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 February 19, 2019.

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).

Outline of the Final Rule

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."[1] 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. 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,

[1] 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.

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),[2] FDA's list of Biotechnology Consultations on Food from GE Plant Varieties (Consultations), and information published by USDA's Economic Research Service (ERS).[3] 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*,[4] 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,[5] to determine what crops and foods currently meet those criteria. The List attempts to 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

[2] 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.

[3] 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.

[4] Statistics Canada, *https://www.statcan.gc.ca/eng/start,* accessed July 26, 2018.

[5] ISAAA GM Approval Database: *http://www.isaaa.org/gmapprovaldatabase/.* Accessed August 10, 2018.

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.