However, AMS could not adopt JDA's methodology – and higher cost and benefit estimates—for the RIA since this methodology incorporates a broader set of impacts and transfers than recommended by OMB for regulatory impact assessment. OMB Circular A-4 admonishes agencies to focus on opportunity costs, the real expenditure of society's resources, and to avoid counting transfers as benefits or costs. JDA uses a partial equilibrium input-output

model (IMPLAN) to estimate the costs of the NBFDS. This model estimates the cost of labeling to specific industries/sectors and then calculates the multiplier effects on other industries and consumers (prices held constant) within the study region. Such an analysis tracks transfers rather than the commitment of real resources to compliance. OMB Circular A-94 states “Employment or output multipliers that purport to measure the secondary effects of government expenditures on employment and output should not be included in measured social benefits or costs.” Moreover, the JDA analysis only tracks half of the equation in that it follows the changes in upstream expenditures resulting from decreased expenditures by food manufacturers, but does not track the increased downstream expenditures related to additional income to label printers. While partial equilibrium models can be very useful for evaluating local effects of a specific policy and for other purposes, its results for purposes of evaluating compliance costs tends to inflate the compliance costs by the velocity of money. However, because the velocity of money is constant within the region, the relative attractiveness of individual policy choices would be the same as if those alternatives were evaluated based on opportunity cost alone.

*Comment:* Many comments addressed the RIA’s discussion of signage in stores selling fresh produce. These generally disagreed with the proposal that retailers be responsible for disclosure in any circumstances because manufacturers and suppliers are better equipped to provide labelling information and costs will be too burdensome on retailers. A common concern identified proposed producer requirements regarding modifying contracts for manufacturers to notify end users when a product is reformulated (or otherwise changed) as time consuming and costly. However, these comments agreed with the RIA that if retailers must be responsible for labeling, signage as posted by the retailer may be an appropriate method to help keep costs low for retailers and provide consistency for consumers. Some comments asked the final rule allow

retailers to post signage such as a single sign near a produce section listing all BE foods in that section, to further reduce retailer burden.

*AMS Response:* Retailers should not have to take into account costs associated with modifying contracts to provide for end user notification of product reformulations since packaged food will be labeled by the manufacturers. For prepared foods sold by grocers in in-store delis or salad bars, § 66.5(a) provides an exemption for food served in a restaurant or similar retail food establishment from disclosure under the NBFDS. Section 66.1 now defines “similar retail food establishment” as a cafeteria, lunch room, food stand, food truck, transportation carrier (such as a train or airplane), saloon, tavern, bar, lounge, other similar establishment operated as an enterprise engaged in the business of selling prepared food to the public, or salad bars, delicatessens, and other food enterprises located within retail establishments that provide ready-to-eat foods that are consumed either on or outside of the retailer’s premises.

*Comment:* Some comments further suggested the proposed exemption for very small food manufacturers be extended to very small food retailers using the standard in FDA’s Menu Labeling Rule applicable only to restaurants and similar retail food establishments that are part of a chain with 20 or more locations doing business under the same name and offering for sale substantially the same menu items.

*AMS Response:* The exemption for “very small food manufacturers” is provided for in the amended Act. The amended Act also provides an exemption for all restaurants and similar food establishments. The amended Act does not contain a similar exemption for retail establishments that are not manufacturers or restaurants. However, the portions of grocery stores and similar retail establishments that prepare food for immediate consumption (e.g. deli or

prepared food section) fall within the definition of restaurant and are exempt from the disclosure requirement. So unpackaged food in the produce section would be subject to disclosure if it meets the definition of bioengineered food, while the same product used as an ingredient in a sandwich in the deli would not.

*Comment:* Some comments noted the RIA does not address all market impacts under a rule that includes products containing highly refined ingredients within the definition of a bioengineered food. The expressed concern was this does not consider price impacts of presuming refined ingredients not containing modified genetic material are BE foods under Position 2, when in fact they are identical to all other refined ingredients from conventional crops. Such input recommended AMS exclude refined ingredients from definition of BE foods because of these unidentified likely significant harmful effects on the agricultural value chain. Related comments addressed economic consequences of presuming beet sugar is a BE food when it is identical to other refined sugar products, noting costs will be greater than the RIA estimates. Citing Vermont's labeling law as an example, such feedback advised there will be significant market consequences resulting from market discrimination resulting in higher consumer prices if refined sugar is included in a BE food definition. Farms will bear the brunt of the economic impact as there are currently no non-bioengineered sugar beets grown for sugar production. A commenter expands this concern and concludes adverse market and agricultural impacts will flow from any RIA presumption that refined food ingredients are presumptive BE foods, and will trigger market discrimination against such entities. Several comments express the broad concern that the RIA and underlying rule presume refined ingredients are BE, resulting in competitive harm and undue costs to the American farmer. Associated comments asserts the RIA significantly understates the costs of the rule to the sugar industry, claiming such industry's

product is identical to all other refined sugar products, but would be selectively burdened under BE standards.

