



July 3, 2018

United States Department of Agriculture
Agricultural Marketing Service
Docket Clerk
1400 Independence Avenue, SW
Room 4543 - South
Washington, DC 20250

Submitted via www.regulations.gov

RE: Proposed Rule – National Bioengineered Food Disclosure Standard – Doc. No. AMS-TM-17-0050
83 Fed. Reg. 19860 (May 4, 2018)

Dear Sir/Madam:

The Coalition for Safe, Affordable Food (“the Coalition”) thanks the U.S. Department of Agriculture (“USDA”) and its Agricultural Marketing Service (“AMS” or “Agency”) for the opportunity to provide feedback on this proposed rule. Its publication is a critical step towards establishing a National Bioengineered Food Disclosure Standard (“NBFDS”), and we encourage the administration to act prudently but expeditiously to promulgate a final rule.

The Coalition is comprised of numerous national, state, and local organizations representing the entire American food and agriculture value chain – from farm to fork – and is committed to increasing the public’s understanding about the science and safety of bioengineered (“BE”) foods and advocating for science-based policies that keep food safe, abundant, and affordable for every American. The Coalition was actively engaged in support of the National Bioengineered Food Disclosure Act (“the Act”) and, through these comments, continues to support Congress’ mandate for the establishment of a uniform national disclosure standard for bioengineered food to prevent a patchwork of state-by-state (or other governmental subdivision) food labeling requirements that would have caused tremendous consumer confusion, significantly disrupted supply chains, and imposed unnecessary costs on U.S. consumers, farmers, and manufacturers estimated to be in the range of \$97.3-129.7 billion dollars.

The Coalition has carefully studied the proposed requirements and procedures, alternatives that are offered, and specific questions that are raised for comment by USDA-AMS and is pleased to present responses on a broad range of topics critical to the successful implementation of the Act. Based on various elements of the USDA-AMS proposal, the Coalition has developed an alternative approach that, together with the Coalition’s responses on the topics raised in the proposal, are aimed at assisting USDA-AMS with fulfilling the multiple goals of the Act, shared by the Coalition, which include giving

consumers access to information about the food they purchase; providing consumers with continued access to an abundant, safe, affordable, and sustainable food supply; ensuring that farmers and ranchers have access to the technologies they need to feed a growing world population; providing certainty to food manufacturers, retailers, and others in the supply chain, and consistency and transparency to customers; while respecting the strong scientific consensus on the safety of bioengineered food and, relatedly, preserving Congress' intention that the Agency implement a disclosure standard for marketing purposes, and not based on health, safety, or nutrition. Because the Coalition represents all segments of the U.S. food value chain with a broad range of interests and perspectives, individual Coalition members, as they find necessary, are filing comments on the specific issues that are a priority for their members, including on issues associated with mandatory refined ingredient disclosure, thresholds, and voluntary disclosure, where individual members have diverging views. However, recognizing that not every member's preference may be reflected in the final rule, the comments that follow are intended to reflect a workable, market-oriented alternative approach to disclosure.

As the rulemaking process proceeds, the Coalition remains available to engage with USDA-AMS as appropriate to reiterate its support for these goals and to provide additional input and comment.

Sincerely,

Agricultural Retailers Association
American Bakers Association
American Beverage Association
American Farm Bureau Federation
American Feed Industry Association
American Frozen Food Institute
American Seed Trade Association
American Soybean Association
American Sugarbeet Growers Association
Biotechnology Innovation Organization
Calorie Control Council
Corn Refiners Association
CropLife America
Food Marketing Institute
Global Cold Chain Alliance
Grocery Manufacturers Association
Institute of Shortening and Edible Oils
International Food Additives Council
International Foodservice Distributors Association
National Association of State Departments of Agriculture
National Association of Wheat Growers
National Black Growers Council
National Corn Growers Association
National Cotton Council
National Council of Farmer Cooperatives
National Grain and Feed Association
National Grocers Association
National Milk Producers Federation

National Oilseed Processors Association
National Potato Council
North American Millers' Association
SNAC International
The Vinegar Institute
U.S. Beet Sugar Association
U.S. Canola Association
United Fresh Produce Association

Attachment

ATTACHMENT

Response of the Coalition for Safe, Affordable Food to USDA-AMS Proposed Rule Doc. No. AMS-TM-17-0050, 83 Fed. Reg. 19860 (May 4, 2018)

For ease of reference, the Coalition's comments on the issues and options raised by USDA-AMS generally follow the outline in the preamble to the proposed rule.

I. OVERARCHING PHILOSOPHY TO BE APPLIED TO THE RULE

The Coalition agrees that the focus of the final rule should be to establish a workable marketing standard, the NBFDS, for disclosure of BE information. The Coalition supports preserving the ability of food companies to voluntarily disclose information above and beyond what is required by the federal standard where that information is consistent with applicable federal law. Further, the Coalition agrees that the NBFDS should be a uniform national standard sufficient to ensure that federal preemption is maintained in accordance with USDA-AMS's statutory mandate.¹

II. APPLICABILITY

A. Definitions

Refined Ingredients. Because the term "highly refined" in describing food ingredients and products is an inaccurate and poorly framed term for use in conjunction with the NBFDS, the Coalition urges USDA-AMS to use the more accurate term "refined" when describing ingredients and products instead. We provide further comments on refined ingredients in the next section of our comments.

Bioengineering. The statutory definition of the term "bioengineering" refers 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." The following recommendations are intended to clarify the use of certain key terms in the definition of "bioengineering."

Conventional Breeding. The Coalition supports inclusion of a definition to clarify "conventional breeding" in the final rule. Modern plant and animal breeding encompasses an evolving set of scientific disciplines and enabling methods that produce more effective breeding outcomes. Any discussion of breeding techniques that attempts to define or delimit "conventional breeding" should recognize this ongoing, continual progression of breeding methods. What is considered "new" today may be deemed conventional or traditional in the future but does not result in fundamentally different breeding outcomes. This is consistent with the Act's bipartisan Senate Report that directed the NBFDS to "be technology neutral and reflect technological changes over time."² However, we recognize that there is value in providing clarification around the terms used in the statutory definition of "bioengineering."

In order to accomplish this clarification it will be necessary to address what is meant by a modification that "could not otherwise be obtained through conventional breeding." We recommend that USDA-AMS do so by providing a definition for those modifications that could be obtained through

¹ The Act amended the Agricultural Marketing Act of 1946, 7 U.S.C. § 1621 et seq.

² S. Rep. No. 114-403 ("Senate Report") at 4 (2016).

conventional breeding together with a non-exhaustive set of examples of resulting modifications that describe an organism's potential genetic variability within its inherently diverse gene pool. USDA-AMS should avoid a static listing of current breeding techniques because any such list would ignore the constantly evolving science and hinder development of future enabling technologies that make the improvement of our food supply more efficient to accomplish. We would also propose that USDA-AMS provide further guidance through explanatory text in the preamble to the final rule. Our suggested definition and explanatory text follow.

"Modifications that could be obtained through conventional breeding" refers to a wide range of modifications obtained through methods that use an organism's potential genetic variability within its gene pool, such as, but not limited to, induced mutagenesis, somaclonal variation, induced haploidy, marker assisted breeding, and other methods that enable movement of existing genetic material between related organisms, such as, but not limited to, breeding crosses within the species, wide and bridging crosses, cell fusion, and embryo rescue.

Suggested Explanatory Text:

The goals of breeders have always been to create new variations of plant or animal characteristics, to provide solutions for diseases and pests, to increase tolerance to environmental stress, to improve quality and yields, and to meet consumer expectations. Breeding depends upon genetic variability within and across related species as a basis for developing new plant and animal varieties with improved traits. Breeders use this genetic variability to create new varieties through the movement of genetic material between different varieties within species, between closely related species, or closely related genera. They utilize a range of breeding methods in the process, such as wide crosses, bridging crosses, and embryo rescue. Breeders can also use in vitro generated nucleic acids to recreate or "mimic" many molecular changes or genetic variations that occur naturally or via conventional breeding. Plants and animals bred using these methods do not contain a transgenic insertion and, therefore, would not meet the definition of "bioengineered" under the statute and are not subject to mandatory disclosure.

