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Comment

RE: Docket No. AMS-TM-17-0050; "National Bioengineered Food Disclosure Standard; Proposed Rule" 83 Federal Register 19860, May 4, 2018

The Grocery Manufacturers Association[i] (GMA) respectfully provides the following comments related to the proposed rule, "National Bioengineered Food Disclosure Standard" in the above-referenced docket.

Executive Summary

The Grocery Manufacturers Association (GMA) is the leading trade association for the food, beverage and consumer products industry. Our member companies have an unwavering commitment to meet consumer demands for more information about the food and beverage products they purchase and consume.

Today, consumers are seeking more and more information about the products they purchase and our industry continually strives to make that information available in the most transparent manner possible. Our ability to provide consumers with the information they seek – and in a way that they understand – will build trust in brands, industry and government institutions. The ease with which the final regulations enable full disclosure of information to consumers will either support or diminish our ability to engage in a dialogue with consumers about technologies that improve lives, society and the environment.

Food and beverage manufacturers have a unique role and perspective as the most consumer-facing portion of the product supply chain, and their products are held to a high standard by consumers. If consumers do not believe that they are getting the transparency and ingredient information they demand, the repercussions will be felt most directly by the companies that make their food and beverage products. Consumers will hold GMA member companies and their brands accountable for any lack of product transparency.

The following are key consumer-facing issues we would like the U.S. Department of Agriculture's (USDA's) Agricultural Marketing Service (AMS) to consider as it finalizes its regulation:

Refined Ingredients

- Consumers expect to know if a product contains an ingredient that was sourced from a bioengineered crop, so it is essential that disclosure of this information be required under the final rule for the National Bioengineered Food Disclosure Standard.

- Our industry's commitment to meeting consumer demands for ingredient information is the foundation for GMA's unwavering support for mandatory disclosure of refined ingredients that are derived from bioengineered crops. The disclosure of refined ingredients in foods, such as oils and sugars derived from bioengineered crops, should be mandatory under the final rule.

- GMA does not expect that consumers will understand or believe the concept that an ingredient starting from a bioengineered ear of corn is not bioengineered after it has been refined. To the contrary, we believe consumers will expect to know if a product contains an ingredient that was sourced from a bioengineered crop regardless of whether the refining process removes the modified genetic material. Not including refined ingredients in the definition of bioengineered food will undermine the intent of the Act. It will confuse consumers, erode trust in brands and the technology and encourage further polarizing activism about what is perceived to be information "hidden" by brands, the food industry, institutions and policy makers.

- The decision to require disclosure of refined ingredients derived from bioengineered crops will have a significant impact on the number of products that would be disclosed under the new federal law.

    - Roughly 90 percent of the U.S. corn, soybean, and beet sugar crops are bioengineered. As a result, a substantial number of food and beverage products contain refined ingredients that come from these bioengineered sources.

    - Based on a 2017 assessment, GMA estimates that excluding refined ingredients from the scope of the mandatory disclosure standard would result in 78 percent fewer products being disclosed under the federal law.

- Consumer interest in bioengineered food is based on the desire to understand how a crop or ingredient was grown. The mandatory disclosure of refined ingredients under the final rule would address this reasonable interest by the consumer in a clear and consistent way.

Disclosure Thresholds

- The final rule should establish a threshold of 0.9% by weight of bioengineered ingredients intentionally added in a finished food product, with products that contain bioengineered ingredient(s) above that threshold required to be disclosed as bioengineered. This threshold would be compatible with voluntary certification standards in the U.S. that make similar *de minimis* allowances for products that are described as non-GMO.

- In addition, the inherent nature of agricultural production and the shared use of storage facilities, transportation and production equipment in the supply chain make it necessary to establish a 5% threshold for the unintentional presence of bioengineered substances in any one product ingredient.

Compliance Date

- While GMA will encourage its members to implement the rule as quickly as possible, the final rule should establish a compliance date of two years after the effective date of the final rule. This would allow sufficient time for companies to manage the logistics and costs associated with determining the status of ingredients and the finished product formulation under the final rule; the designing, printing and applying of labels to products subject to the disclosure standard; as well as updating any electronic or phone number disclosure materials.

- The final rule should specify that companies will be allowed to exhaust existing label inventory until two years after the compliance date. Additionally, to provide clarity to regulated entities, AMS should make clear that the compliance date applies to the date products are "labeled," where only those products labeled on or after the compliance date are subject to the new requirements.

II. Applicability: What is to be disclosed?

A. DEFINITIONS

GMA has no comments on this section.

B. FOOD SUBJECT TO DISCLOSURE

GMA is supportive of the provisions to define foods subject to disclosure. However, we ask AMS to address two key points in its final rule: amenability of certain broths or stocks, and the impact of so-called "component" versus "composite" ingredient listing.

Meat and Poultry Broth/Stock
GMA appreciates the guidance provided in the proposed rule for determining if multi-ingredient food products would be subject to disclosure. AMS should provide more clarity in determination

of disclosure requirements for "multi-ingredient food products that contain broth, stock, water, or similar solution as the first ingredient, and a meat, poultry, or egg product as the second ingredient on the food." Depending on the type of broth, meat versus poultry, this ingredient may or may not fall under USDA Food Safety and Inspection Service (FSIS) jurisdiction. We would ask that the final rule clarify that if the first ingredient in the ingredient statement is a "broth" that is amenable to FSIS jurisdiction, such as beef broth, the product is exempt from the disclosure requirement.

Component vs. Composite Ingredient Listing

GMA supports AMS's proposed definition of "predominance" utilizing the same methods the Food and Drug Administration (FDA) uses to identify predominance at 21 C.F.R § 101.4(a)(1). However, we seek clarity on how AMS would assess the predominance of ingredients for products labeled using component versus composite ingredient labeling. Component declaration requires ingredients which themselves contain two or more ingredients to be listed by their common or usual name followed by a sub-listing in parentheses.[1] Composite labeling allows declaration of each of the sub-ingredients in descending order of predominance by weight without listing the multi-component ingredient itself.[2] Based on the proposed rule as drafted, disclosure requirements for multi-ingredient foods could then vary depending on the type of chosen ingredient listing by a manufacturer (i.e., component or composite). Determination of the predominant ingredient for disclosure purposes of a USDA amenable product for disclosure purposes should be based on formulation by weight (composite methodology) to allow consistency amongst companies and to align with the intent of the law.

Consider the following examples:

Example 1. Meatball with Sauce. The product would be subject to the disclosure standard because the predominant ingredient is "breadcrumbs," which are regulated by FDA. However, using the component format the product would not be subject to disclosure solely because the predominant ingredient is "meatballs," which are regulated by USDA.

- **Composite Format:** INGREDIENTS: BREADCRUMBS, GROUND BEEF, CRUSHED TOMATOES ONIONS, SALT, PEPPER, WATER.
- **Component Format:** INGREDIENTS: MEATBALLS (BREADCRUMBS, GROUND BEEF), TOMATO SAUCE (CRUSHED TOMATOES, ONIONS, SALT, PEPPER)

Example 2. Chicken & Dumplings. This USDA-inspected product would not be subject to disclosure based on component labeling because water and beef are the first and second ingredient in the ingredient statement but it could be subject to disclosure based on the composite format.

- **Composite Format**: INGREDIENTS: WATER, CORN FLOUR, WHITE CHICKEN, CHICKEN FAT, CHICKEN BROTH…

[1] 21 C.F.R § 101.4(b)(2)(i)
[2] 21 C.F.R § 101.4(b)(2)(ii)

- **Component Format**: INGREDIENTS: WHITE CHICKEN, WATER, DUMPLINGS (ENRICHED CORN FLOUR, WATER, EGGS, MODIFIED FOOD STARCH, BAKING POWDER (SODIUM BICARBONATE, SODIUM ALUMINUM SULFATE, CORN STARCH, CALCIUM SULFATE, MONOCALCIUM PHOSPHATE), CORN SYRUP SOLIDS), CHICKEN FAT, CHICKEN BROTH…

Example 3. Beef Empanada. This USDA-inspected product would not be subject to disclosure based on component labeling because water and beef are the first and second ingredient in the ingredient statement but it could be subject to disclosure based on the composite format within filling.