*AMS Response:* The commenter is referring largely to incidence of costs rather than the estimated magnitude. The RIA did not estimate cost increases across the board and does not believe that doing so is consistent with recent real-world experience. What the RIA does do is assume that manufacturers of 20 percent of products will seek to replace BE ingredients with non-BE alternatives. The costs associated with trying to avoid a cost differential is, therefore, accounted for in the RIA. Nevertheless, the final rule would allow manufacturers to demonstrate through records (potentially including test results) that a food or ingredient does not contain modified genetic material and would not be required to disclose the food or ingredient as BE. The concern raised by the commenter has been addressed by the final rule.

*Comment:* A number of commenters suggested that there could be distributional effects of the NBFDS that were not considered in the RIA, including impacts on farmers through segregation costs and consumers through higher food prices.

*AMS Response:* Potential impacts on farmers arise in the case where manufacturers and retailers take the marketing decision to replace BE ingredients with their non-BE counterparts. The RIA notes that this decision would entail higher costs stretching back to the farm, including the extra cost to farmers of supplying non-BE commodities and crops include the costs of sourcing non-BE seeds; avoiding cross contamination with BE varieties during planting, harvesting and transporting; driving to an elevator or handler that is farther away than the nearest bulk elevator; and foregoing the benefits of BE production. However, as noted in the RIA, these extra costs are reflected in price premiums paid to farmers for non-BE varieties. The RIA provides current estimates of this price premiums in the United States. AMS does not include

estimates of impacts on consumer food prices in the RIA for two reasons. First, in the case of BE labeled products, it is unlikely that manufacturers will pass labeling costs on to consumers (manufacturers will not want to jeopardize demand for these newly labeled products). Second, in the case of non-BE labeled products, there is no evidence that the extra costs for production and segregation are any higher than currently paid by consumers who prefer non-BE products. As a result, while availability of these products could rise as a result of the NBFDS, non-BE prices could remain constant or actually decline in the long run as production expands.

*Comment:* Some comments found the RIA inadequately assessed societal costs associated with electronic and digital disclosure. Such input asserted these disclosure methods would ultimately burden consumers who would not have sufficient product information, given retailers will be reluctant to purchase expensive scanning equipment. Consumers in low-income rural areas already lacking connective capabilities equivalent to urban areas would be especially burdened.

*AMS Response:* Potential impact associated with electronic and digital disclosure is more fully addressed by comment responses directly assessing electronic and digital link disclosures herein. AMS strikes a reasonable balance between offering various label disclosure alternatives, realizing stakeholder phone, internet or digital access may vary by locale, customer expertise, income or related factors. Not all BE food packaging and presentation will be amenable to electronic or digital disclosure. By offering several disclosure alternatives, AMS seeks least burdensome commercial impact consistent with the regulatory objective to meet public demand for consistent accurate label information.

*Comment:* Several comments identified specific burden to small entities from labeling and associated requirements, asserting food retailers would also be selectively burdened by

labelling and other regulatory aspects. Other negative input alleged inconsistency and conflict with international norms, potentially promoting trade disputes.

*AMS Response:* On analysis of comments and other data, including studies, AMS concludes impacts to producers are mitigated by exemptions for qualifying “small” and “very small” entities, by offsetting efficiencies of a uniform standard, and by consideration to international norms and trade. The proposed rule subjects importers to the same disclosure and compliance regimen as domestic entities. AMS’s interest is to facilitate imports and exports under arrangements where BE labeling is consistent with the NBFDS. Under such arrangements, countries could agree to recognize each other’s BE labeling requirements as comparable. This would allow foreign food products with comparable BE labeling to be sold in the US, assuming they meet all other labeling and safety requirements. Overall, AMS’s economic analysis indicates it is likely this rule would not have a significant impact on a substantial number of small businesses.

*Comment:* A number of commenters referred to an assessment conducted by the Grocery Manufacturers Association (GMA) in 2017 that found that the exclusion of refined ingredient would result in 78 percent (78%) fewer products being disclosed, as opposed to USDA’s assessment that exclusion of refined ingredients would result in 25 percent (25%) fewer products being disclosed.

*AMS Response:* The GMA assessment considered a categorical exemption of *all* refined ingredients. In contrast, USDA’s estimate for scenario 2 considered an exemption for only sugar and oil and in scenario 3, an exemption for ingredients that test negative for rDNA (not a blanket exemption of all refined ingredients). In both cases, since the exemptions are smaller than assumed in the GMA study, it is reasonable to expect that the number of exempted food products

would also be smaller. In addition, the USDA study considered “nesting” when calculating the impact of exempting refined ingredients such as sugar. Nesting recognizes that most labeled foods contain more than one ingredient. If products are not required to label due to the presence of sugar, for example, that does not mean that the product itself does not need to be labeled if it contains other ingredients that are not part of the categorical sugar exemption. For example, just looking at the first product that shows up on a search of food products that contain “sugars” as an ingredient in LabelInsight, we find a breaded chicken product. The first few ingredients listed on the product label include Salt, Spice, Sugars, Water, Onion Powder, Garlic Powder, Dextrose, and Modified Food Starch. The categorical exemption would apply to Sugars and Dextrose, but the product would still require disclosure to the presence of Spice and Modified Food Starch. Nesting results in fewer products being exempted from labeling than might be assumed from a count of refined ingredients. Since the USDA and GMA assessments are based on two different data sets, it is impossible to directly compare results.