Regarding microbes, the concepts of "breeding techniques" and "conventional breeding" have limited applicability, especially with respect to methods for genetically modifying microbes that are food, that produce molecular substances added to food, or that carry out biological processes used in food production and processing. Over many decades, a wide array of methodologies, all derived from or based upon natural microbial methods of genetic modification, have been used to change the prokaryotic and eukaryotic microbes used in the manufacture of food and food ingredients. These methodologies are viewed as "conventional" because of their long history of safe use in many common foods. Over time, these methods have been altered and improved, and these improvements will continue as more is learned about microbial molecular genetics. Each of these methods should be considered "conventional breeding" under the Act and products resulting from these techniques would not be subject to mandatory disclosure.

Found in Nature. The Coalition proposes that USDA-AMS include a definition for “found in nature” in the final rule and provide further guidance through explanatory text in the preamble to the final rule. Our suggested definition and explanatory text follow.

“Found in nature” refers to the kinds of genetic modifications which can occur in nature within the genome of an organism, without human intervention.

Suggested Explanatory Text:

Examples of such genetic modifications found in nature include, but are not limited to, deletions, insertions, substitutions, duplications, and translocations of genetic sequences within the organism’s own genome. Changes can vary from single nucleotides to whole genes or larger segments of genetic material. Such modifications can occur through a variety of natural processes, including, but not limited to: crossing over in meiosis and sexual reproduction; microbial conjugation, transformation and transduction; transposon activity; horizontal gene transfer; and spontaneous gene mutations in somatic and germline cells.

In vitro recombinant DNA techniques can also be used to “mimic” the end points of various types of changes to genes that occur in nature, independent of human intervention including, but not limited to, crossing over in meiosis and sexual reproduction; microbial conjugation, transformation and transduction; transposon activity; horizontal gene transfer; and spontaneous gene mutations in somatic and germline cells. These are the types of techniques that would result in modifications that could “otherwise be found in nature” and the resulting food products would not be considered BE and would not be subject to disclosure under the NBFDS. When in vitro recombinant DNA techniques are used to create combinations of genetic elements that could not “otherwise be found in nature,” food products containing these constructs would be considered BE and subject to mandatory disclosure under the NBFDS, unless otherwise excluded.

The Coalition recommends against an approach that would rely on intellectual property protections as a method in determining whether a modification could not otherwise be found in nature. As a threshold matter, whether a bioengineered trait is patentable (i.e., is a natural product but not a product of nature) is a distinct and completely separate question from whether the trait could be found in nature. That said, even if the tests were analogous, there is much uncertainty in the state of patent law and biotechnology such that guidance from the U.S. Patent and Trademark Office on the issue would be of little help.

Comments on additional definitions are included under the heading of Bioengineered Food below. For purposes of clarity and to avoid any potential confusion regarding applicability, the Coalition recommends that Section 66.1 begin with a statement that “As used in this part, the following terms shall have the meanings set forth below.”

B. Food Subject to Disclosure

The Coalition agrees with the explanation provided by USDA-AMS regarding the statutory scope of “food” for purposes of the NBFDS and with the proposed use of the same methods used by the Food and Drug Administration (“FDA”) to identify predominance of ingredients in food.

C. Bioengineered Food

The Coalition has developed an alternative approach to the identification of the food products that would be subject to the NBFDS. The various elements of that approach are discussed in this section, including an explanation of the reasons why the proposal has the support of the Coalition. In keeping with the Congressional directives in the bipartisan Senate Report, this approach is designed to adhere to the intent of the statute while at the same time reducing compliance costs for regulated entities and providing the most efficient administrative process for USDA-AMS³ resulting in benefits for all parties concerned, including the consumer.

Because the Coalition represents all segments of the U.S. food value chain with a broad range of interests and perspectives, individual Coalition members, as they find necessary, are filing comments on the specific issues that are a priority for their members, including on issues associated with mandatory refined ingredient disclosure, thresholds, and voluntary disclosure, where individual members have diverging views. However, recognizing that not every member's preference may be reflected in the final rule, the comments that follow are intended to reflect a workable, market-oriented alternative approach to disclosure.

1. Definition of "Bioengineering" and "Bioengineered Food"

The Coalition supports incorporation of the statutory definition of "bioengineering" into the final rule, as suggested by USDA-AMS in the proposed rule.

The Act expressly prohibits "food derived from an animal to be considered a bioengineered food solely because the animal consumed feed produced from, containing, or consisting of a bioengineered substance."⁴ This exclusion is unequivocal and should be adopted as an exclusion from the definition of bioengineered food.

Recognizing that states that had passed labeling mandates provided exceptions for a range of food products, the bipartisan Senate Report encourages USDA-AMS to clarify exclusions from the definition of a bioengineered food. These clarifications to the definitional exclusions would be included in the rule, but would not be subject to decisions made under the formal "factors and conditions" process outlined by USDA-AMS in its proposed rule. The Coalition agrees and, to the extent these products would otherwise be subject to mandatory disclosure, urges USDA-AMS to exclude food products and ingredients including but not limited to:

- Incidental additives, processing aids, secondary direct additives;
- Food derived from insects or microorganisms that grow or feed on a bioengineered substrate, such as a bioengineered crop or other substance;
- Enzymes;

³ See, e.g., Senate Report at 7-8.

⁴ Section 293(b)(2)(A), 7 U.S.C. § 1639b(b)(2)(A).

- Ingredients derived via fermentation regardless of whether the microorganisms used in the fermentation are derived using rDNA technology;
- Food products for medicinal or dietary supplementary applications.

For the reasons stated by USDA-AMS in the preamble to the proposed rule, the Coalition agrees that the rule should expressly exclude from the definition of “bioengineered food” any “incidental additive present in food at an insignificant level and that does not have any technical or functional effect in food, as described in 21 CFR 101.100(a)(3) or any successor regulation.” While the definition of incidental additives encompasses processing aids and secondary direct additives, the Coalition urges USDA-AMS to expressly add processing aids and secondary direct food additives that may come from a bioengineered source material to the exclusion to avoid any uncertainty about the scope of the excluded substances. Non-exclusive examples of processing aids include carriers for flavor components and substances that have a functional role in ingredients but no function in the final product. By their very definition, processing aids, incidental additives, and secondary direct additives are present at insignificant levels in the finished food and have no technical or functional effect in that food. For that reason, as USDA has acknowledged, FDA regulations do not require the declaration of processing aids or incidental additives in the ingredient statement on food labels. Therefore, their use in processing is not material to whether the finished food is bioengineered. Indeed, the EU recognizes that processing aids are outside of the scope of the EU’s GMO disclosure regulation. Similar to processing aids and incidental additives, a secondary direct food additive has a technical effect in food during processing, but not in the finished food.

These exclusions will simplify compliance and reduce costs and burdens for regulated entities in the food value chain, without undermining the intent of the statute. The reliance on the FDA’s exemptions from inclusion in the ingredient statement on a food label is also consistent with the linkage between Act’s definition of “food” and the definition of “food” in the Federal Food, Drug, and Cosmetic Act (“FFDCA”)⁵ and with the Congressional directive to limit the disclosure requirement under the NBFDS “only to those foods subject solely to the labeling requirements under the [FFDCA].”⁶ Moreover, these exclusions address the provisions in the Senate Report directing USDA-AMS to ensure consistency with other regulatory requirements and definitions and to minimize the impacts of the NBFDS on processors and manufacturers, among others, and ultimately on costs to the consumer.⁷

The Coalition also urges USDA-AMS to use its authority to exclude the following food products from the definition of a bioengineered food, to the extent these products would otherwise be subject to mandatory disclosure, solely because of the below-described characteristics:

- Food derived from animals, insects, or microorganisms that grow or feed on a bioengineered substrate, such as a bioengineered crop or other substance or ingredients derived from such a crop or substance. Non-exclusive examples of such foods include meat, milk, eggs, honey, alcohol, amino acids, citric acid, and vinegar.

⁵ Section 291(2), 7 U.S.C. § 1639(2).

⁶ Senate Report at 3.

⁷ See Senate Report at 2, 4, 7 and 8.