- **Composite Format**: INGREDIENTS: WATER, CORN FLOUR, CORN OIL, BEEF, ONIONS, HYDROLYZED SOY PROTEIN…
- **Component Format**: INGREDIENTS: FILLING (WATER, BEEF, ONIONS, HYDROLYZED SOY PROTEIN…), CRUST (CORN FLOUR, WATER, CORN OIL, SALT) …

C. BIOENGINEERED FOOD

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

Bioengineering

Historically, the terms "genetic engineering," "biotechnology," and "genetic modification" have been used practically interchangeably, and consumers may be confused about the new, significantly narrower meaning of "bioengineering" in this proposed standard. GMA does not take direct issue with the incorporation of the Act's new definition of "bioengineering" into the proposed rule. (As discussed further below, however, GMA has concerns about incorporating "bioengineering" directly into the proposed rule's definition of "bioengineered food".)

However, GMA is concerned about the use of the terms "bioengineering" and "bioengineered" in reference to federal preemption (V. Rulemaking Analysis and Notices, Subtitle F. Executive Order 13132 of the proposed rule). The BE Food Disclosure Act, Sec. 295. Federal Preemption, specifies that preemption covers "genetically engineered foods" and all foods and seeds "developed or produced using genetic engineering." Preemption is not limited to requirements related to the smaller subset of foods now defined as "bioengineered," which, as proposed, excludes refined ingredients and products of gene editing.

Congress clearly and unambiguously intended to preempt State regulation related to the labeling of a broader set of products, not only products of "bioengineering." The Senate Committee Report explains that Congress specifically selected the term "genetic engineering" in the preemption provision "because it is the intent for the provision to broadly preempt state, tribal, and local requirements regarding genetically engineered foods or seed regardless of whether the

technology used to develop the food or seed falls within the definition of bioengineering."[3] In addition, Under-Secretary Edward Avalos made clear in his letters sent August 1, 2016, to the Governors of every state, that the scope of preemption was products of "genetic engineering," rather than being limited to products of "bioengineering." This is a crucial distinction that should be made clear in the preamble to the eventual final rule and the text of the rule itself by incorporating into Subtitle F the specific wording from Sec. 295 of the Act. One of the primary purposes of this law is to ensure consistent national labeling requirements for all genetically engineered foods and prevent a state-by-state patchwork of different labeling laws. In order to implement Congressional intent and ensure the appropriate scope of the preemption provision, we ask AMS to make clear that the term "genetically engineered" as it is used in section 295 is broader than the term "bioengineering."

Bioengineered Food

GMA does not support AMS's intention to directly incorporate the statutory definition of "bioengineering" into the definition of "bioengineered food." Doing so would likely result in refined ingredients not being required to be disclosed.

GMA supports the inclusion of refined ingredients and foods, such as oils and sugars derived from bioengineered crops, within the mandatory disclosure standard. The national bioengineered food disclosure standard is a marketing standard and not a safety standard. As such, our support for mandatory disclosure of refined ingredients is grounded in our industry's commitment to transparency and to building consumer trust in the use of bioengineered ingredients and foods.[4] Consumers are seeking more information about the food, beverage, and consumer products that they use and consume and our industry is committed to providing them with the tools and information they need to make informed choices about those products.

The question of whether the disclosure standard includes refined ingredients derived from bioengineered (BE) crops will have a significant impact on the number of products that would be disclosed under the new federal law. Roughly 90 percent of the U.S. corn, soybean, and beet sugar crops are bioengineered. As a result, a substantial number of food and beverage products contain refined ingredients that come from these products. Based on an assessment conducted by GMA in the summer of 2017, we estimate that excluding refined ingredients from the scope of the mandatory disclosure standard would result in 78 percent fewer products being disclosed under the federal law, thus we urge AMS to not to exclude them.

AMS has clear legal authority to require disclosure of refined ingredients and foods containing refined ingredients as bioengineered foods. The statute defines the technology that is the subject of the standard through the definition of "bioengineering" in section 291(1), but does not define the term "bioengineered food" nor does it specify the scope of foods that are subject to the

[3] S. Rep. No. 114-403, Report of the Committee on Agriculture, Nutrition, and Forestry, S. 2609, Related to Roberts Senate Amendment #4935 to S. 764, A National Bioengineering Labeling Disclosure Standard, at 6 (2016).
[4] J. Kolodinsky, J.L. Lusk, Mandatory labels can improve attitudes toward genetically engineered food. *Sci. Adv.* 4, eaaq1413 (2018)

disclosure. Instead, Congress directs AMS to establish a national mandatory disclosure standard with respect to "any bioengineered food and any food that may be bioengineered." The law provides AMS broad discretion under section 293 to define the term "bioengineered food" for purposes of determining which foods are subject to the disclosure requirements. As part of that discretion, AMS is directed by Congress in section 293(b)(2)(C) 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 bioengineered food" (emphasis added). AMS has discretion, therefore, to determine via its rulemaking process that refined ingredients should be "considered a bioengineered food" due to other factors and conditions not expressly stated in the statute.

Additionally, under section 293(b)(2)(B) of the law, USDA has authority to "determine the amounts of a bioengineered substance that may be present in food, as appropriate, in order for the food to be a bioengineered food." Under this provision, AMS could conclude that refined ingredients are "bioengineered substances" because they are ingredients derived from bioengineered crops.

Under the landmark U.S. Supreme Court case *Chevron USA v. National Resources Defense Council (NRDC)*,[5] when a statute is unambiguous on its face, an agency must give effect to the intent expressed by Congress. Where Congress has not directly addressed the precise question at issue, however, the agency's construction of the statute merely needs to be "reasonable." The statute unambiguously defines the technology that is at the heart of the mandatory disclosure standard via the definition of "bioengineering" in section 291(1). The statute does not, however, define the scope of which foods require disclosure as "bioengineered foods." It instead directs USDA to define by regulation which foods are "considered a bioengineered food" and provides the agency with discretion to consider certain "other factors and conditions." As long as USDA reasonably interprets the statute when defining the term "bioengineered food" by regulation, the agency has some discretion to which courts will defer. For these reasons, we do not interpret the statute as prohibiting USDA from including refined ingredients within the scope of foods or ingredients subject to the mandatory disclosure standard for "bioengineered foods."

This interpretation is consistent with that of USDA's General Counsel with respect to AMS's authority in defining the term "bioengineered food." In a July 1, 2016 letter from Jeffrey M. Prieto to Senator Debbie Stabenow, Ranking Member, Senate Committee on Agriculture, Nutrition, and Forestry, Mr. Prieto explained that the law provides authority to USDA to require disclosure of refined ingredients:

> Section 291(1) of the Senate bill provides authority to include food in the national disclosure program, including products which may or may not contain highly refined oils, sugars, or high fructose corn syrup that have been produced or developed from genetic modification techniques. As a practical matter of implementation, the Department would look not only at the definition in Section 291(1) regarding the genetically modified crops used to produce the refined or extracted materials, but also consider authority provided under Section 293(b)(2)(B) and Section 293(b)(2)(C) with respect to the amount of a

[5] 467 U.S. 637 (1984).

bioengineered substance present and other factors and considerations which might deem the product to be considered bioengineered food.

GMA agrees that AMS has authority to require disclosure of refined ingredients under the law, under the agency's discretion to define the term "bioengineered food."

In addition to being permitted under USDA's statutory authority, a determination that refined ingredients are bioengineered foods would be consistent with reasonable consumer expectations. In a recent survey by a manufacturer of its consumers in June 2018, 76% of respondents said that ingredients from bioengineered crops should be disclosed, regardless of whether they can be detected in a finished product. Thirteen percent said such ingredients do not need to be disclosed and 11 percent had no opinion. Consumer interest in bioengineered foods is based on a desire to understand how a crop was grown, not whether the food contains rDNA. The disclosure standard should seek to provide clear and consistent information that responds to this reasonable interest.

The reasonable nature of this interest is underscored by the FDA's guidance to manufacturers on voluntary labeling, which similarly focuses on whether the food was "derived" from a bioengineered plant and not on whether it "contains" rDNA.[6] The guidance explains "it is the plant" that is bioengineered rather than the food, and therefore it is appropriate to refer to "food derived from" bioengineered plants. For that reason, the FDA examples of appropriate labeling statements are focused on the source of the plant: "This product contains cornmeal from corn that was produced using modern biotechnology" or "Some of our growers plant soybean seeds that were developed through modern biotechnology…" The term "contains" is only used in reference to the ingredient contained in the food, and not in reference to whether the food "contains" rDNA.