Also, the two estimates are based on different data sources. USDA relied on ingredient data reported on food labels while GMA relied on a survey of its membership. It is not surprising that the two approaches might come up with somewhat different results.

That said, the final version of the RIA takes another look at which ingredients are likely to be exempt under the condition that mandatory disclosure only applies to foods or ingredients that meet the statutory definition of bioengineering. This reevaluation has led us to remove some ingredients that we had assumed would universally require disclosure. This has resulted in an estimate that is closer to the GMA estimate.

*Comment:* One commenter specifically took issue with the USDA’s use of shielding to explain why administrative costs could increase for products still required to disclose in the

instance of an exemption of refined products. The commenter argued that since manufacturers look at the BE status of all ingredients when they develop a new product the existence of low administrative costs ingredients does not obviate the need for manufacturers to understand the BE status of administratively higher cost ingredients especially for products seeking non-GMO project certification.

*AMS Response:* AMS disagrees with the commenter. First, the rule requires a disclosure determination to be made for existing as well as new products and the RIA is based exclusively on the costs associated with making this determination for existing products. As the commenter points out, making this determination for new products is lower because the BE status of ingredients is something that manufacturers do today as a matter of course. However there is no reason to believe that a product that is already on the market looked at the issue in as much detail as new products might. Manufacturers of existing products would therefore need to evaluate their ingredients and would be able to stop doing so as soon as they discovered an ingredient that caused the product to require disclosure. The fact that manufacturers may voluntarily subject themselves to costs beyond what the rule requires is not relevant to the RIA. Also, the RIA assumes that products that have obtained non-GMO project certification incur no costs as a result of this rule.

*Comment:* One commenter noted that the RIA makes many references to uncertainty in the estimates, and often provides upper and lower estimates to account for some level of uncertainty. The commenter goes on to note, however, that the RIA does not include a formal uncertainty analysis.

*AMS Response:* As noted by the commenter, in the RIA we provided upper and lower bound estimates where necessary to account for uncertainty. We incorporated more formal

uncertainty analysis where distributional information was available, such as for the estimates for printing and label design costs (the upper bound represents the 95<sup>th</sup> percentile of the distribution of costs estimated by FDA for its Labeling Cost Model while the lower bound represents the 5<sup>th</sup> percentile) and for the analytical testing costs for bioengineered ingredients (with lower bound estimate set at the 5<sup>th</sup> percentile of the cost distribution and the upper bound at the 95<sup>th</sup> percentile, as per FDA's Labeling Cost Model).

*Comment:* One commenter stated that for the most part, the RIA is based on quality data but that the supporting documentation for the RTI (FDA) labeling cost model was not available to the public.

*AMS Response:* AMS posted the description of the FDA Labeling Cost Model in the supporting documentation for the rule.

*Comment:* One commenter stated that OMB requires a discount rate of 0.2 percent and that because AMS used discount rates of three percent and seven percent, the discounting performed for the RIA was not properly conducted.

*AMS Response:* AMS used the discount rates specified in OMB Circular A-4 that are still commonly used for regulatory analysis. The 0.2 percent discount rate referenced in the comment is from OMB Circular A-94 and represents the cost of money to the Federal Government to be used in cost-effectiveness analysis of Federal projects, not the average before-tax rate of return to private capital in the U.S. that is appropriate for regulatory analysis.

## **VI. Rulemaking Analyses and Notices**

### *A. Paperwork Reduction Act*

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), AMS published a 60-day notice on reporting and recordkeeping requirements related to the proposed

NBFDS published in the Federal Register on May 4, 2018. AMS submitted a request to OMB on May 7, 2018, for approval for a new information collection totaling 7,973,566 hours. OMB subsequently assigned reference number 0581-0315 to the reporting and recordkeeping requirements. As part of the preparation of the final rule, AMS has recalculated the information collection estimates based on the final requirements of the NBFDS. Based on this, AMS is requesting approval of a new information collection totaling 20,512,720 hours. Comments received on the reporting and recordkeeping burden are referenced below.

*1. Comments on Information Collection and Recordkeeping*

AMS solicited comments concerning the information collection and recordkeeping required as a result of this rule. Specifically, AMS wanted to know if the proposed collection of information had a practical use and if the information would be needed for the agency to properly conduct its functions. AMS requested feedback regarding its estimate of the burden the proposed information collection and process would pose on businesses. The proposed rule also sought comments on ways to enhance the quality, utility, and clarity of the information to be collected, as well as ways to minimize the burden of the information collection on those required to respond.

*Comment:* Many commenters generally support the required collection of records to demonstrate compliance with the NFBDS, including the requirement for entities to maintain records for two years after a food's distribution for retail sale. Many commenters also agree that required records should rely on existing records that are customary, reasonable, and regularly kept and maintained in the ordinary course of business, and urge AMS to retain these principles in the final rule. One commenter asked for clarification on the rule's definition of "sufficient detail."