- Food derived from animals treated with bioengineered animal drugs and pharmaceuticals.
- Food ingredients derived by the chemical transformation of materials directly obtained from a bioengineered crop. Non-exclusive examples include caramel flavoring and color, vitamin C, and sugar alcohols.
- Food produced from microbially-derived products, including fermentation products, regardless of whether rDNA technology is used in the development of the microorganism. Non-exclusive examples of such products used in food include ingredients such as enzymes, vitamins, alcohol, amino acids, citric acid, and vinegar.

The Coalition supports the application of the definition of “bioengineering” to future technologies, the same as it is applied to existing technologies.⁸ The Coalition agrees that the procedures used by USDA-AMS in reviewing new technologies should be designed to ensure that foods resulting from a new technology would be consistent with the statutory definition of “bioengineering” and commercially available and that an opportunity for notice and comment should be provided prior to any listing of foods from new technologies as BE foods.

2. Lists of Bioengineered Foods

BE Source List and Excluded Ingredients List

As an essential element of its proposed alternative approach, the Coalition supports having a single “BE Source List” that is not based on an adoption rate. Entries on the BE Source List should be made with as much specificity as possible, so as to prevent an entire commodity from being considered BE if only a certain type is BE, e.g., through identification by brand name of varieties of commodities grown in a closed-loop system that are not intended to be included in the general commodity stream. An example would be listing “Summer Squash” as opposed to the entire commodity “squash.” This list would include those BE food crops that have satisfactorily completed applicable federal reviews and are currently in commerce in the form of a human food product, as well as a listing for BE animals that meet these criteria. Additionally, a second “Excluded Ingredients List” would identify food ingredients and other food products for which it has been demonstrated that they do not contain modified genetic material and, therefore, would not be subject to the disclosure requirements of the NBFDS rule. The Coalition also recommends specific science-based and other fact-based criteria that will ensure certainty, pre-decision transparency, and durability of both lists.

The Coalition’s alternative proposal establishes a transparent process for parties to request placement of refined ingredients or other food products on the Excluded Ingredients List where modified genetic material is not present in excess of a de minimis level. Products on this list would be excluded from mandatory disclosure. Initially, such determinations would be made by the AMS Administrator (“Administrator”) prior to publishing the BE Source List and Excluded Ingredients List in conjunction with the final rule. These initial determinations of exclusions would be based on information already available to AMS, as well as information submitted by individual Coalition members and other regulated parties with their comments on the proposed rule. The final rule, accompanied by initial BE Source and Excluded Ingredients Lists, will set out the process mentioned above for interested parties to request

⁸ See Senate Report at 4.

the Administrator to modify the lists based on the specified criteria. For ingredients placed on the initial Excluded Ingredients List, no subsequent requests would be required to maintain those listings.

Ingredients may be added to the Excluded Ingredients List as ingredient characteristics warrant based on USDA-AMS review of a request addressing the ingredient, its means of production, and the absence of genetic material. This would provide clarity to the food industry and consumers and would help minimize the burden of compliance with the new requirements. The final rule should provide that a regulated entity, or group of regulated entities (e.g., an association), may submit to USDA-AMS a request demonstrating that a food product or ingredient as a class and its derivatives does not contain modified genetic material in excess of a de minimis level, including records demonstrating testing conducted via a method that has been performed by a laboratory accredited under ISO/ICE 17025:2017.

The Coalition recommends that USDA-AMS utilize a protocol that allows regulated entities to have a firm understanding of the process that is to be followed for maintaining the Excluded Ingredients List, including the types and breadth of samples, testing, etc. required to establish absence of genetic material.

In the proposed rule, USDA-AMS suggests that for ingredients to be deemed “highly refined ingredients” or, as the Coalition proposes, “refined ingredients” not subject to mandatory disclosure, regulated entities would be required to demonstrate that “genetic material cannot be detected.” The proposed rule’s undetectable standard may be construed as establishing “absolute zero” as the standard for disclosure of refined ingredients, which would impose substantial regulatory burden due to significant substantiation difficulty based on the inherent nature of test methods having established “analytical/detectable zero” criteria, not absolute zero. Instead, the Coalition recommends that the final rule establish a “de minimis” level of recombinant DNA (rDNA) at or below which ingredients qualify as refined ingredients not subject to mandatory disclosure. The Coalition recommends that the “de minimis” level be set at the generally recognized level of detection of 0.1% rDNA. Specifically, the Coalition recommends that the final rule specify that ingredients qualify as refined ingredients not subject to mandatory disclosure if rDNA is at or below a “de minimis” level set at 0.1%, as measured by the relative proportion of rDNA compared to total DNA using a standard DNA control.

The Coalition acknowledges that 0.1% is below the level of rDNA detection in some ingredients and, therefore, recommends that on a case-by-case basis USDA-AMS consider adding such ingredients to the Excluded Ingredients List based on a request that demonstrates rDNA is undetectable in that ingredient at “the limit of detectability of modified rDNA as determined by results developed and practiced in accordance with the ISO/ICE 17025:2017 standard, using methodology validated according to Codex Alimentarius guidelines.”

By establishing a “de minimis” level for refined ingredients, the rule would avoid the regulatory burden associated with an on-going search to substantiate zero genetic material in various ingredients and the regulatory uncertainty that may accompany advances in scientific methods. Many European countries have adopted a “technical zero” of 0.1% rDNA. This adoption is a result of many sources recognizing a common limitation in detection and quantitation when the overall content is below 0.1%. This burden-reducing strategy is particularly appropriate in this rulemaking where the statute expressly requires a threshold for disclosure and where disclosure is not a matter of public health relevance.

Further, the proposed rule indicates that testing for presence of genetic material would need to be conducted “by a laboratory accredited under ISO/ICE 17025:2017 standards, using methodology validated according to Codex Alimentarius guidelines.” The Coalition supports this proposed framework for standardized laboratory accreditation and rigorous analytical method validation for determining the presence of rDNA.

Should USDA-AMS believe a “de minimis” level not to be appropriate, USDA-AMS should allow and define undetectable rDNA to mean “the level below the limit of detectability of modified rDNA as determined by results developed and practiced in accordance with the ISO/ICE 17025:2017 standard, using methodology validated according to Codex Alimentarius guidelines.” The final rule should clearly state that test methodology in accordance with the ISO/ICE 17025:2017 standard and accreditation (specific to rDNA/PCR testing) is required to validate or challenge presence of modified rDNA in an ingredient whether or not the level of its presence is at a uniform “de minimis” level or the limit of detection determined by each tested ingredient. We submit that failure to require use of an appropriate validated and accredited methodology to detect modified genetic material in an ingredient would add significantly to USDA-AMS’s burden in administering the rule and could undermine the scientific integrity of rule administration.

Beyond this proposed framework, the Coalition also encourages USDA-AMS to provide expectations regarding PCR (polymerase chain reaction) testing, as PCR has become the standard analytical tool used for the detection, identification, and quantification of specific DNA sequences, including rDNA. Specifically, the Coalition requests that USDA-AMS establish minimal standards for selecting appropriate PCR primers for each and any rDNA event that would be subject to the definition of bioengineering.

In regards to timing, the Coalition recommends that AMS communicate with stakeholders, via a Federal Register Notice, its anticipated timing for finalizing the initial Excluded Ingredients List and the deadline for regulated entities to submit any additional requests. The Coalition recommends that USDA-AMS have 6 months after the final rule is published to update the initial Excluded Ingredients List published with the final rule. Further, the Coalition proposes that, during that 6-month period, regulated entities have the first 2 months (or 60 days) to file requests, supported by data or other information, to add or subtract from the list based on objective scientific criteria. After the Excluded Ingredients List is completed by USDA-AMS and published as a notice in the Federal Register, the Coalition requests that the rule give regulated entities 24 months to comply with the NBFDS.

The Coalition believes it is necessary for the initial versions of both lists to be issued simultaneously with the final rule and published in the Federal Register for ease of reference and to provide certainty throughout the value chain that certain foods are not BE for purposes of the NBFDS. The Coalition also proposes that the initial lists be specifically referenced in the rule, discussed in the preamble, and available on the USDA-AMS web site. The Coalition supports USDA-AMS establishing a transparent process to add items to or remove items from either list. However, in contrast to the proposed rule, changes to the Excluded Ingredients List would not rely on rulemaking under the formal process outlined in proposed Section 66.200 for handling petitions regarding other factors and conditions under which a food is considered a BE food. Rather, the Coalition proposes that requests to add or remove items be submitted through the AMS website so as to be available for public comment. In response to such requests, AMS would periodically update the Excluded Ingredients List, as appropriate. The process proposed by the Coalition will help to keep the lists current, ensure public participation and

transparency, and provide more lead time for adoption of the rule's disclosure requirements without unnecessary regulatory process.