2. Lists of Bioengineered Foods

GMA supports the proposed use of a list of bioengineered foods as the linchpin for disclosure. We further support basing the list on crops and foods generally as proposed, rather than attempting to list out specific derivatives or ingredients. AMS would be challenged to maintain an accurate list of all the ingredients that could be derived from bioengineered sources. As evidenced by the National Organic Program, maintaining this type of ingredient-specific list is time-consuming and resource intensive and can quickly become obsolete as new ingredients are developed. GMA also suggests that AMS consider condensing the two proposed crop lists based on adoption rates into a single bioengineered foods list for simplicity. If the highly adopted and not highly adopted lists are combined into one list, AMS should specify the cultivars of the not highly adopted crops that would be subject to disclosure. We request that AMS further define the specific types of corn that are considered "sweet corn" and "field corn," to help eliminate

[6] FDA Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants (Nov. 2015), https://www.fda.gov/RegulatoryInformation/Guidances/ucm059098.htm.

confusion on which types fall under these categories. For example, popping corn would typically not be considered field corn.

GMA asks that AMS define the term "commercially available" as it pertains to the maintenance of bioengineered crop lists. GMA members note that some crops (e.g., potato) listed in the notice of proposed rulemaking are not widely available, nor have they been recognized by groups who offer certification of GMO absence claims. We question whether it is appropriate to list them on such bioengineered food lists at this time.

Regarding updates to the list, GMA supports a process that is transparent and inclusive through notification in the Federal Register. However, the proposal to update the list on an annual basis could prove burdensome to USDA. Furthermore, GMA requests that the grace period granted to regulated entities match the time given to comply with the final rule, including the flexibility to use up existing label stock. AMS proposed that this grace period should be 18 months. As indicated in our comments, a compliance time of two years would be more appropriate and that timing should be extended to updates to the list for the same reasons the compliance deadline for the proposed rule should be more flexible.

3. Factors and Conditions

GMA supports the proposed Factors and Conditions process. However, we ask that AMS clarify the parameters for submitting a petition for determining additional factors or conditions under which a food is considered a BE food. AMS proposes requiring that the requested factor or condition be within the scope of the definition of bioengineering. We ask that AMS consider altering the standard or including an additional standard so that this process could be used to help a regulated entity determine whether a new technology (perhaps not yet invented) falls within the definition of "bioengineering" or the product thereof falls within the definition of a "bioengineered food."

a. Incidental Additives

GMA supports excluding incidental additives from disclosure through the Factors and Conditions process. GMA has maintained through the rulemaking process that components of foods that are exempt from inclusion on the ingredient statement according to 21 C.F.R. §101.100(a)(3) should also be exempt from disclosure. Examples include carriers and substances that have a functional role in ingredients but no function in the final product. By their very definition, incidental additives are present at insignificant levels in the finished food and have no technical or functional effect in that food.[7] For that reason, FDA regulations do not require the declaration of incidental additives in the ingredient statement on food labels.[8] Therefore, incidental additive use in food is not material to whether the finished food is bioengineered.

[7] 21 C.F.R. § 101.100(a)(3)(i) and (ii).
[8] *Id.*

Processing aids are considered incidental additives and we request that AMS make direct mention of processing aids in its final rule to ensure regulated entities are confident those components are exempt from disclosure. Indeed, the European Union (EU) recognizes that processing aids are outside of the scope of the GMO disclosure regulation.[9] We reiterate our request that AMS expressly exclude the category of secondary direct additives from disclosure. Like incidental additives, a secondary direct food additive has a technical effect in food during processing, but not in the finished food.[10]

AMS asked for public input on enzymes and similar products. AMS should clarify that products of bioengineered microorganisms, in which the microorganism is no longer present, such as products of fermentation produced using bioengineered microorganisms, are not considered a bioengineered food because the microorganism is considered a processing aid. This is consistent with the FDA labeling requirements noted above and it is consistent with bioengineered labeling requirements in the EU. To be clear, however, products from bioengineered microorganisms where the organisms remain active and functional in the finished food (e.g., certain yeasts, yogurt cultures) are not considered processing aids and therefore should be disclosed.

b. Undetectable Recombinant DNA

GMA opposes the proposed concept that the lack of quantifiable recombinant DNA would indicate that the food is not a bioengineered food under the standard (i.e., refined ingredients). It would be more practical for manufacturers to comply with a standard based on the realities of the current U.S. agricultural supply chain rather than one based on testing for many reasons. As FDA has recognized in its final guidance to industry on voluntary labeling statements on whether foods are genetically engineered, it is difficult to differentiate through validated test methods between plant-derived foods developed through bioengineering and those developed using traditional breeding methods. FDA explained that testing tends to be less useful in demonstrating the ***absence*** of bioengineered material in foods, particularly for refined ingredients. While methods for detection are becoming increasingly sensitive and can detect ever smaller amounts of rDNA, they cannot always be used to ***quantify*** the amount of rDNA present. A ***process***-based standard based on traceability rather than testing would be consistent with how industry currently keeps records to substantiate whether or not a food is bioengineered or produced with bioengineering.

For crops such as corn, soy, canola, and cotton where over 90 percent of the seeds planted are developed through the use of bioengineering, it is appropriate to take the position the ingredients derived from these crops are from a BE crop. It is fair to take that position because the current system has different channels for conventional crops and those that are "identity preserved" or "organic." Products marketed as "identity preserved" or "organic" rely on a system based on traceability and segregation rather than testing. Manufacturers do not keep documentation about the content or genetic material or results of Polymerase Chain Reaction (PCR) testing. The

[9] Regulation (EC) No 1829/2003 (clause (16)), http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:268:0001:0023:EN:PDF.
[10] 21 C.F.R. § 173.

proposal would impose significant costs by requiring manufacturers to acquire and maintain new types of records if AMS chose to rely on the detectability of recombinant DNA as an indication of whether a food is bioengineered or not. To further complicate matters, a manufacturer could be required to conduct multiple tests on the same ingredient. Most of the tests available today are crop specific in that one test is designed to detect BE corn while another test is designed to detect BE soy. Because BE corn and soy are grown on the same farms, a prudent manufacturer could be forced to test refined soy and corn ingredients using both tests to confirm nondetectable levels of BE content. Doing so would place an additional burden on manufacturers and ingredient suppliers. It is one of the reasons GMA members support disclosure of refined ingredients in a system that relies on the practicalities of today's market and the current methods of traceability and segregation for identity preserved and organic products. By requiring companies to test ingredients to confirm the absence of BE content, AMS would be ignoring the statutory mandate in section 293(g)(2) that AMS require those records that are customary or reasonable in the food industry to establish compliance with the standard.

From a practical perspective, if AMS establishes an "other factor or condition" based on testing demonstrating whether the food/ingredient "contains" modified rDNA, GMA would be concerned about the potential for inconsistency and needless litigation. For example, if ingredients derived from a crop on one of the two proposed bioengineered crop lists are presumed to be bioengineered unless there is testing that shows the ingredient or food contain no detectable levels of BE substances, this could result in a situation where some companies disclose a particular ingredient as BE while others do not, depending only on whether the company chooses to have testing done. For example, high fructose corn syrup could be treated as a BE ingredient by one company that does not do the testing but treated as a non-BE ingredient by another that does testing. Consumer confusion would result because the same HFCS sourced from BE corn would be treated as BE in some instances but not in others. It also could result in a situation where there is needless litigation over whether the food or ingredient "contains" detectable levels of modified rDNA. Another complicating factor is the potential for test methodologies to become increasingly sensitive. While today's methods may be unlikely to find BE content in a refined ingredient such as high fructose corn syrup it is possible a method of detection could be developed in the future that could detect the rDNA. The status of the ingredient as BE would be independent of the status of the source grain and dependent on analytical methods of detection. Including ingredients derived from bioengineered crop within the disclosure standard, regardless of the levels of rDNA in the finished ingredient/product, would avoid the inconsistency and potential for litigation described above.

D. EXEMPTIONS

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

GMA has no comments on this section.