While many commenters support using the twelve categories of documentation AMS identified as appropriate to verify that foods are not bioengineered and not subject to disclosure, several have requested AMS offer flexibility in the types of records required to document BE status as long as the documentation can sufficiently prove that foods are not subject to mandatory disclosure. A few commenters suggest supplier documentation is the most important recordkeeping component since the disclosure requirement for finished products are based on how the component ingredients are derived. For foods subject to disclosure, some commenters believe that maintaining a record documenting the presence of BE ingredients should be sufficient.

Many commenters support AMS's decision to exempt foods certified under the National Organic Program from BE disclosure so manufacturers of these certified products would not be required to maintain additional records to demonstrate a certified product is not bioengineered. Similarly, a commenter suggests AMS should also exempt from disclosure any foods verified as "non-GMO" through commercial verification systems, like the Non-GMO Project, whose standards may meet or exceed the proposed BE standard. The commenter further suggests this type of verification suffices as records that establish a food or ingredient is not bioengineered. For other exempt foods --- such as those derived from animals fed BE food --- another commenter strongly agrees no records should be required from the entity producing these products.

Some commenters believe BE labeling requirements on BE products on the "highly adopted" or "not highly adopted" lists are appropriate and what Congress intended. These commenters also believe that, as proposed, the BE recordkeeping requirements inappropriately place the burden of proof on conventional food producers that have chosen not to use or produce

BE products. The commenters contend the expense, time and responsibility of additional recordkeeping should fall on the entities that use or produce BE products, not those who have chosen not to use BE products. As such, they suggest the rule provides for an alternate approach to the currently proposed recordkeeping burden. The new approach would allow AMS to challenge foods not properly labeled as BE.

Several commenters support the rule's requirement for imported foods to provide the same recordkeeping documentation as food produced domestically. According to this input, without such requirements, U.S. food manufacturers would be at a profound disadvantage to international food manufacturers. Another commenter suggests the rule may not need to require a mutual recognition agreement when a prior processing agreement exists between the U.S. and a foreign country, unless a BE ingredient is introduced to a product during processing in that foreign country. For example, when products are shipped to a foreign country for further processing, shipped back to the U.S. for secondary processing, and then sold in the U.S. market, the mutual recognition agreement would not be needed.

*AMS Response:* AMS appreciates the range of comments provided regarding recordkeeping requirements resulting from this rule and notes commenters generally support AMS's need to collect customary business records to establish a regulated entity's compliance with the NBFDS. AMS agrees that regulated entities may need flexibility in the types of records required to document compliance with the NBFDS. As such, AMS does not specify the records that must be maintained, but allows regulated entities discretion in determining what records will demonstrate compliance. AMS also notes that, for the purposes of this rule, any food manufacturer, importer or retailer offering for retail sale foods on the List of Bioengineered Foods is considered a regulated entity. Regulated entities must maintain records on foods that

trigger a BE disclosure and to verify food without a disclosure is not bioengineered. Section IV.A.1 further details AMS's position on recordkeeping.

*Comment:* Commenters suggest, in the final rule, AMS establish an exemption from the NBFDS for raw fruits and vegetables, consistent with the exemption in FDA's traditional nutrition facts panel (NFP) labeling requirements. Commenters contend labeling raw fruits and vegetables is not practical and would be burdensome to the regulated entities. They further explain fruits and vegetables of the same variety may be sourced from different suppliers and are often mixed together in large bins. As such, requiring BE disclosure for these unpackaged foods would be difficult and may lead to consumer confusion.

In addition, commenters suggest AMS should explore other methods of traceability similar to those used by major U.S. trading partners. Because highly refined products may not always have detectable modified genetic material, this input suggests AMS seek recordkeeping, reporting and compliance methods that validate a food's BE status based on the entire food production process that led to the final product's labeling.

*AMS Response:* AMS appreciates comments suggesting raw fruits and vegetables be excluded from the BE disclosure requirements. AMS believes that such an exemption would conflict with the statutory requirement that foods subject to FDCA's labeling requirements are subject to disclosure under the NBFDS. We also appreciate that some commenters would like AMS to explore other traceability methods to detect modified genetic material in highly refined products, thereby causing the products to be subject to BE disclosure. However, AMS believes that determinations about what constitutes BE food for the purposes of the NBFDS should focus on the characteristics of the biotechnology product and not on the process by which the product

is created. As such, highly refined products remain outside the scope of products subject to mandatory BE disclosure.

*Comment:* Many commenters did not specifically address accuracy of the estimated cost of compliance. A commenter averred prescriptive requirements such as the mandatory placement of disclosure text or symbol would add significant costs for label redesign or revamping of handling practices. The commenter suggests BE disclosure requirements remain adequately flexible to facilitate practical implementation.

*AMS Response:* AMS agrees that regulated entities may need some flexibility when determining the size and placement of a BE disclosure. The NBFDS allows flexibility for both. For further details regarding AMS's position on the appearance and placement of the BE disclosure, refer to Section III.A.3 and Section III.A.4 of this rule, respectively

*Comment:* Most commenters believe foods on or containing ingredients from either of the proposed lists of commercially available foods are BE or contain BE ingredients, thereby requiring no additional documentation. Many also believe AMS should not create recordkeeping requirements for foods not on nor containing ingredients from either list. Other feedback supports the proposed presumption foods on or containing ingredients from either list are BE or contain BE ingredients, unless the regulated entity maintains records to demonstrate non-disclosure is appropriate.