Voluntary Disclosure

In order to preserve the ability for food manufacturers to disclose information above and beyond what is required under the NBFDS, the Coalition's alternative approach supports a rigorous voluntary disclosure option linked to the BE Source List.⁹ For products that do not meet the definition of "bioengineered food," but contain an ingredient derived from the BE Source List, manufacturers should be permitted to make voluntary disclosures using phraseology that is distinctly different from the mandatory disclosure language, provided that any such claims are truthful, not misleading, and otherwise consistent with applicable federal law, as noted in proposed Section 66.118. Any such voluntary disclosures must be otherwise consistent with the Act.

As an example of such a voluntary claim, a manufacturer should be allowed to disclose the presence of a refined ingredient that has been placed on the Excluded Ingredients List, but which was derived from a BE crop. For purposes of clarity, the Coalition requests including the following non-exclusive examples of such voluntary truthful and non-misleading claims in the text of the final regulation:

- Bioengineered crops used in the production of this food
- Ingredients sourced from bioengineered crops
- Derived from a bioengineered source
- Produced from a bioengineered source
- Sourced from bioengineered crops but does not contain any bioengineered substances

3. Factors and Conditions

For petitions submitted under Section 293(b)(2)(C) of the Act¹⁰ proposing other factors or conditions under which a food is considered a BE food, i.e., other than those included in the Act and the final rule, the Coalition agrees that any change to the rule's definition of the term "bioengineered food" would require notice and comment rulemaking as proposed in Section 66.200. In that regard, however, the Act places very tight constraints on any such change. As the bipartisan Senate Report states: "the definition of bioengineering is set in statute and establishes the scope of the disclosure standard."¹¹ Accordingly, the Standards for Consideration of petitions in proposed Section 66.202 correctly require the Administrator to determine whether any "requested factor or condition is within the scope of the definition of 'bioengineering'" in the Act. Similarly, the proposed Standards require the Administrator to "evaluate the difficulty and cost of implementation and compliance."¹² Finally, the proposed Standards appropriately authorize the Administrator to consider other relevant information, including whether the proposed factor or condition "is compatible with the food labeling requirements of other agencies or countries."¹³ If the Coalition's recommendations are adopted and USDA-AMS establishes an Excluded Ingredients List, the Agency should make clear in the preamble and final regulation that the Excluded Ingredients List can be amended and modified without going through notice and comment rulemaking.

⁹ See Senate Report at 5 and proposed Section 66.116.

¹⁰ 7 U.S.C. § 1639b(b)(2)(C).

¹¹ Senate Report at 2 and 3.

¹² Proposed Section 66.202(b); see also Senate Report at 7 and 8.

¹³ Proposed Section 66.202(c); see also Section 294(a), 7 U.S.C. § 1639c; Senate Report at 2, 4 and 6.

As part of its discussion of factors and conditions, the preamble cites incidental additives and undetectable recombinant DNA. The discussion is based on requests that USDA-AMS has received involving (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. As USDA-AMS indicates, the ultimate impact of excluding foods in these two categories through rulemaking would be to potentially exclude certain products from disclosure, and the proposed definition of bioengineered food already excludes incidental additives.¹⁴ As previously discussed, however, rulemaking is not necessary in order to maintain an ingredients list. The exact same result would be achieved and with greater efficiency through implementation of the Coalition's transparent process for adding ingredients to and removing ingredients from the Excluded Ingredients List.

For the reasons explained in Section C.1. of this comment, the Coalition encourages USDA-AMS to exclude from the definition of bioengineered food: (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.

D. Exemptions.

The proposed rule creates uncertainty as to whether the foods listed in Section 66.5, "Exemptions," are BE foods that are exempt from mandatory disclosure or whether they are excluded from the definition of BE food. The Act clearly excludes from the definition of BE food those foods (i) derived from animals that consumed BE feed produced from, containing, or consisting of a BE substance and (ii) foods with BE substance content below the threshold. Proposed Section 66.5 classifies as "exempt" from disclosure foods that fall outside the definition of BE foods and BE foods that are exempt from disclosure, such as foods served in restaurants and food produced by very small manufacturers. The Coalition therefore urges the Agency to clarify in the final rule that a below-threshold food and food derived from an animal that consumed feed produced from, containing, or consisting of a BE substance are, by definition, not BE foods, rather than BE foods exempt from disclosure.

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

Definition of Similar Retail Establishment

The Coalition supports USDA-AMS's approach to defining the establishments to which the NBFDS's exclusion of foods served in restaurants and similar retail food establishments applies. Specifically, the Coalition supports USDA-AMS's proposed Section 66.5(a), which exempts from mandatory disclosure food served in restaurants or similar retail food establishments. The exemption establishes consistency with the Act, the Senate Report, regulatory frameworks administered by FDA, and the National Organic Program, as the Agency notes in the preamble to the Proposed Rule.

The Coalition also supports the Agency's proposed definition of "similar retail food establishment" in Section 66.1, which USDA-AMS has indicated is based on 7 C.F.R. § 60.107 and 7 C.F.R. § 65.140, with

¹⁴ While the proposed definition of bioengineered food, endorsed by the Coalition, would specifically exclude incidental additives present at an insignificant level and that do not have any technical or functional effect in the food, the proposal does not address detection.

minor modifications. We urge USDA-AMS to maintain this important exemption and definition in the final rule.

Clarifying Foods Exempted

As described in the Coalition's response to USDA-AMS's Proposed Rule Questions Under Consideration, grocery stores offer a large variety of products, ranging from large national brands of manufactured foods to unique local and seasonal offerings. Some are traditional grocery items. Others are offered for sale in diverse ways and in varying packaging formats, including, for example, made-to-order sandwiches packed by a store clerk in food-grade paper, customer-assembled salads eaten on site in a reusable bowl, pasta salad sold by weight and packed by the retailer into a plastic container, unpackaged bulk apples sourced from a farm down the road, among many others. Accordingly, grocery stores occupy a unique position with respect to implementation of the NBFDS, particularly given that manufacturers and suppliers of the foods sold by grocery stores are in many instances best positioned to provide information regarding individual food items and ingredients used. As such, it is important that we provide feedback regarding food retailers' unique position as it relates to the NBFDS proposed rule.

While USDA-AMS has confirmed the Act's exemption from the NBFDS of "[f]ood served in a restaurant or similar retail food establishment," the Coalition suggests that USDA-AMS provide three additional clarifications regarding which specific foods served in a restaurant or similar retail establishment USDA-AMS intends to exempt from disclosure.

First, the Coalition asks that USDA-AMS clarify in the final rule that all foods prepared, processed, or packaged in the retail food establishment are exempt from the disclosure requirement and that USDA-AMS define the term "packaged" using the definition established in 21 C.F.R. § 1.20, FDA's general food labeling requirements. Doing so will provide additional clarity regarding to whom the obligation to disclose rests and will provide consistency with FDA's regulations, ensuring that the NBFDS is easy to understand and implement, leading to reduced compliance costs. This requested exemption is also consistent with the Senate Report, which stated that "[u]npackaged foods and food processed or prepared in a restaurant or similar retail food establishment are also excluded from the scope of the disclosure requirement."¹⁵

Foods considered to be "packaged in the retail food establishment" should also include foods packaged in retailer-owned or -operated facilities. In particular, grocery stores often utilize "central kitchen" locations for certain prepared foods. These facilities range in variety, from a kitchen located across the parking lot from a two-store chain, to those serving a number of stores. These centralized locations allow grocery stores to develop efficient preparation processes, while ensuring the same strict food safety protocols utilized in-store are followed. In particular, offsite kitchens allow stores to focus employee efforts and training solely on food preparation, such that sufficient quantities of various ready-to-eat foods can be safely prepared and distributed to stores. A final regulation clarifying that foods packaged in retailer-owned or -operated facilities are treated the same as those packaged in the retail food establishment under the NBFDS will help minimize the burden and preserve the use of these offsite facilities as a safe and efficient option for food retailers.