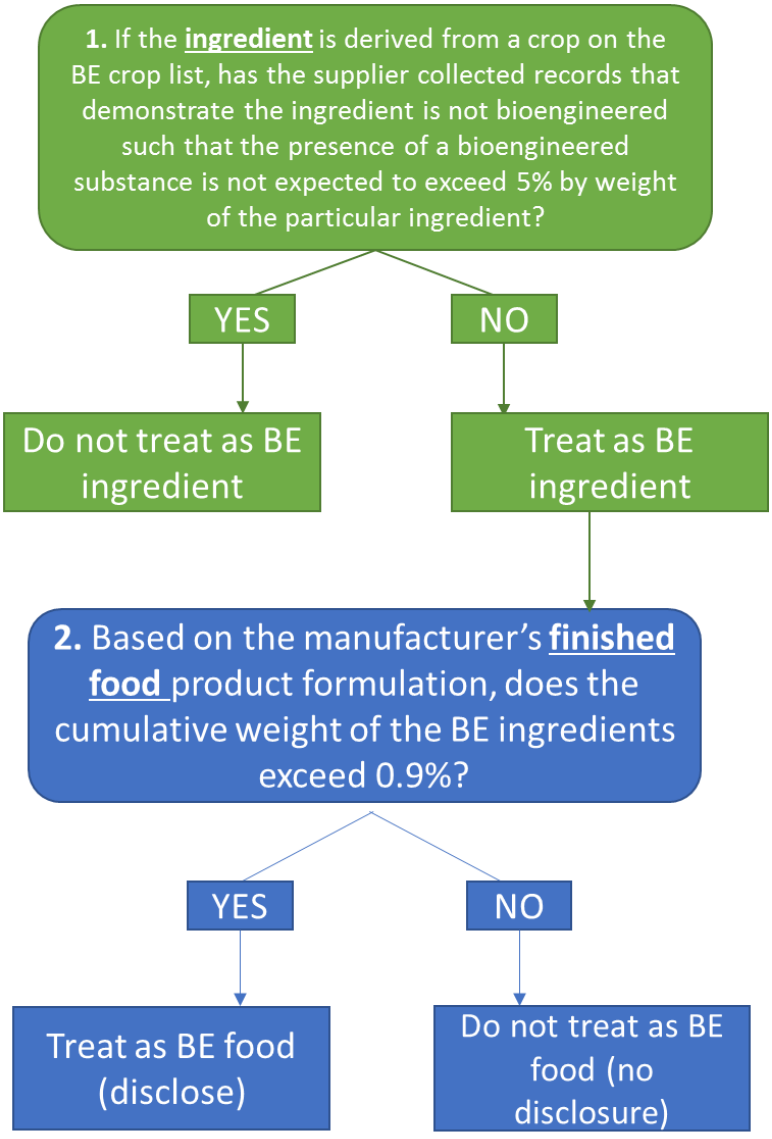
2. Very Small Food Manufacturers

GMA has no comments on this section.

3. Threshold

GMA does not support any of the three alternative thresholds proposed by AMS. We reiterate our request that AMS consider a dual threshold that considers low levels of presence from both unintentional, technically unavoidable sources in the supply chain and also from minor bioengineered ingredients in a finished food. We suggest a 5% threshold for unavoidable or adventitious presence for each ingredient, in conjunction with a cumulative 0.9% threshold by weight for all intentionally added bioengineered ingredients in a finished food.

The diagram below depicts how we envision this two-part test would function for ingredients that are derived from one of the BE crops that is commercially available. The decision tree that follows would not be followed for any ingredient or substance that is exempt under the BE food definition, such as incidental additives.



Unintentional and Technically Unavoidable Presence Threshold for Ingredients

AMS should establish a threshold of 5% unintentional and technically unavoidable presence of a bioengineered substance in each ingredient. When setting a threshold of this type, AMS should ensure that it is attainable, should not significantly add to costs for those entities that disclose, and should be credible and build trust with consumers. There is no international standard for bioengineered thresholds, nor is there any scientific basis for the threshold percentages because bioengineering does not raise safety, health or nutrition concerns. We recognize that some consumers may look to the European Union standards and we have emphasized harmonization with that standard throughout this comment when doing so makes sense in the U.S. context. However, European supply chains are very different from those in the U.S. given the difference in bioengineered crop adoption, planting, and transportation.

We note that USDA was unable to analyze the cost impact of various proposed alternative thresholds for unintentional and technically unavoidable presence. We estimate that the costs would increase for all entities if a threshold below 5% per ingredient is chosen for unintentional presence, whether they intend to disclose foods as bioengineered or choose to source non-bioengineered ingredients and therefore not disclose.

We also looked to other U.S.-based marketing programs to inform our recommendation of 5% per ingredient unintentional presence. AMS also administers the U.S. Standards for Grains Act of 1916, which authorizes USDA to establish official standards for grains and oilseeds to facilitate marketing, not for health or safety purposes. These standards define each grain, explain classes of grain, and specify numerical grades. For example, the standards for corn, soy, wheat, and canola allow up to 10% other grains. We therefore believe a standard of 5% inadvertent presence would be appropriate under the National Bioengineered Food Disclosure Standard.

We note that even the USDA organic regulations do not specify tolerance levels for bioengineered substances in organic foods. Trace amounts of bioengineered substance may occur in organic foods, but such presence does not jeopardize the food's organic status if the facility uses validated segregation practices.[11] We ask for the same flexibility to acknowledge that cross-contact is inevitable even with robust segregation practices. The level set by AMS should allow for current grain handling and segregation practices to continue and be considered sufficient under the bioengineered food disclosure standard.

We would urge AMS to adopt a pragmatic and appropriately flexible approach when it comes to the 5% inadvertent BE substance threshold in ingredients. In an instance when an ingredient is found to exceed the threshold, AMS should contact the regulated entity to determine whether the entity maintained records to support compliance with the threshold. In instances when the regulated entity can document supply chain controls demonstrating the farmer planted non-BE seed and every segment of the supply chain maintained proper segregation, the ingredient should

[11] See, "Can GMOs Be Used in Organic Products?" May 2013, https://www.ams.usda.gov/sites/default/files/media/Can%20GMOs%20be%20Used.pdf; and "Organic 101: Can GMOs Be Used in Organic Products," May 17, 2013, https://www.usda.gov/media/blog/2013/05/17/organic-101-can-gmos-be-used-organic-products.

not be deemed a BE food merely because factors beyond the farmer's, supply chain, or manufacturer's control resulted in the 5% threshold being exceeded for a particular ingredient. It is possible, for example, that the farmer planted non-BE corn with a proper buffer between the farmer's field and BE corn but an unusually strong wind during pollination carried a large quantity of BE pollen into the non-BE corn. In situations when the regulated entity can document it had the controls in place to prevent the inadvertent presence, AMS should allow the regulated entity to implement the appropriate corrective actions to ensure that future production will be within the 5% threshold. Such a pragmatic approach would reflect the practicalities of the market and supply chain without resulting in a product being deemed improperly labeled for reasons beyond the control of the regulated entity.

While we support a 5% threshold for unintentional and technically unavoidable presence per ingredient, we reiterate that the resulting standard should not rely on testing alone and instead should focus on traceability and segregation. In applying the 5% threshold, the recordkeeping requirements should be established as follows:

- When an ingredient is not derived from a crop on the bioengineered crop list, such as popcorn or wheat, regulated entities should not be required to keep specific records documenting that the ingredient does not contain more than 5 % of a bioengineered substance due to unintentional and technically unavoidable presence.
- When an ingredient is derived from a crop on the bioengineered crop list, and the regulated entity makes a disclosure for the food, no recordkeeping related to the 5% threshold would be required.
- When an ingredient is derived from a crop on the bioengineered crop list, such as corn meal, and the regulated entity does not make a disclosure for the food, regulated entities would need to keep records related to the 5% threshold. Appropriate records could include documentation showing the identity preserved seed is produced and handled throughout the supply chain in a manner to mitigate the potential for cross-contact with BE substances in the supply chain. In such instances the manufacturer would not need to have test results to support its conclusion that the ingredient contained less than or equal to 5% adventitious presence. In the event the data or information indicate that even when good manufacturing practices for segregation are followed, an ingredient will contain more than 5% by weight of a BE substance, the ingredient would be considered a bioengineered ingredient, and the regulated entity would then turn to step two and determine whether the 0.9% threshold for a finished food is exceeded.

Threshold for a Finished Food

AMS should establish a threshold of 0.9% bioengineered ingredients by weight, in a finished food. Above that level, foods should be required to be disclosed as bioengineered. AMS has authority under section 293(b)(2)(C) of the Law to establish a threshold of a bioengineered substance that a food may contain below which it is not considered a bioengineered food.