*AMS Response:* AMS agrees that regulated entities may be able to demonstrate compliance with the NBFDS for foods on or containing ingredients from the consolidated List of Bioengineered Foods using their customary business records. AMS contends that, for the purposes of this rule, any food manufacturer, importer or retailer offering for retail sale foods on the List of Bioengineered Foods is considered a regulated entity. As stated in an earlier

comment response, regulated entities must maintain records on foods that trigger a BE disclosure and must keep records to verify food without a disclosure is not bioengineered. Section IV.A.1 further details AMS's position on recordkeeping.

*Comment:* In the proposed rule, AMS provided flexibility to responsible record keepers by enabling use of multiple documentation sources. As such, several commenters asked that AMS incorporate examples of appropriate records into final rule text. Suggested examples include identity preserved (IP) certification, supplier affidavits, continuing guarantees, and statements from suppliers. Commenters also requested AMS clarify in the final regulation that appropriate records to support non-disclosure when foods contain ingredients from either list are not limited to testing results and should include traceability records. For example, if a regulated entity does not make a disclosure for a food containing a soy ingredient, it could maintain supplier records demonstrating non-BE soybeans were used in a product or records showing the soy ingredient accounts for less than 0.9% of total product weight. The commenter suggested that by recognizing traceability records are sufficient to support non-disclosure, AMS would help ensure recordkeeping requirements are consistent with records customary or reasonable to maintain in the food industry. The commenter contended food manufacturers generally do not maintain or receive from their suppliers testing records for ingredients or finished foods that demonstrate presence or absence of rDNA.

One commenter asserted AMS should clarify what "supplier attestations" refers to when regulated entities opt not to disclose under the rule, but choose to rely on such attestations. This input suggests "supplier attestations" is intended to refer to contractual documents, confirmations or other certifications entered into or provided by suppliers, and does not require buyers to

engage in supplier verification programs for a marketing rather than food safety standard which would impose significant costs and regulatory burdens.

Some commenters requested AMS clarify disclosure and recordkeeping requirements for foods included on the commercially available, but not highly adopted list, be more narrowly focused on cultivars directly the result of bioengineering. More specifically, several commenters highlighted the need for AMS to avoid consumer confusion and incorrect labeling of certain cultivated varieties of apples by clarifying correct application of the definition of cultivar.

A commenter urged AMS to adopt the 5% total BE food substance option in the final rule as the threshold for exempting foods from BE disclosure. Since records for BE status of ingredients, as well as amounts of any ingredients present in a food already exist as common business practice, this option would not present an excessive recordkeeping or cost burden on regulated entities.

*AMS Response:* AMS appreciates the range of comments offering ways to improve the information collection and recordkeeping processes. For information regarding recordkeeping flexibilities, see our responses to other comments in the Paperwork Reduction Act section. In addition, Section IV.A.1 further details AMS's position on recordkeeping.

*Comment:* Commenters generally support many of the proposed rule's recordkeeping and information collection requirements. Some, however, identified requirements that would pose undue burden on entities; others proposed ways AMS could minimize the burden. Several commenters proposed AMS simplify recordkeeping requirements for food manufacturers by establishing one consolidated list of BE foods. Some requested any information necessary for verification of compliance be limited to protect confidential business information like product formulations and recipes. Since organic food processors and manufacturers regularly secure

written verification from ingredient suppliers that highly refined sugars and oils are not derived from genetically engineered crops or organisms, commenters from that industry contend stakeholders across the food supply chain have already developed necessary recordkeeping systems to provide this type of verification regarding ingredients. Thus, including these types of ingredients under labeling disclosure requirements would not introduce new burdens or complications for the food industry.

Other commenters suggest it would be burdensome to require entities provide specific attestation or testing documentation from suppliers to confirm a highly adopted crop is BE based on merely being on the list of highly adopted, commercially available BE foods. Several other commenters believe 5 business days is not a reasonable timeframe for companies to produce records to AMS on the bioengineered status of a food/food ingredient; instead, they suggest AMS should provide businesses four to six weeks to respond to records requests. Some input explains the longer timeframe, consistent with FDA's Menu Labeling requirements, recognizes the Disclosure Standard is a marketing standard not requiring the priority of a health and safety concern. Another commenter states maintaining records for two years is burdensome for regulated entities, and suggests the final rule should establish a one year maintenance period as is the case for COOL.

Some commenters stated analytical testing to detect presence of modified genetic material would present undue financial burden on the industry and unnecessarily increase food prices without significantly increasing reliability of proof in support of non-disclosure. Such input encouraged AMS to allow recordkeeping to focus on traceability and segregation, rather than analytical testing. Another commenter states unless a "non-GMO"-type claim is made about a food or ingredient, manufacturers do not typically test for, nor maintain documentation

about, genetic material content. The testing is costly when performed and it is cost-prohibitive to buy equipment and hire skilled laboratory personnel for in-house testing. According to the commenter, screening tests, which are less expensive, are often unreliable or inappropriate for certain products.