Additionally, finished products in grocery stores may be partially prepared in these kitchens and partially prepared in-store. For example, a store-owned facility might provide a particular store with 25 turkey sandwiches a day. If the sandwiches sell out, the grocery store itself may prepare additional sandwiches

¹⁵ Senate Report at 3 (emphasis added).

to meet demand. Because these sandwiches are identical to the end-customer, it is important that those prepared in-store versus in the store-owned facility be treated the same under the NBFDS to eliminate potential confusion.

Second, the Coalition asks that USDA-AMS clarify in the final rule that unpackaged foods are exempt from disclosure, an exemption also contemplated in the Senate Report.

Third, the Coalition asks that USDA-AMS recognize the impracticality of labeling certain foods categories and establish an exemption from the NBFDS in the final rule for those foods that are exempt from FDA's traditional nutrition facts panel (NFP) labeling under 21 C.F.R. § 101.9 ("Nutrition labeling of food"), including but not limited to the exemption in 21 C.F.R. § 101.9(j)(10) for raw fruits and vegetables subject to Section 403(q)(4) of the FFDC. Incorporating these exemptions into USDA-AMS's rule would be in keeping with Congress' expectation that the rule implementing the Act be consistent with "other federal requirements."¹⁶

2. Very Small Food Manufacturers

The Coalition appreciates USDA-AMS's providing a definition for "very small food manufacturers" as a means of clarifying which entities are responsible for disclosing under to the NBFDS. The Coalition recommends that USDA-AMS revise the definition of "very small food manufacturer" so that it aligns with the definition under the Food Safety Modernization Act's final rule on Preventive Controls for Human Food for a "very small business," which is defined as "a business (including any subsidiaries and affiliates) averaging less than \$1,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee)." 21 C.F.R. § 117.3.

Although the NBFDS is a marketing standard, the FSMA definition for "very small business" is nonetheless a relevant metric for use in implementing the Act because the definition was promulgated through notice and comment rulemaking and is based on FDA's recent consideration of which food manufacturers are considered very small businesses, accurately reflecting the current state of the industry.

3. Threshold

The Coalition appreciates USDA-AMS's efforts to comply with the Act's requirement that the final rule "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."¹⁷ The Coalition also supports the proposed definition of the term "bioengineered substance" and encourages the Agency to adopt this definition in the final rule.

Regarding the amount of a BE substance present in a food that would render the food a BE food, the Coalition proposes that in the final rule, USDA-AMS adopt a dual threshold comprised of a 0.9% threshold for intentional presence, as a percentage of the total weight of the finished food product, and a 5% threshold for unintentional (adventitious) presence in a specific ingredient. The dual threshold addresses two separate issues as described below.

¹⁶ Senate Report at 4.

¹⁷ Section 293(b)(2)(B), 7 U.S.C. § 1639b(b)(2)(B).

The 5% threshold measures BE substances based on inadvertent or technically unavoidable presence and acknowledges and preserves current best practices on identity preservation within the grain handling/supply chain for non-BE food or ingredients, recognizing the realities of growing BE and non-BE crops in nature and the coexistence of BE and non-BE foods during production, transportation, and processing, as well as the sampling and quantification issues when the crop has multiple (stacked) BE traits in the same seed. Low, unworkable, unrealistic thresholds increase costs throughout the supply chain as well as the chances of trade disruptions.

In applying the 5% threshold, when an ingredient, such as wheat flour, is not derived from a food crop or animal on the BE Source List, regulated entities should not be required to keep specific records documenting that the ingredient does not contain more than 5% of a BE substance from inadvertent or technically unavoidable presence. However, if an ingredient is, contains, or is derived from a food crop or animal on the BE Source List, such as corn meal, regulated entities would need to keep such records if they do not make a disclosure for the food. Examples of appropriate records would include records of identity preservation on the farm and throughout the supply chain or analytical data demonstrating less than 5% inadvertent BE content.

Meanwhile, the 0.9% threshold would provide flexibility for manufacturers to intentionally source a de minimis level of BE ingredients without triggering disclosure and would be used to determine whether a finished food product is subject to disclosure based on total percentage by weight of BE ingredients in the finished food. The regulation should allow the calculation of the level of the BE content in the BE food based on food formulation and not testing of a finished food, particularly for multi-ingredient foods. By way of example, an Asian stir fry that contains vegetables, rice, and 10% soy sauce (a multi-ingredient food made with 90% non-BE ingredients and 10% BE ingredients), the threshold would be determined based on the quantity of the BE ingredient in the soy sauce. Because the soy sauce is 10 percent BE, the stir fry would contain 1% BE substance, which is above the 0.9% threshold and the stir fry would be a BE food subject to disclosure.

The Coalition underscores that these two standards operate separately. For example, the weight of an ingredient that unintentionally or inadvertently contains less than 5% of a BE substance would not be included in calculating the intentional BE content of a finished food product for purposes of the 0.9% threshold, which is calculated based on the product's weight. In addition, the Coalition asks that the final rule also make clear that foods not considered BE foods under the factors and conditions process, e.g., incidental additives, are not BE substances for purposes of threshold calculation.

4. Animals Fed with Bioengineered Feed and their Products

The Coalition supports the inclusion in the proposed rule of Section 66.5(d), which, consistent with the Act and the Senate Report, states that “[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.” The Coalition asks that USDA-AMS retain Section 66.5(d) in its final rule to acknowledge in the implementation regulations the Act’s directive that foods of animal origin are not subject to the NBFDS solely because they are derived from animals fed bioengineered substances.

5. Food Certified Organic Under the National Organic Program

The Coalition agrees with the USDA-AMS's proposed Section 66.5(e), which expressly exempts from the NBFDS "[f]ood certified organic under the National Organic Program." Section 66.5(e) is consistent with the Act, which provides that, in the case of a "food certified under the national organic program ... 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."¹⁸

The Act directs USDA-AMS to consider establishing consistency between the NBFDS and the Organic Foods Production Act of 1990. The Coalition supports consistency between the two standards, where appropriate, and the fact that the proposed rule does not impact the organic standards or the authorities or obligations under the Organic Foods Production Act, or propose or suggest modifications to the USDA Organic rules solely as a result of the proposed rule.

III. DISCLOSURE

A. General.

In conjunction with publication of USDA-AMS's final rule, the Coalition encourages the Agency to develop and implement a consumer education campaign to ensure that adequate understanding by consumers regarding the various disclosure options and what they mean with respect to whether a product is produced with bioengineered ingredients.

1. Responsibility for Disclosure.

The Coalition appreciates USDA-AMS's work in proposing a rule that seeks to clarify which entities are responsible for disclosure under the NBFDS, and appreciates the clarification provided during the June 1 webinar regarding what constitutes a food manufacturer for purposes of NBFDS compliance. The Coalition has concerns with the proposal as it relates to food retailers and below shares its recommendations for ensuring that implementation of the Act is as efficient and cost-effective as possible.

Flexibility in Disclosure Methods for Retailers

As discussed above, the Act is intended to ensure that food manufacturers, rather than the retailer, of a packaged food product bears responsibility for compliance with the NBFDS. Despite this intent, the proposed rule makes food retailers responsible for BE disclosure under certain scenarios. As background for the Coalition's recommendations, it is important to understand the difference in labeling capabilities between the retailer and the manufacturer. While manufacturers may have plentiful resources¹⁹ for labeling their products, retailers have only what is available in-store, which generally includes limited store personnel, and even more limited printing and labeling abilities.

The Coalition notes that USDA-AMS has provided additional disclosure flexibility for small food manufacturers and exempted very small food manufacturers from the rule altogether. Given the particular challenges faced by food retailers with respect to disclosure, the Coalition asks that USDA-AMS promulgate a final rule that extends the flexibility provided to small and very small food

¹⁸ 7 U.S.C. § 6524.

¹⁹ Manufacturers will have access to any available labeling format, including printing technology, adhesives, etc., and often utilize companies specializing in these services to label their products.

manufacturers to small retailers by establishing a threshold for “small retailers,” using the standard incorporated into FDA’s Menu Labeling rule²⁰, and exempting such retailers from the NBFDS. The Coalition believes such an exemption would help alleviate the burdens on small retailers while being consistent with the Act.