Manufacturers are committed to transparency with consumers. However, without this small allowance for BE ingredients in a finished food, the rule as proposed could result in foods currently bearing common "non-GMO" claims (made via third party certification programs) also requiring a "bioengineered foods" disclosure. For example, the Non-GMO Project Standard version 14.2 sets a 0.9% threshold for ingredients that are likely to be from genetically modified sources.[12] Likewise the NSF Non-GMO True North standard allows certain ingredients derived from a GMO source, even if the ingredient is functional in the finished product (i.e., not a processing aid). Examples could include soy lecithin at a level of 0.4% in chocolate. If the 0.9% threshold is not established, a product could bear a "non-GMO Verified" claim under the NSF True North Standard and *also* be a BE food under the AMS regulations. Mandatory disclosures on foods currently certified as "non-GMO" could be confusing for consumers.

We ask that AMS recognize the 0.9% threshold should be calculated on the basis of the product formulation without making adjustments for water and salt. When Vermont passed its now preempted labeling law it issued guidance stating the thresholds should be calculated excluding the weight of the water and salt in the food. As a result of that guidance, companies had to calculate eligibility for the threshold on a dry substance basis exclusive of added salt. The requirement introduced significant complexity to the threshold calculations. By allowing companies to base the threshold on the product formula they can use their existing product formulation data and information to determine thresholds. This approach is also consistent with the statutory mandate to require recordkeeping consistent with customary and reasonable industry recordkeeping practices.

Examples of How the Two Thresholds Apply

GMA requests that AMS include in the preamble to the final rule numerous examples of how the two thresholds would apply. We are providing a few examples here to further explain the proposed threshold framework discussed above.

> **Example 1.** A tofu product contains two ingredients: identity preserved (non-bioengineered) soy protein at 99.5% of the formulation and hydrolyzed soy protein from BE soy at 0.5% of the finished product formulation. The soy protein contains 4.9% BE soy due to adventitious presence and the supplier has records demonstrating that the soy is identity preserved throughout the supply chain, so it is not considered a BE ingredient. The hydrolyzed soy protein is a BE ingredient but because it is present at no more than 0.9% of the finished product by weight, the finished food is not considered a BE food.
>
> **Example 2.** A product contains soy lecithin as a processing aid, and ascorbic acid and vinegar as ingredients. All other ingredients are not derived from BE crops. The product is not considered a BE food, regardless of the levels at which the ascorbic acid and vinegar are used in the formulation, because these ingredients are exempt from the

[12] Non-GMO Project Standard v. 14.2, https://www.nongmoproject.org/wp-content/uploads/2017/09/Non-GMO-Project-Standard-Version-14.2.pdf, accessed June 26, 2018.

definition of BE food since they are products of microorganisms that consumed feed that may have been bioengineered.

Example 3. A product contains soy sauce at a level of 5% by weight of the formulation. The soy sauce is a multi-ingredient food that contains 10% BE soy. When calculating whether the food made with the soy sauce is a BE food, the calculation should be based on the amount of the BE soy in the soy sauce, because soy sauce itself is a multi-ingredient food, and not the amount of the soy sauce in the finished food. When soy sauce is present at 5% of the weight and the soy sauce contains 10% BE soy, the food formulated with the soy sauce would contain 0.5% BE soy and the finished food would not be considered a bioengineered food because it contains less than 0.9% by weight of BE soy.

Example 4. A product is a corn bread mix that is 80% corn meal and is found to contain 2% BE corn. The BE corn should be presumed to be adventitious and the product is in compliance with the 5% threshold, so no disclosure is required based on the corn meal.

Example 5. A low-calorie carbonated soft drink contains 95% carbonated water, 0.9% high fructose corn syrup, 0.5% nonnutritive sweetener, and the remaining ingredients are phosphoric acid, citric acid, preservatives, colors and flavors. We are asking AMS to exempt fermentation products from the definition of BE food so the acids would not be included in the calculation. The only BE ingredient would be the HFCS and it is present at 0.9% or less on the basis of the product formulation including water and salt, so the food would not be a BE food.

Example 6. A chocolate product is made with 1% by weight soy lecithin from bioengineered soy. The manufacturer does not have records indicating the soy lecithin is derived from identity-preserved soy, so the soy lecithin is considered a bioengineered ingredient and the food is subject to disclosure because it is present in an amount greater than 0.9% by weight of the finished chocolate product.

4. Animals Fed With Bioengineered Feed and Their Products

GMA supports AMS's proposal to incorporate in the final regulation the concept clearly laid out in the Act that animals should not be considered bioengineered solely because they consumed bioengineered feed into the proposed rule. We further ask that AMS broadly define an "animal" as any animal, fish, insect, or microorganism whose nutrition comes from a substance that is produced from, contains, or consists of a bioengineered substance is not considered bioengineered solely for that reason.

Doing so would be consistent with the rationale behind the Act that eating something that is bioengineered does not make the consuming organism bioengineered. Examples include milk and eggs from animals that consumed bioengineered feed and honey from bees that may have fed on pollen from bioengineered plants such as alfalfa. Like bioengineered feed consumed or

pollen collected by an animal, bioengineered substrates are consumed by the microorganism during the fermentation process and therefore should not result in the need for a disclosure. For example, microorganisms used for this purpose feed on a bioengineered substrate, consuming it as part of the fermentation process for products such as alcohol, amino acids, enzymes, carbon dioxide, citric acid, and vinegar.

5. Food Certified Organic Under the National Organic Program

GMA supports AMS's proposal that foods certified organic should not be subject to disclosure. GMA further agrees that organic certification would be sufficient to document that a food is not bioengineered.

III. Disclosure: What will the disclosure look like?

A. GENERAL

1. Responsibility for Disclosure

AMS requested input on the development of mutual recognition of appropriate foreign governments. GMA supports this concept and suggests AMS consider prioritizing the following when establishing recognition to ensure that appropriate minimum standards are met: the eventual threshold; disclosure of refined ingredients; an understanding of whether there are different crops bioengineered in that country compared to the U.S. lists; and ease of mutual recognition of documentation (e.g., if a regulated entity is meeting the standard required by the European Union, that documentation should be sufficient for the U.S. standard).

2. Appearance of Disclosure

GMA appreciates the flexibility AMS is proposing on the appearance of the disclosure. The flexibility on type size requirements helps reduce implementation costs for regulated entities. The requirement that the disclosure must appear prominently and conspicuously on a label and be visible under normal shopping conditions is one manufacturers are familiar with and ensures consumers have appropriate access to this information. Although we appreciate the flexibility on prominence, we ask AMS to recognize in the preamble that when the disclosure is made by written text such as "bioengineered food," a type size of at least 1/16th inch, or at least 1/32nd inch for smaller packages, would be considered prominent and conspicuous, consistent with FDA regulations. 21 C.F.R. §101.2(c). We believe such a statement from AMS is necessary to mitigate the potential for litigation over whether a disclosure in a particular type size meets the "prominence and conspicuousness" requirements.

3. Placement of Disclosure

GMA appreciates the flexibility AMS is proposing on the placement of disclosure. However, we seek additional flexibility on the information panel placement option. The disclosure statement

should be allowed to appear not only adjacent to the manufacturer/distributor statement as proposed, but also near the ingredient statement or Nutrition Facts panel, so long as the disclosure does not become intervening material. Consumers typically look at the Nutrition Facts panel and ingredient statement for additional information about the products they are purchasing. Therefore, positioning the disclosure adjacent to the Nutrition Facts panel or ingredient statement would be a logical location for consumers to seek out the bioengineered food disclosure.

Furthermore, we seek recognition from AMS that some products technically have more than one information panel, and request flexibility to use either panel to disclose this information to consumers. 21 C.F.R. §101.2 (Information panel of package form food) recognizes the Information Panel (IP) as the part of the label immediately contiguous and to the right of any principal display panel (PDP), or the panel immediately contiguous and to the right of the IP if the area to the contiguous right of the PDP is too small. We request alignment to the FDA definitions of the terms "principal display panel" and "information panel" as described in 21 C.F.R. §101.2. This additional flexibility on placement requirements would help to reduce implementation costs for regulated entities.

4. How BE Food Lists Relate to Disclosure

As stated above, GMA supports the proposed use of a list of bioengineered foods as the linchpin for disclosure.

B. TEXT DISCLOSURE

As discussed above, GMA recommends AMS consider combining the two bioengineered food lists based on adoption rate into a single list for simplicity.