If AMS decides to exempt refined ingredients from disclosure when they do not contain modified genetic material, one commenter suggests AMS establish and maintain a list of refined ingredients considered to be devoid of modified genetic material. This list would significantly reduce the burden on entities and eliminate the need for testing and maintaining documentation to demonstrate an ingredient is refined.

Some commenters believe AMS efforts to align effective date of this rule with compliance date for FDA's Nutrition Facts and Supplement Facts label final rule will have limited effectiveness in reducing cost and burden of this rule. In their view, implementation of this rule will require completely separate cost and burden.

Some commenters request the proposed rule not require complicated calculations to demonstrate if a food falls below the set threshold level to be maintained. The commenters further explain dairy manufacturers were subject to such requirements to demonstrate compliance with Vermont's disclosure law. According to commenters, these records were time-consuming and extremely burdensome to compile.

*AMS Response:* AMS appreciates the many comments submitted offering ways to minimize the recordkeeping burden resulting from this rule, and we have made changes to the final rule to reflect commenters input. We consolidated the List of Bioengineered Foods to simplify recordkeeping requirements. We agree that recordkeeping requirements under the NBFDS should align with those under other AMS programs to minimize the recordkeeping

burden on regulated entities, and we have provided recordkeeping flexibilities, as outlined in responses to previous comments in this section.

### *B. 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.

### *C. 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.

A 60-day comment period was provided to allow interested persons to respond to the proposed rule. All written comments received in response to the proposed rule by the date specified were considered. A number of commenters expressed concern that the proposed labeling options were discriminatory in some fashion. The major issue expressed was that the lack of a smart phone would inhibit older, more rural, poorer, and/or minority groups from being able to access bioengineering information that is not visible and available directly on the packaging. Some commenters argued that the USDA study, conducted by Deloitte, on access to bioengineering disclosures using electronic and digital link disclosures showed that the alternatives to on-package labeling (QR codes, website URLs, text messaging numbers, and other alternatives) will be ineffective and are discriminatory. A commenter cited a Pew

Research Center study from 2015 which purportedly shows that of the U.S. citizens owning a smartphone at the time, 23% had to cancel or suspend service due to financial constraints. The same study, being cited by the same commenter, is said to show that “African Americans and Latinos are around twice as likely as whites to have canceled or cut off their smartphone service.”

Other commenters argued that there are access problems even for those who have a smartphone. Some asserted that where stores don’t provide internet access, it could be difficult for people to access information provided by alternatives to on-package labeling. A commenter pointed to the 2015 Pew Research data alleging that African Americans have disproportionate functionality problems with smartphones, some of which is related to “running out of data during the month.” It was also pointed out that the Deloitte report showed certain tribal lands had limited broadband capabilities, thus preventing consumers in those areas from obtaining adequate access to the BE disclosure outside of on-package labels.

This final rule does not require regulated entities to alter their operations in ways that could adversely affect such persons or groups, in a discriminatory fashion. Although the electronic or digital disclosure option is mandated by the amended Act, the amended Act does not require regulated entities to utilize that disclosure option. Rather, the amended Act allows regulated entities to select a disclosure method from among several options (text, symbol, electronic or digital link, or text message). Regulated entities that select the electronic or digital disclosure option must also provide options for the consumer to access the BE disclosure, regardless of time of day, by calling a phone number. Requiring the electronic or digital disclosure to be accompanied by a telephone number that consumers may call to access the BE disclosure provides the disclosure in an accessible manner. Accordingly, this final rule offers

several distinct avenues of compliance for regulated entities that can be catered to the needs of their consumers. Applying this approach does not deny any persons or groups the benefits of the program or subject any persons or groups to discrimination.

*D. 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 NBFDS would range from \$569 million to \$3.9 billion for the first year, with ongoing annual costs of between \$51 million and \$117 million. The annualized costs in perpetuity would be \$68 million to \$234 million at a three percent discount rate and \$91 million to \$391 million at a seven percent discount rate.

These cost estimates represent the cost of the standard relative to a baseline in which there are no requirements for the labeling of food containing bioengineered foods or ingredients.

The 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 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 annualized net benefit from replacing the

Vermont BE labeling law would be between \$40 million and \$49 million at a three percent discount rate and between \$70 million and \$84 million at a seven percent discount rate. This is our best estimate of these potential benefits, but we note that there is uncertainty in these estimates given the difficulty in predicting how implementation of the Vermont BE labeling law would have occurred absent the prospect of a national labeling law.

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).

The status of the rule under Executive Order 13771 depends on its costs relative to the regulatory requirements that would have applied to the regulated community before enactment of the new Federal standard. The analysis presented here finds that in comparison to a state-level approach to mandatory BE labeling, the NBFDS would impose less cost on the regulated community and would therefore be deregulatory. While acknowledging the uncertainties associated with estimating the magnitude of the actual reduction in costs, we use the midpoint of the estimated net benefits as an approximation of the primary estimate of annualized savings in perpetuity. This results in an estimated annual savings of \$77 million using a discount rate of seven percent (\$45 million using a discount rate of three percent).