The proposed rule briefly discusses retailer options for disclosure of bulk foods. In particular, USDA-AMS proposes that “[t]he disclosure would be required to appear on signage or other materials (stickers, bindings, etc.) on or near the bulk item.” Additionally, the Regulatory Impact Analysis (“RIA”) for the proposed rule also discusses signage for use in the produce section of the store. As described above, it is the Coalition’s position that unpackaged products, like bulk foods and fresh produce, were neither intended to be nor should be covered by the NBFDS. If USDA-AMS proceeds to include them, the Coalition asks that the final rule provide retailers having disclosure responsibility with additional flexibility. Specifically, the Coalition asks that the final rule give retailers the option to comply by using signage in cases where retailers are responsible for disclosure. As noted in the RIA, permitting disclosure through signage will help keep costs and other burdens as low as possible for retailers. Additionally, the Coalition asks that the final rule permit signage near the item, like a single sign in the produce section listing all BE foods in that section.²¹ A single sign approach will provide retailers with the necessary flexibility to disclose in the least costly and least burdensome way possible.

Disclosure of Information by Manufacturers to Retailers

USDA-AMS has proposed scenarios under which the retailer is responsible for compliance with the NBFDS. The Coalition notes that, although grocery stores fully support providing customers with this information, food manufacturers and suppliers are generally better positioned to provide information regarding individual food items and their ingredients. Manufacturers may frequently shift ingredient suppliers, depending on prices, availability, and many other factors. As drafted, however, the proposed rule would place NBFDS responsibility solely with the retailer in certain circumstances.²² Accordingly, the Coalition asks that USDA-AMS clarify in the final rule that manufacturers are responsible for disclosing to the retailer that a food contains BE ingredients or is otherwise subject to the NBFDS in situations where the retailer is responsible for final disclosure to the customer.

International Impact

In response to USDA-AMS’s request for comments on impacts on importers, the Coalition reiterates its Response to USDA-AMS’s Proposed Rule Questions Under Consideration, which stated that “[i]mported products must be required to follow the same disclosure requirement as products manufactured in the United States. The U.S. is obligated to apply any requirement in a nondiscriminatory way that is consistent with U.S. obligations under World Trade Organization and other international trade and investment agreements.”

²⁰ Under that rule, a “small retailers” is a “restaurant or similar retail food establishment that is part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership of the locations) and offering for sale substantially the same menu items.” 21 U.S.C. § 343(q)(5)(H)(i); 21 C.F.R. § 101.11(a).

²¹ For example, USDA’s Country of Origin Labeling regulations provide that “[a] bulk container (e.g., display case, shipper, bin, carton, and barrel) used at the retail level to present product to consumers, may contain a covered commodity from more than one country of origin provided all possible origins are listed.” 7 C.F.R. § 65.400(d) (applicable to lamb, chicken and other agricultural commodities); see also 7 C.F.R. §60.300(d) (similar provision for fish and shellfish).

²² The proposed rule suggests, for example, that retailers should disclose BE ingredients for bulk foods. Although we do not necessarily agree that mandatory disclosure should apply to bulk foods, this serves as an example where retailers often may not have adequate information to provide such disclosure.

Regarding potential recognition arrangements, the Coalition encourages USDA-AMS to look to other USDA marketing programs, like the National Organic Program, which have established mutual recognition programs for evaluation as potential exemplars.

2, 3. Appearance and Placement of Disclosure.

The Coalition commends USDA-AMS on its proposal with respect to the placement of the disclosure and options for type, text, and size. In contrast to more proscriptive approaches proposed under separate regulatory frameworks, the Agency's proposal is workable and provides significant flexibility to regulated entities, thereby enabling continued work toward sustainable packaging, other packaging innovation, and lower packaging costs generally. The Coalition urges the Agency to maintain this flexibility in the final rule.

4. How BE Food Lists Relate to Disclosure.

With respect to USDA-AMS's request for comments regarding this topic, the Coalition refers to its comments in Section II.C.2 above regarding "Lists of Bioengineered Foods."

B. Text Disclosure

The Coalition appreciates USDA-AMS's efforts to develop a simple, workable standard for on-pack text disclosure for use with the NBFDS, including USDA-AMS's proposal to distinguish between foods comprised solely of BE foods and foods that are comprised of both BE foods (or BE substances) and non-BE foods. The Coalition supports use of the term "bioengineered food" for foods that are entirely a product of bioengineering, but suggests that the Agency establish in the final rule the term "Includes (a) bioengineered food ingredient(s)" for foods that are a mix of BE and non-BE ingredients, rather than the proposed rule's language, which states "Contains (a) bioengineered food ingredient(s)." The Coalition is concerned that use of the term "Contains" may suggest to consumers that the statement is a safety or health warning, rather than a marketing statement. For example, FDA requires use of the phrase "CONTAINS PHENYLALANINE" as an indication to individuals with phenylketonuria (i.e. PKU), a disorder that causes the amino acid phenylalanine to build up in the body. Given this potential association, and the fact that Congress prohibited disclosures under the NBFDS from suggesting that a covered food is "not as safe as" a counterpart food not covered by the NBFDS,²³ the Coalition urges USDA-AMS to use the term "includes" rather than "contains."

As noted previously, the Coalition has proposed above a workable alternative approach consisting of a single BE Source List. Should USDA-AMS proceed with a single list like the one proposed above, the Coalition supports use by regulated entities of phrases such as "May be bioengineered food" or "May include (a) bioengineered ingredient(s)" for those foods or ingredients that are not excluded under the Excluded Ingredients List. Such language will provide flexibility for regulated entities unable to consistently source food or food ingredients throughout the year without significantly increasing their costs. However, the Coalition anticipates that most regulated entities will be able to consistently identify foods or food ingredients as BE or non-BE and, therefore, will use "bioengineered food" or "includes (a) bioengineered food ingredient(s)" to the extent they opt for on-pack text.

²³ Section 293(b)(3), 7 U.S.C. § 1639b(b)(3); see also Senate Report at 2, 4.

C. Symbol Disclosure.

Regarding the options for disclosure by symbol proposed by the Agency, the Coalition recommends that USDA-AMS adopt in the final rule the symbols listed under Alternative 2-A, rather than the symbols under 2-B and 2-C.

In addition, the Coalition commends USDA-AMS for the flexibility it has proposed related to placement of the disclosure and the use color or black and white, should a regulated entity opt to comply with the NBFDS using the symbol. Relevant to USDA-AMS's requests for comment on the economic impacts of the proposed rule, the Coalition notes that color printing can involve as few as one color ink (which may not be black), such as a simple sticker label printed in a dark blue, and emphasizes the importance of providing flexibility for color options as well. The Coalition further notes that adding additional colors to the printing process solely for BE symbol disclosure will increase printing costs or disrupt product design in other ways. Additionally, it is important that the symbol be conspicuous on the package, regardless of the color of the package, including where the background color of the package closely matches the colors suggested in the proposed rule. For all of these reasons, the Coalition emphasizes the importance of providing regulated entities with flexibility with respect to color options. Ensuring maximum flexibility and including additional color options in the final rule would best place regulated entities to ensure that the symbol is clear and readable without having to change the overall color design for the product, which often may be subject to "trade dress" protection. The Coalition believes that maintaining the black and white option and providing similar flexibility for color symbols would limit disruptions to the printing process, help keep costs down, and allow clear communication of the BE food disclosure to consumers.

D. Electronic or Digital Link Disclosure

The Coalition appreciates that USDA-AMS has provided additional detail regarding the electronic or digital link disclosure option established in the Act. The Coalition supports the fact that the proposal provides regulated entities with flexibility in determining the placement of digital links on the physical package, as set forth in Section 66.100(d), and for flexibility with the call to action in light of potentially changing disclosure technologies. The Coalition asks that USDA-AMS retain these provisions in the final rule.

The Coalition has concerns with other aspects of USDA-AMS's proposal related to the electronic or digital link disclosure, however.

First, the Coalition has significant concerns with the Agency's requirement in proposed Section 66.106 that the electronic or digital link disclosure "be accompanied by a telephone number that will provide the bioengineered food disclosure to the consumer, regardless of the time of day." The Act provides that the NBFDS "require that the form of a food disclosure ... be a text, symbol, or electronic or digital link ... with the disclosure option to be selected by the food manufacturer."²⁴ The Act also provides that the NBFDS "ensure that ... (4) the electronic or digital link disclosure also includes a telephone number that provides access to the bioengineering disclosure...."²⁵ Although those Act provisions do not require that the telephone number be provided on pack, USDA-AMS's proposal would require that the digital or

²⁴ Section 293(b)(2)(D), 7 U.S.C. § 1639b(b)(2)(D).