GMA supports the proposed distinction between foods that are comprised of only bioengineered foods, and foods that are a mixture of bioengineered foods and not bioengineered foods. We support use of the term "Bioengineered food" for the first case. However, we suggest that AMS consider a slightly different phrase for the second case such as "Includes [a] bioengineered food ingredient(s)" instead of "Contains [a] bioengineered food ingredient(s)" as was proposed. The use of the term "Contains" may suggest to consumers that the statement is a warning. For example, FDA requires use of the phrase "CONTAINS PHENYLALANINE" as an indication to individuals with phenylketonuria (PKU), a disorder that causes the amino acid phenylalanine to build up in the body. Likewise, many manufacturers comply with mandatory allergen labeling with a statement with the word, "CONTAINS" as a warning for the eight major food allergens if such information is not provided in the ingredient list. Given consumers are accustomed to seeing "contains"-type language associated with warnings or allergens and because the statute and proposed rule are meant to not disparage the technology of bioengineering or bioengineered food, we suggest AMS consider the use of "Includes" instead of "Contains."

Even if the two lists based on adoption are condensed into a single list, the use of phrases such as "May be bioengineered food" or "May include [a] bioengineered food ingredient(s)" should still

remain an option for manufacturers. AMS should allow those phrases to be used in the case of products where the origin of an ingredient triggering disclosure can periodically switch from a bioengineered crop to a non-bioengineered crop. This option is important to accommodate current and potential future applications of bioengineering. Current examples of situations where this type of disclosure would be appropriate include foods that are or contain:

- Sugar, which can be derived from cane (non-bioengineered) or sugar beet (largely bioengineered).
- Blends of oils, where FDA ingredient labeling regulations permit the use of the term "and/or" with a listing of the specific oils, some of which may be derived from bioengineered crops (e.g., corn oil) and others from non-bioengineered crops (e.g., sunflower oil).
- An ingredient for which the manufacturer can demonstrate in some instances the ingredient is bioengineered while in other instances it is not, such as with powdered summer squash or papaya juice concentrate, where the supplier may use bioengineered or non-bioengineered varieties of summer squash or papaya.
- Flavorings in which the level of genetic material content may fluctuate between detectable or non-detectable levels, or when one flavoring may substitute for another.

Additionally, qualified language using the term "may" should be permitted for any other situation where the sourcing of an ingredient might change, but no change to the labeled ingredient statement is needed.

In such cases, if the sugar, oil(s), or other ingredient is the only potentially bioengineered food or ingredient in the product bringing it above the 0.9% threshold for ingredients, AMS should provide an option where the disclosure language conveys that the product may be sourced from bioengineered crops (e.g., "high fructose corn syrup sourced from bioengineered corn"). Use of this type of qualifying language should be optional and manufacturers should be permitted to use the standard disclosure statement instead of the qualified statement. The situations in which such an option may be used should be clearly and narrowly defined. In addition, the terminology used should be clear to consumers and consistent with the regular disclosure statement.

Finally, GMA requests that AMS permit bilingual translations of mandatory and voluntary disclosure statements for labels that use two languages.

C. SYMBOL DISCLOSURE

GMA has not taken a position on any of the proposed alternative symbols. We ask AMS to clarify a few points in its eventual final rule so that implementation is clear for regulated entities and we ask that AMS simplify the alternatives proposed to address printing concerns.

We note that none of the proposed alternatives included an option that would distinguish a between a symbol that communicates a food is, "Bioengineered food" and a food that, "Includes a bioengineered food ingredient." GMA seeks clarification on this point.

GMA appreciates the option for a black and white symbol. However, the number of colors accompanying any of the proposed alternative color symbol options (anywhere from four to six) could discourage or prohibit the use of the color symbol disclosure option. There is a cost associated with each new color that is introduced to a package. To address this, we suggest that AMS allow flexibility for a symbol option with a fewer number of colors, perhaps two to three at a maximum as well as other single-color options like navy or dark green when no black color is otherwise used on a graphic.

In addition to the reduction of the number of colors, we are requesting flexibility to allow for additional color options for the symbol to minimize the costs that will be incurred if new colors are added to the pantone palette of a package. The symbol will still meet the appearance requirements by being of sufficient size and clarity to appear prominently and conspicuously on the label. Sixty-percent or more of packaging printers do not print with process inks and therefore we recommend a single-color black or spot color option to match the Nutrition Facts panel. Adding an extra color that is specific to the BE disclosure symbol could increase print pricing by 25%. Most printing presses utilize six to eight colors at a time and a majority of these are used for primary design and messaging of the product. We ask that the symbol be made more flexible to utilize existing print inks on packaging so as to not raise the cost of printing.

In addition to the requests for a simplified and/or more flexible symbol option, we note that the technical CMYK proposals for some of the symbols need to be corrected. For example, proposed alternative symbol 2-C would require 0.05% Cyan. However, the typical minimum for printers of food packaging is 1% for Offset/Gravure and 2-3% for Flexographic printing techniques.

Furthermore, GMA appreciates the inclusion of a color symbol with "May be" text in each of the proposed alternatives. However, GMA has concerns that the small type size and reverse font coloring (i.e. the green outline with white font) associated with this symbol would make the text information illegible to consumers. Reverse copy and lines must be 7-point or greater to be read. GMA suggests AMS use the same wraparound text format that was proposed for the symbol with "Bioengineered" text (i.e. green text placed below the symbol) for the "May be" option.

Finally, whichever symbol option AMS makes available, GMA encourages USDA to inform the public about what the symbol means. We would welcome any opportunity to assist the Department on this effort.

D. ELECTRONIC OR DIGITAL LINK DISCLOSURE

GMA appreciates the flexibility provided in the proposed rule for placement of digital links on the physical package and for the truncation options for the call to action language for small and very small packages. However, we object to the proposed requirement for an additional phone number and call to action statement ("Call for more food information") in conjunction with the digital disclosure link and digital call to action statement ("Scan here for more food information"). Such a requirement will be costly to implement and is unnecessary when the regulated entity chooses the digital disclosure option because existing toll-free numbers already

appear on many labels, the package will also bear a link to the digital disclosure, and consumers have sufficient and growing access to digital disclosure methods. In short, Congress laid out three equally valid disclosure options in the Act that were to be made available to regulated entities: text, symbol, or an on-package link to digital disclosure. We ask that AMS not make one mode of disclosure significantly more burdensome than the others.

The requirement for an additional phone number and phone call to action statement with digital disclosure is unnecessary because consumers already have sufficient and growing access to digital disclosures. GMA supports consumer access to information about their food. In a study commissioned by USDA, a vast and growing (77%) majority of Americans own smart phones capable of accessing digital disclosures and that Wi-Fi is nearly universal in retail establishments (97%).

An additional phone number disclosure with the digital disclosure is duplicative. An informal survey among GMA members indicated that consumer phone numbers are already ubiquitous on packaging. It is common practice to include a toll-free consumer hotline on packaging to address consumer concerns and questions about their food. In its notice of proposed rulemaking, AMS already recognized that these existing telephone numbers are appropriate to be used for disclosure on very small packages stating, "…if the preexisting label includes a Uniform Resource Locator for a website or a telephone number that a person can use to obtain other food information, that website or telephone number may also be used for the BE food disclosure…" We suggest that when the digital disclosure option is chosen, AMS allow bioengineered food disclosure information to be accessed via these existing phone numbers, with the same placement and call to action to which consumers are accustomed. We ask that the same flexibility provided in proposed §66.112(d) be available to manufacturers that already provide consumers with the option to access food information through a phone line, regardless of the size of the package. By not allowing that flexibility, consumers could face two competing phone numbers on a single package, which would cause confusion.

Finally, the proposed requirement that phone lines be staffed 24/7 will be extremely costly to implement. Manufacturers have found that shoppers only access consumer information phone lines during normal shopping hours and therefore do not currently maintain 24/7 phone lines. In an informal survey among GMA members, manufacturers estimated the additional cost of maintaining existing lines on a 24/7/365 basis versus the standard practice of normal business hours in the range of hundreds of thousands or millions of additional dollars per year, per regulated entity. Since most phone lines are operated during normal business hours (typically Monday through Friday, 9:00am-5:00pm or 6:00pm) members looked at the costs of adding two additional 8-hour shifts during the week, adding service on the weekends, holiday and overtime pay, as well as operating and overhead costs. We note that USDA did not account for these costs in its original Regulatory Impact Analysis. Recognizing the Department seeks to minimize costs associated with the NBFDS, USDA should consider the less costly alternatives of allowing existing phone lines to serve this purpose and specify in the final regulation that phone lines should be available during normal business/shopping hours and eliminate the proposed provision requiring 24/7 maintenance of phone lines.