## *E. Final Regulatory Flexibility Analysis*

### *1. Introduction*

We have examined the economic implications of this 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 concluded that the rule will not have a significant economic impact on a substantial number of small entities.

### *2. Economic Effects on Small Entities*

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. Under SBA's definition of small firms within the each 6-digit NAICS code 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 potentially affected manufacturers now classified as small is 96 percent (26,213 out of 27,176 total manufacturing firms).

### *3. Definition of Small Business*

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

### *4. Coordination of Definition of Small Food Manufacturers with FDA Definition*

For the purposes of the implementation of the delay for “small food manufacturers,” AMS proposed 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 definition of *small food manufacturer* is “any food manufacturer with annual receipts of at least \$2,500,000, but less than \$10,000,000.” 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).

The final rule maintains this definition of *small food manufacturer*.

This maintains consistency between the NBFDS and the FDA nutrition labeling requirements. The delay provided to small food manufacturers applies only to the initial compliance date. Where the final rule provides additional time to use up existing label stock the deadline for exercising this additional flexibility is the same for all manufacturers regardless of size.

#### 5. *Exemptions for Very Small Food Manufacturers*

AMS proposed 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 presents data showing the number of establishments by size classification according to the different definitions of very small, small, and large manufacturers.

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
<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

#### 6. Costs to Small Entities

We compared the maximum annualized cost in our analysis of the rule to the revenue of firms in each size category (by receipts) using 2012 Census data. There was no covered size category of firms for which costs were greater than one percent of revenues.

#### 7. Summary

Under the Regulatory Flexibility Act (5 U.S.C. 606(b)), we conclude that the rule will not 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.

#### F. 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.

AMS has assessed the impact of this rule on Indian tribes and determined that this rule would not, to our knowledge, have tribal implications that require tribal consultation under E.O. 13175. AMS hosts a quarterly teleconference with Tribal Leaders where matters of mutual interest regarding the marketing of agricultural products are discussed. Information about the congressionally mandated NBFDS was shared during those quarterly calls, and Tribal leaders were invited to provide input into the development of the new national Standard. As well, in the NPRM that was published on May 4, 2018 (83 FR 19860), AMS invited Tribal Leaders to consult on the Tribal implications of the proposed rule. AMS received no requests for a consultation. On June 21, 2018, AMS hosted a quarterly conference call with Tribal representatives to update them on upcoming policies, regulations, programs, and services that could have a substantial effect on or benefit to Tribes. During the call, AMS provided fourteen (14) Tribal representatives with an overview of the proposed rule and extended opportunities for questions or requests for more information. At that time, none were expressed.

On July 3, 2018, the comment period for the proposed rule closed. None of the approximately 14,000 responses received on the NPRM were identified as being submitted from Tribal representatives. AMS did receive public comments in response to the NPRM's request for input about the use of electronic or digital disclosures to convey information about bioengineered food content to consumers. Commenters asserted that Native Americans, along with elderly Americans and other U.S. minority populations, may lack adequate access to

smartphone technology that would enable them to use electronic or digital disclosures. The Secretary acknowledged this potential lack and determined to provide a comparable bioengineered food disclosure option to allow greater access to food information for all consumers. Such provision is made in § 66.108 of the final rule.

Based on the above, AMS has concluded that this final rule will not have Tribal implications that require a consultation. In implementing the final rule, AMS will develop and deliver outreach and education for and to all regulated entities. In addition, AMS will work with the Office of Tribal Relations to ensure ongoing meaningful consultation is provided, where needed or requested. If a tribe requests consultation, AMS will work with the USDA Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions, and modifications identified herein are not expressly mandated by Congress.

#### *G. Executive Order 12988*

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. The final 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 national bioengineered food disclosure standard that is not identical to the mandatory disclosure requirements under that 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.

#### *H. 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.

Upon establishment of 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/be>.

#### **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, 7 CFR chapter I is amended 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.
- 66.6 List of Bioengineered Foods.
- 66.7 Updates to the List of Bioengineered Foods.
- 66.9 Detectability.
- 66.11 Severability.
- 66.13 Implementation and compliance.

### **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.
- 66.109 Required disclosure with actual knowledge.
- 66.110 Small food manufacturers.
- 66.112 Small and very small packages.
- 66.114 Food sold in bulk containers.
- 66.116 Voluntary disclosure.
- 66.118 Other claims.

### **Subpart C – Other Factors and Conditions for Bioengineered Food**

- 66.200 Request or petition for determination.
- 66.202 Standards for consideration.
- 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:

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

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

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

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

(ii) [Reserved]

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

*Compliance date* means--

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

(2) *Updates to the List of Bioengineered Foods*. When AMS updates the List of Bioengineered Foods pursuant to §66.7, entities responsible for bioengineered food disclosures must comply with the updates no later than 18 months after the effective date of the update.

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

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

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

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

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

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

- (1) Upon any article or any of its containers or wrappers; or
- (2) Accompanying such article.

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

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

*Predominance* means an ingredient's position in the ingredient list on a product's label. Predominant ingredients are those most abundant by weight in the product, as required under 21 CFR 101.4(a)(1).