²⁵ Section 293(d)(4), 7 U.S.C. § 1639b(d)(4).

electronic ink disclosure be accompanied on-pack with a telephone disclosure and call to action “in close proximity.” In effect, these provisions require a regulated entity to comply with two different modes of disclosure simultaneously, making compliance with the digital or electronic link disclosure option significantly more onerous in terms of label space, and increasing compliance costs. These outcomes and increased costs of compliance are in direct contravention with the Act, which intended regulated entities to have the option of choosing a single disclosure method from the three, equally valid disclosure options described in the Act.

Second, the Coalition is concerned that USDA-AMS’s on-pack telephone number proposal will require regulated entities to unnecessarily duplicate existing telephone food information disclosures. The Coalition notes that it is already common practice for manufacturers to list a toll-free consumer hotline on food packages. In fact, customer service representatives increasingly use digital transparency programs such as SmartLabel® to answer consumer questions about a food. Accordingly, the Coalition asks that USDA-AMS promulgate a final rule that permits regulated entities choosing the digital or electronic link disclosure option to provide the BE disclosure using existing telephone hotlines and to retain the same placement and call to action for those numbers, much like USDA-AMS has proposed for telephone disclosures used for very small packages as set forth in Section 66.112(d). Without this flexibility, consumers may face two competing phone lines on a single package, which would cause confusion, while regulated entities are faced either with the cost and burden of establishing and maintaining two separate food information hotlines or shrinking the amount of food information available to consumers by replacing its existing hot line with the NBFDS-compliant telephone disclosure.

Third, the Coalition has concerns regarding the requirement that the telephone disclosure be available “regardless of the time of day,” effectively mandating that a regulated entity choosing the digital or electronic link disclosure option be required establish and maintain a 24-hour a day, 7-day a week hotline, a significant and unnecessary expense and at odds with the intent of the Act. Coalition members have found that shoppers only access consumer information phone lines during normal shopping hours. The requirement for 24/7 availability is unnecessarily burdensome and will increase the costs of compliance, as manufacturers currently do not maintain 24/7 lines.

The Coalition also notes that the on-pack telephone disclosure requirements are firmly at odds with the Act’s requirement that USDA-AMS undertake a study regarding the availability of access to the disclosure via digital or electronic methods. No such study would have been necessary had Congress intended that the telephone disclosure accompany the digital or electronic link on pack. In light of these tensions with the Act and Congress’ intent, the Coalition asks that USDA-AMS revise the telephone disclosure provisions in the final rule to ensure parity between the three disclosure options, provide maximum flexibility and efficiency to regulated entities.

Finally, the Coalition has concerns with USDA-AMS’s proposal in Section 66.107(b)(1) that the “product information page be the first screen to appear on an electronic or digital device after the link is accessed as directed.” The Act requires a regulated entity “provide access to the bioengineering disclosure located, in a consistent and conspicuous manner, on the first product information page,”²⁶ but does not require the disclosure itself to appear on the first product information page. The Coalition asks that

²⁶ Section 293(d)(2), 7 U.S.C. § 1639b(d)(2) (emphasis added).

USDA-AMS provide additional flexibility in the final rule on the required location of disclosure after a consumer has accessed a digital link, consistent with the statutory language, and to provide a mock-up or examples of compliant disclosures.

E. Study on a Digital or Electronic Link Disclosure Option or a Text Message Disclosure Option

The Coalition also appreciates USDA-AMS's efforts to comply with the Act's requirement that the Secretary 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. The Act required that the study consider five factors: (i) the availability of wireless internet or cellular networks; (ii) the availability of landline telephones in stores; (iii) challenges facing small retailers and rural retailers; (iv) the efforts that retailers and other entities have taken to address potential technology and infrastructure challenges; and (v) the costs and benefits of installing in retail stores electronic or digital link scanners or other evolving technologies that provide bioengineering disclosure information. The 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.

Specifically, the Coalition appreciates USDA-AMS's work in conducting and analyzing the results of the study. Coalition member the Food Marketing Institute (FMI) conducted a study²⁷ and found, consistent with the Agency's findings, that overall customers have overwhelming access to WiFi while shopping. As technology evolves and retailers continue to expand their WiFi offerings, the Coalition, which represents the entire American food and agriculture value chain, anticipates this access to increase in the coming years. These studies also found that:

- The majority of Americans own a smartphone (77%) and ownership rates are trending upward. The adoption of smartphones will continue to rise in all age groups.
- Most Americans live in areas with sufficient broadband access (93.6%) to scan a digital link to access bioengineering food disclosure information.
- All national chain stores and most regional chain stores (97%) provide WiFi in store.
- Of small retailers, 37 percent already provide WiFi to consumers in store. FMI's study found this number to be increasing. Customers may also access information by utilizing cellular data if WiFi is unavailable.
- Consumers may recognize digital links, but lack familiarity with scanning. As digital links become more ubiquitous we would expect their understanding regarding the technology to grow. For example, FMI and GMA are undertaking a comprehensive educational campaign through multiple media outlets to help inform consumers about SmartLabel. The initial consumer education campaign was launched in June 2018 and has already achieved significant outreach in less than one month. Additionally, during Q1 2017, SmartLabel received over 1,300,000 visits across participating brands. More than 50% of those visits were via smartphone. SmartLabel has seen over 80% growth in QR scans since September of 2017. Further, 30,000 products are

²⁷ FMI surveyed its member companies using a brief online survey to assess the degree to which WiFi (wireless internet) service is currently available to customers in store. A total of 43 companies representing more than 16,000 stores responded to the survey, comprising roughly 50% of the retail food industry in the United States. The companies responding range from independent operators with less than ten stores (31) to some of the largest chains in the country.

already labeled with a SmartLabel digital link – a number that is growing each day and will continue to grow following publication of a final rule. Based on current trends, FMI and GMA expect SmartLabel adoption to reach 40,000 product pages by the end of 2018.

- As consumers become more comfortable with technology, including the ability to access digital information related to whether a food is produced with BE foods, the concern related to access will diminish significantly.

Although the Coalition views the digital or electronic link disclosure option as sufficiently accessible to support its reliable use for BE disclosure, the Coalition also supports USDA-AMS's proposed text message disclosure, finds it to be another effective method of delivering BE information to consumers, and asks that the Agency come to a decision on whether to include this additional disclosure option as soon as possible.

As proposed, the text message option would operate similarly to the electronic or digital disclosure under proposed § 66.106, but it would not rely on broadband access and would not require consumers to have smart phones in order to access the disclosure. Regulated entities choosing this option would be required to include a statement on the package that instructs consumers to "Text [number] for more food information," where the number would be a phone number or short code. Proposed Section 66.108(a). The Coalition asks that, because text messaging could be a useful tool for providing consumers with other information regarding their food, any final rule provisions enabling use of text message disclosure be sufficiently flexible so as not to restrict the disclosure so that BE information is the only information that could be provided to consumers through that method. As drafted, the Coalition views the proposal as overly restrictive in this regard.

The Coalition also recommends that, as technologies continue to evolve, that the Agency consider providing additional disclosure options that may be appropriate for consumers. For example, artificial intelligence technologies may provide additional opportunities for innovation with respect to food disclosure, and USDA-AMS should ensure that the final rule enables the Agency to accommodate advances in these new and evolving technologies going forward.

F. Small Food Manufacturers.

The Coalition appreciates USDA-AMS providing clarity with respect to the definition of a "small food manufacturer" and supports the additional telephone and internet website disclosure options proposed for manufacturers meeting the definition of a small food manufacturer. Regarding USDA-AMS's proposal that the telephone BE food disclosure be available "regardless of the time of day," the Coalition refers to its comments in Section III.D above.

The Coalition suggests that USDA-AMS adopt a definition of "small food manufacturer" in the final rule based on the number of employees, rather than on annual receipts. A definition based on number of employees would establish consistency with the definition for "small business" under the Small Business Administration regulations,²⁸ easing compliance burdens by establishing a more stable, durable metric.