In addition to our concerns with the aspects of digital disclosure that impact the physical label, we have concerns regarding the proposed placement of information in a digital platform after a consumer has accessed a digital link. The Act requires that the "the electronic or digital link *will provide access to* the bioengineering disclosure located, in a consistent and conspicuous manner, *on the first product information page* that appears for the product on a mobile device, Internet website, or other landing page, which shall exclude marketing and promotional information" (emphasis added). However, the proposed rule changed the wording in a significant way, proposing "[t]he amended Act requires the electronic or digital link *to provide the bioengineering disclosure on the first product information page*" (emphasis added)[13]. There is a clear difference between the original wording of the statute and AMS' proposed interpretation. By omitting the word "access," AMS has significantly changed the meaning and we urge AMS to revert to the statutory language. The language in the statute would allow the first product information page to have links to multiple product attributes such as nutrition information, ingredient information, BE information, and manufacturing information. A consumer could then access the BE information by clicking on that particular link. Such an approach would reflect the statutory language and the manner in which manufacturers are making more information available to consumers such as through the SmartLabel® program. As proposed, AMS would require the BE information to be on the very first page of the link, equating the importance of the BE disclosure with nutrition information.

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

USDA's Study on Electronic or Digital Link Disclosure shows a large and growing number of consumers have sufficient access to digital disclosure methods. While we do not believe an additional option is necessary due to consumer access to other methods, GMA appreciates the additional possibility of a text message option. We ask AMS to clarify, however, the proposed language on fees related to the text message disclosure option. When a company sends or receives text messages via short codes (i.e., five- or six-digit shortened phone numbers that can only be used to send and receive text and multimedia messages), wireless carriers require that it comply with the CTIA Short Code Monitoring Handbook, available at https://www.tatango.com/resources/ctia-short-code-monitoring-handbook/. (CTIA – The Wireless Association is a trade association representing the wireless communications industry.) Among other things, the Handbook requires a disclosure reading "Message and data rates may apply" to be provided in the call-to-action. Proposed § 66.108 states that the entity responsible for the disclosure "must not charge a person any fee" to access the disclosure. We ask AMS to clarify in the final rule that this language does not prohibit parties from making the

[13] By way of comparison, the states of California and New York have recently passed Cleaning Product Ingredient Disclosure laws and both require information to be disclosed digitally, accessible from the package. Both of these laws recognize that digital links can be multi-purpose and require that the consumer has the ability to access the regulatory required information in no more than four clicks from the product-specific internet site. As use of digital disclosure increases as a compliancy tool for multiple disclosure requirements, we ask USDA to create a standard that facilitates consumer access to information beyond the bioengineered food disclosure. Requiring that the digital link provide "access to" the bioengineered food disclosure on the first product information page, would allow the product information page to also provide access to other required disclosures.

"message and data rates may apply" disclosure and does not prohibit consumers being charged their normal text messaging or data rates if they do not have an unlimited plan.

GMA further suggests that if AMS requires use of a phone number to accompany the digital disclosure, that the text message should also be an option for that purpose. GMA suggests that AMS consider flexibility for future disclosures and allow the text message to serve more than one disclosure purpose (as the electronic and phone options could). GMA requests clarification that manufacturers could use a shared, centralized text message code for each disclosure option to be maintained by the industry in order to minimize costs (i.e. one code for "Bioengineered food", one for "Includes bioengineered ingredients", one for "May be bioengineered food", and one for "May include bioengineered ingredients", etc.).

F. SMALL FOOD MANUFACTURERS

1. Definition

GMA has no comments on this section.

2. Telephone Number

GMA has no comments on this section.

3. Internet Website

GMA has no comments on this section.

G. SMALL AND VERY SMALL PACKAGES

GMA supports AMS's proposed definition for "small packages" as those with a total surface area of less than 40 square inches.

GMA also supports AMS's proposed definition for "very small packages" as those with a total surface area of less than 12 square inches. However, in defining "very small packages." AMS cites an FDA reference as 21 C.F.R. § 101.9(j)(13)(i)(B). GMA is not aware of such a reference and notes AMS may have intended 21 C.F.R. § 101.9(j)(13)(i) instead. We seek clarification on the intended citation.

Furthermore, with regards to defining "very small packages" we also ask that AMS incorporate the additional exemptions found in 21 C.F.R. §1.24 which provides additional accommodation for individual serving-size packages of foods containing less than ½ ounce or ½ fluid ounce for use in restaurants (e.g., single use condiment packets) and individually wrapped pieces of penny candy and other confectionery of less than one-half ounce net weight per individual piece.

Relatedly, we reiterate our previous request that AMS establish an exemption for individual units in multi-unit retail packages when the following conditions are met: (1) the outer packaging of

the multi-unit retail package bears the required disclosure; (2) the individual unit is enclosed within and not intended to be separated from the retail package under conditions of retail sale; and (3) each unit container is labeled with a statement such as "this unit is not labeled for retail sale" or "this unit not labeled for individual sale." Such an exemption would be consistent with FDA's nutrition labeling regulations at 21 C.F.R. § 101.9(j)(15).

H. FOODS SOLD IN BULK CONTAINERS

GMA has no comments on this section.

I. VOLUNTARY DISCLOSURE

GMA members support broad mandatory disclosure of bioengineered foods that ensures all regulated entities are subject to the same requirements; this includes the mandatory disclosure of refined ingredients, regardless of whether the ingredient contains the modified genetic material. The vague voluntary disclosure provision included in the proposed rule has the potential to do more harm than good by creating additional confusion for consumers and an uneven playing field for manufacturers.

In addition to the mandatory disclosure requirements, GMA believes it is crucial for AMS to recognize that companies may make voluntary disclosures that go above and beyond the disclosure standard. This includes both (1) additional information about foods that meet the definition of "bioengineered food" – such as information explaining FDA's view that there is no significant difference between bioengineered foods and those with ingredients derived from conventional breeding techniques, or disclosures identifying the specific ingredients or percentage of ingredients that are bioengineered; and (2) information about foods that do not meet the definition of bioengineered food. As drafted, the proposed rule only addresses voluntary disclosures for foods that meet the definition of "bioengineered food." There is no provision addressing such disclosures for foods that do not meet the definition, and such a provision would become particularly important in the event AMS exempts refined ingredients that do not contain DNA from the definition of BE foods.

GMA requests that AMS recognize that voluntary disclosure statements for foods that do not meet the definition of "bioengineered food" are appropriate, provided they are neither false nor misleading. GMA also asks AMS to list in the text of the regulation several examples of appropriate such claims. Providing these examples in the text of the regulation would be extremely helpful to GMA member companies looking to communicate with consumers about the sourcing of ingredients. AMS should make clear that these are examples only and not an exhaustive list of appropriate statements.

- Statements identifying the source of an ingredient or ingredients as bioengineered:
  - "Bioengineered crops used in the production of this food"[14]
  - "Includes ingredients sourced from bioengineered crops"
  - "Ingredients derived from a bioengineered source"
  - "Includes soybean oil derived from bioengineered soybeans"
- Statements about the amount of ingredients that meet the "bioengineered food" definition, regardless of whether the finished food meets the definition:
  - "Contains x% bioengineered ingredients"
  - "Made with BE ingredients"
- Disclosures about technology that falls outside the definition of bioengineering:
  - "Includes an ingredient sourced from a gene edited crop"
- Statements about the safety of bioengineering:
  - "FDA has found no significant difference showing that bioengineered foods and ingredients differ from other foods in any meaningful or uniform way, or that, as a class, foods developed by the new techniques present any different or greater safety concern than foods developed by traditional plant breeding."[15]

We also ask AMS to recognize it is appropriate to identify individual ingredients that meet the definition of "bioengineered food" within the ingredient statement by using an asterisk next to the relevant ingredient and the statement "bioengineered ingredient" placed elsewhere on the same panel, below or adjacent to any other FDA-mandated labeling elements. This should be permitted regardless of whether the finished food meets the definition of BE food.