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

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

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

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

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

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

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

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

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

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

### **§ 66.3 Disclosure requirement and applicability.**

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

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

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

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

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

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

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

### **§ 66.5 Exemptions.**

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

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

(b) Very small food manufacturers.

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

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

(e) Food certified under the National Organic Program.

#### **§ 66.6 List of Bioengineered Foods.**

The List of Bioengineered Foods consists of the following: alfalfa, apple (Arctic<sup>TM</sup> varieties), canola, corn, cotton, eggplant (BARI Bt Begun varieties), papaya (ringspot virus-resistant varieties), pineapple (pink flesh varieties), potato, salmon (AquAdvantage®), soybean, squash (summer), and sugarbeet.

#### **§ 66.7 Updates to the List of Bioengineered Foods.**

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

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

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

(3) AMS will post public recommendations on its website, along with information about other revisions to the List that the agency may be considering, including input based on consultation with the government agencies responsible for oversight of the products of biotechnology: USDA's Animal and Plant Health Inspection Service (USDA-APHIS), the U.S. Environmental Protection Agency (EPA), and the Department of Health and Human Services'

Food and Drug Administration (FDA), and appropriate members of the Coordinated Framework for the Regulation of Biotechnology or a similar successor.

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

(5) If AMS determines that an update to the List is appropriate following its review of all relevant information provided, AMS will modify the List.

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

#### **§ 66.9 Detectability.**

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

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

*or*

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

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

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

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

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

- (1) Laboratory quality assurance must ensure the validity and reliability of test results;
- (2) Analytical method selection, validation, and verification must ensure that the testing method used is appropriate (fit for purpose) and that the laboratory can successfully perform the testing;
- (3) The demonstration of testing validity must ensure consistent accurate analytical performance; and
- (4) Method performance specifications must ensure analytical tests are sufficiently sensitive for the purposes of the detectability requirements of this part.

#### **§ 66.11 Severability.**

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

#### **§ 66.13 Implementation and compliance.**

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

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

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

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

## **Subpart B – Bioengineered Food Disclosure**

### **§ 66.100 General.**

(a) *Responsibility for disclosure.* (1) For a food that is packaged prior to receipt by a retailer, the food manufacturer or importer is responsible for ensuring that the food label bears a bioengineered food disclosure in accordance with this part.

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

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

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

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

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

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

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

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

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

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

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

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

#### **§ 66.102 Text disclosure.**

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

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

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

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

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

#### **§ 66.104 Symbol disclosure.**

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

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

(b) If a food (including any ingredient produced from such food) is on the List of Bioengineered Foods, and records maintained by a regulated entity demonstrate that the food is

bioengineered, or do not demonstrate whether the food is bioengineered, the symbol disclosure must be the following:

Figure 1 to § 66.104



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

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

#### **§ 66.106 Electronic or digital link disclosure.**

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

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

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

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

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

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

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

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

**§ 66.108 Text message disclosure.**

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

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

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

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

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

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

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

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

**§ 66.109 Required disclosure with actual knowledge.**

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

**§ 66.110 Small food manufacturers.**

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

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

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

**§ 66.112 Small and very small packages.**

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

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

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

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

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

**§ 66.114 Food sold in bulk containers.**

(a) Bioengineered food sold in bulk containers (e.g., display case, bin, carton, and barrel), used at the retail level to present product to consumers, including a display at a fresh

seafood counter, must use one of the disclosure options described in § 66.102, § 66.104, § 66.106, or § 66.108.

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

**§ 66.116 Voluntary disclosure.**

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

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

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

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

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

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

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

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

(2) A symbol disclosure using the following symbol:

Figure 1 to § 66.116



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

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

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

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

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

**§ 66.118 Other claims.**

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

### **Subpart C – Other Factors and Conditions for Bioengineered Food**

#### **§ 66.200 Request or petition for determination.**

(a) Any person may submit a request or petition for a determination by the Administrator regarding other factors and conditions under which a food is considered a bioengineered food. A request or petition must be submitted in accordance with § 66.204.

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

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

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

#### **§ 66.202 Standards for consideration.**

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

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

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

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

**§ 66.204 Submission of request or petition.**

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

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

(1) Description of the requested factor or condition.

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

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

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

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

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

## **Subpart D - Recordkeeping**

### **§ 66.300 Scope.**

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

### **§ 66.302 Recordkeeping requirements.**

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

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

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

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

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

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

**§ 66.304 Access to records.**

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

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

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

**Subpart E - Enforcement**

**§ 66.400 Prohibited act.**

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

**§ 66.402 Audit or examination of records.**

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

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

- (i) Complete identifying information about the product in question;
- (ii) A detailed explanation of the alleged regulatory violation; and
- (iii) Name and contact information of the person filing the statement or complaint.

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

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

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

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

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

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

#### **§ 66.404 Hearing.**

(a) Within 30 days of receiving the results of an audit or examination of records or similar activity to which the entity that was the subject of the investigation objects, the entity

may request a hearing by filing a request, along with the entity's response to the findings and any supporting documents, with AMS.

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

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

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

**§ 66.406 Summary of results.**

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

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

Dated: December 12, 2018.

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Erin Morris,

Associate Administrator.

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