²⁸ 13 C.F.R. § 121.201.

G. Small and Very Small Packages.

The Coalition supports USDA-AMS's proposed rule provisions relating to small and very small packages, including the modified disclosure options relevant to those packages. The Coalition also reiterates its Response to the Proposed Rule Questions Under Consideration and asks that the Agency acknowledge in the final rule that disclosure information required under this Act should be sufficient disclosure for items sold through vending machines.

H. Foods Sold in Bulk Containers.

Regarding the Agency's proposal with respect to bulk foods, the Coalition refers to its comments in Section III.A.1 above.

I. Voluntary Disclosures.

Regarding USDA-AMS's proposals related to voluntary disclosures, the Coalition refers the Agency to its comments in Section II.C.2 above.

IV. ADMINISTRATIVE PROVISIONS.

A. Recordkeeping Requirements.

The Coalition generally supports USDA-AMS's proposal related to recordkeeping to demonstrate compliance with the NBFDS, including provisions enabling persons required to keep records to rely on existing records that are customary, reasonable, and regularly kept and maintained in the ordinary course of business, and urges the Agency to retain these principles in the final rule.

More specifically, the Coalition supports the twelve (12) categories of documentation identified by the Agency as appropriate to verify that foods are not BE and/or not subject to disclosure. The Coalition urges the Agency not to limit regulated entities to those categories. The final rule should make clear that recordkeeping entities should be allowed to retain any documentation relating to BE foods, or foods containing BE ingredients, provided such documentation is sufficient to verify that such foods are not subject to mandatory disclosure. The Coalition also appreciates that the proposed rule provides flexibility to responsible record keepers by enabling the use of multiple documentation sources and asks that the examples of appropriate records be incorporated into the text of the final rule. The Coalition notes that USDA-AMS has suggested in the preamble to the rule that regulated entities opting not to disclose under the rule may choose to rely on "supplier attestations." The Coalition reiterates that the phrase "supplier attestations" is intended to refer to contractual documents, confirmations or other certifications entered into or provided by suppliers, and does not provide an obligation by the buyer to engage in supplier verification programs for a marketing, rather than food safety standard, and which would impose significant costs and regulatory burdens. The Coalition also supports USDA-AMS's proposal that recordkeeping entities maintain records for two years after a food's distribution for retail sale.

The Coalition has concerns with the proposal to provide only five business days for an entity to provide records to AMS, and asks that the final rule provide recordkeeping entities with between four and six weeks to provide records to AMS, which would establish consistency with FDA's Menu Labeling

requirements.²⁹ It is also consistent with the fact that the NBFDS is a marketing standard and does not require the haste of a health and safety concern. The Coalition supports at least three-days' notice for an on-site visit by USDA-AMS, but asks that the final rule permit the recordkeeping entity to determine the location of the audit at the record keeper's discretion. The Coalition reiterates its opposition, as described in its Response to the Proposed Rule Questions Under Consideration, to any provisions requiring that a recordkeeping entity be required to provide access to confidential business information, including but not limited to product formulation information or recipes, in connection with the NBFDS.

B. Enforcement.

Regarding enforcement, the Coalition appreciates the Agency's acknowledgment that the Act does not authorize USDA-AMS to recall any food subject to the NBFDS "on the basis of whether the food bears a disclosure that the food is bioengineered" or to impose civil penalties for violations and asks that those limitations of authority be included within the text of the final rule. The Coalition otherwise supports USDA-AMS's proposal with respect to enforcement.

C. Proposed Effective and Initial Compliance Dates.

The Coalition appreciates USDA-AMS's proposal to harmonize compliance dates for the NBFDS and for FDA's new nutrition labeling rules. Such harmonization would significantly alleviate the expense of making two sets of changes to food labels in a short period of time. However, given the timing of USDA-AMS's proposal and anticipated timing for the final rule, which appears destined to extend well beyond July 2018, the Coalition is concerned that a compliance date of January 1, 2020 for the NBFDS would provide inadequate time for regulated entities to comply with the new standard, even accounting for the flexibility AMS proposed to allow regulated entities to exhaust existing label inventory until January 1, 2022. Instead, the Coalition requests that USDA-AMS establish in the final rule a compliance date of two years (24 months) after the effective date of the final rule, and retain in the final rule the provision providing regulated entities additional flexibility to exhaust existing label inventory until two years after the compliance date. Ensuring an adequate and orderly compliance timeline is key to preventing dramatically increased compliance costs and will ensure that regulated entities have sufficient time to manage costs associated with supplier verification of BE ingredients, assessing and managing changes to ingredients or formulations, and designing, printing, and applying the label to products subject to the NBFDS.

The Coalition also urges the Agency to specify that the compliance date only applies with respect to the date that products are being shipped into interstate commerce. This will ensure continued marketability for products previously labeled, held in storage, in shipment or offered for sale at retail establishment.

The Coalition also urges USDA-AMS to include in the final rule provisions providing to regulated entities flexibility as to the means of applying NBFDS-compliance text, symbols or electronic or digital link.

²⁹ 21 C.F.R. §101.11(c)(3) ("A covered establishment must provide to FDA, within a reasonable period of time upon request, information substantiating nutrient values including the method and data used to derive these nutrient values."); see also FDA, Menu Labeling: Supplemental Guidance for Industry, Q&A 7.3 at 36-37 (May 2018), available at <https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM583492.pdf> ("We consider a reasonable period of time to be about 4-6 weeks after the request is made.").

Although most labels will need to be redesigned and printed to comply with the standard, the Coalition asks that the Agency permit compliance through the traditional printing of food labels or, alternatively, through application of stickers or ink-jet printing of an existing label.

V. ECONOMIC ANALYSIS

The Coalition also appreciates the in-depth and detailed economic analysis contained within the Agency's Regulatory Impact Analysis (RIA). The Coalition agrees that the costs of compliance with the Act and the final rule must be viewed in the context of the significant costs food manufacturers and retailers were facing related to compliance with state labeling requirements enacted and effective in Vermont, and additional labeling initiatives that may have taken effect in other states or would be passed in states should a national preemptive standard not be in place under the Act. As the Agency notes in its RIA, "[t]he benefits of the proposed NBFDS would be the elimination of costly inefficiencies arising from a state-level approach to BE disclosure."³⁰ Elimination of these inefficiencies justifies the costs to consumers, manufacturers, and producers that this regulation would impose.

The Food Marketing Institute (FMI) developed additional data based on the RIA undertaken by USDA-AMS to test the RIA's conclusion that a federal disclosure standard is the most cost-effective method for providing the information consumers are seeking while minimizing inefficiencies resulting from inconsistent standards. The data³¹ was developed by John Dunham and Associates (JDA), a firm that has previously completed economic impact studies for a number of the farm and food sectors as well as the farm to fork, "Feeding the Economy" analysis. The JDA study states that:

- Multiple labeling systems requiring significant design costs and higher reformulation costs bring the initial cost of complying with 20 separate and distinct state rules to \$19.5 billion and the overall discounted 20-year cost to \$97.3 billion.
- Costs are higher if different labeling provisions are adopted in 51 different states, not to mention the potential of stricter local labeling requirements in states that do not preempt them. The potential benefit of the proposed rule is as high as \$129.7 billion discounted over 20-years, with \$35.5 billion of that being initial labeling, reformulation and recordkeeping costs.

JDA's analysis agrees, in large part, with the results yielded through the USDA's RIA, finding that a federal disclosure standard is the most cost-effective method to address providing information and minimizing inefficiencies caused by inconsistent standards. It further concluded that mandating one standard disclosure practice nationally dispels some uncertainty and removes inefficiencies from the manufacturing and distributing process.

By providing consumers with the information they are seeking in a way that minimizes inefficiencies and decreases the regulatory burden on those tasked with compliance, USDA is conforming to Congress' direction in the Senate Report that the Agency "take every effort to minimize the impacts on growers, handlers, processors, manufacturers, distributors, retailers, and consumers."³²

³⁰ RIA at 1.

³¹ John Dunham and Associates, National Bioengineered Food Disclosure Standard: A Review of the United States Department of Agriculture's Regulatory Impact Analysis (Brooklyn, NY: June 2018).

³² Senate Report at 7-8.