By recognizing examples of such voluntary claims that may be made for foods or ingredients that do not meet the definition of BE foods and by allowing companies to disclose voluntarily the BE food ingredients in a product, AMS would make it clear voluntary statements are authorized under the regulation. Such clarity would deter future litigation over the appropriate voluntary disclosures that may be made. The voluntary disclosure provision that we are requesting also would help drive consistency in the terms used by manufacturers to identify such foods and would allow for greater transparency for consumers.

[14] In a recent survey by a manufacturer of its consumers in June 2018, 44% of respondents chose "Bioengineered crops used in the production of this food" as the best way to communicate that these ingredients are used in products, followed by 31% who thought that "Ingredients sourced from bioengineered crops" was best. Thirteen percent believed "Produced from a bioengineered source" was best and 12% indicated "This food is derived from bioengineered crops" was best.

[15] *See* FDA Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants (Nov. 2015), https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm059098.htm.

IV. Administrative Provisions

A. RECORDKEEPING REQUIREMENTS

1. What Records are Required

GMA appreciates the flexibility provided to regulated entities in the types of records that can be maintained to establish compliance with the Act, and supports keeping product formulations and recipes confidential. GMA agrees that reasonable and customary records already in use in the industry should be sufficient to establish compliance with the Act. Further examples include identity preserved (IP) certification, supplier affidavits, continuing guarantees, and statements from suppliers.

In its proposed rule, AMS suggests that regulated entities would need to maintain records showing that foods subjected to a specific process have been tested to demonstrate that modified genetic material cannot be detected. Unless a "Non-GMO"-type claim is being made about a food or ingredient, food manufacturers do not typically test for, nor maintain documentation about, genetic material content. This testing is very costly when performed by 3rd party laboratories - $200 per test for many of the common assays – and cost-prohibitive to buy equipment and hire skilled laboratory personnel for in-house testing. Screening tests, which are less expensive, are often unreliable or inappropriate for certain products. If compliance is based on testing and verification to ensure thresholds are met, testing may need to occur with each new lot of ingredients. For large lots, multiple samples may need to be taken to obtain a representative composite sample, depending on the ingredient. Manufacturer situations vary; depending on the ingredient, new lots could be received as frequently as daily, weekly, or monthly.

As discussed above, GMA continues to express its unwavering support for the mandatory disclosure of refined ingredients derived from bioengineered crops. However, in the event that AMS decides to exempt refined ingredients from disclosure when they do not contain the modified genetic material, we urge AMS to establish and maintain a list of refined ingredients considered to be devoid of modified genetic material. This list would eliminate the need for testing and maintaining documentation which demonstrates that an ingredient is refined. Since the food industry wants to disclose the presence of refined ingredients sourced from bioengineered crops, and consumers seek this information, testing for detectability of modified genetic material represents an undue financial burden on industry and an unnecessary increase in food prices.

GMA also asks for clarification that regulated entities may entirely rely on traceability records, particularly supplier records, rather than testing results, to establish compliance with the Act. GMA believes this is critical to avoid placing undue burdens on industry facilities, particularly considering the Act covers a marketing issue and not a food safety issue.

2. How Recordkeeping Applies to Disclosure

As discussed above, GMA suggests AMS condense the two bioengineered food lists based on adoption rate into a single list for simplicity.

a. Non-Disclosure of Foods on Either List

GMA supports the proposed presumption that foods on or containing ingredients from either list are BE or contain BE ingredients, unless the regulated entity maintains records to demonstrate that non-disclosure is appropriate. AMS should make clear in the final regulation that appropriate records to support non-disclosure when a food contains ingredients from either list are not limited to testing results and would appropriately include traceability records. For example, in the event a regulated entity does not make a disclosure for a food containing a soy ingredient, it could maintain supplier records demonstrating non-BE soy beans were used in a product or records showing the soy ingredient accounts for less than 0.9% of the total weight of the product. By recognizing that traceability records are sufficient to support non-disclosure, AMS would help ensure the recordkeeping requirements are consistent with the records that are customary and reasonable to maintain in the food industry, as required by the statute. Food manufacturers generally do not maintain or receive from their suppliers testing records for ingredients or finished foods that demonstrate the presence or absence of rDNA. With respect to how the inadvertent presence threshold relates to recordkeeping requirements, please see GMA's comments above under the "threshold" section.

GMA also supports AMS's proposal to not create any recordkeeping requirements for foods not on nor containing ingredients from either list.

b. Disclosure of Foods on Either List

GMA supports the proposed presumption that foods on or containing ingredients from either list are BE or contain BE ingredients, with no additional documentation required.

3. Other Recordkeeping Provisions

GMA supports the proposed two-year retention period for records as this is consistent with FDA's nutrition labeling regulations for records supporting nutrient declarations. We request that AMS recognize that relevant records may reside at a corporate office or headquarters, not just the manufacturing facility. GMA also supports allowing electronic and offsite storage of records (provided that such records can be made available with reasonable notice by AMS).

However, GMA does not support the proposed rule allowing for only five business days' notice to produce records. GMA does not believe this is sufficient time for regulated entities to produce the necessary records, given that they could be held in several locations as described in the paragraph above. GMA stresses that the NBFDS is meant to be a marketing standard not related to food safety. As with the record keeping requirements, it is more appropriate for record production requirements to be consistent with other marketing programs, such as the 4- to 6-

week notice given to produce records establishing compliance with FDA menu labeling requirements.[16]

B. ENFORCEMENT

Immediate posting of non-compliance without the opportunity for a regulated entity to dispute the findings would invite unnecessary litigation. Therefore, GMA supports the proposed regulations for enforcement, including record audit and examinations, notice of non-compliance to regulated entities with a 30-day window to object and request a hearing, and making the results public if a hearing is not requested or the Administrator/designee upholds the finding of non-compliance. GMA suggests making such findings public via posting on the AMS website, similar to how AMS publicizes compliance findings under the Organics program. GMA also suggests that the results remain on the website for 6 months, as afterwards this information has diminishing relevance but can still be accessed via FOIA requests.

GMA asks AMS to clarify that enforcement of the disclosure standard would be conducted as follows. When conducting an audit of a regulated entity to determine whether the entity is in compliance with the disclosure standard – either on its own initiative or in response to a complaint by a consumer, competitor, state regulator, or another party – AMS should begin by contacting the regulated entity and providing a 4 to 6-week period for the entity to produce appropriate records. If the company can provide records demonstrating the food is not subject to disclosure, the entity would be deemed in compliance. Additionally, where appropriate, AMS should provide an opportunity for the regulated entity to implement corrective actions rather than being found out of compliance. For example, if the food is found to contain more than 5% presence of a bioengineered substance from a particular ingredient, the regulated entity should be provided an opportunity to demonstrate that its suppliers had appropriate controls in place to segregate the product. If such records exist, the entity should not be found to be out of compliance but should be given an opportunity to implement corrective actions. Such an approach is consistent with the NBFDS as a marketing standard and not a health or safety standard.

C. PROPOSED EFFECTIVE AND INITIAL COMPLIANCE DATES AND D. USE OF EXISTING LABEL INVENTORIES

GMA appreciates AMS' proposal to harmonize compliance dates for the NBFDS and for FDA's extension of 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 AMS' proposal and anticipated timing for the final rule, which appears destined to extend well beyond July 2018, a compliance date of January 1, 2020 for the NBFDS would

[16] FDA Guidance for Industry: A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods (Part II) Menu Labeling Requirements in Accordance with 21 C.F.R. § 101.11), April 2016, question 6.4, available at https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM461963.pdf.

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.

Therefore, GMA requests AMS establish 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 and designing, printing, and applying the label to products subject to the NBFDS.

GMA urges AMS to further specify that the compliance date applies to the date the products are produced. This will ensure continued marketability for products previously produced, labeled, held in storage, in shipment or offered for sale at a retail establishment. We further ask that AMS permit compliance through the traditional printing of food labels or, alternatively, through application of stickers or ink-jet printing of an existing label.

In addition to the compliance date for all foods, GMA asks that AMS recognize some manufacturers continue to use disclosure language that complies with former Vermont Act 120, which went into effect on July 2016 before being preempted by passage of the National Bioengineered Disclosure Standard in the same month. GMA requests that AMS permit the use of disclosure language that complies with the requirements of Vermont Act 120 and Vermont Consumer Protection Rule 121 (i.e., "[May Be] [Partially] Produced with Genetic Engineering") for an additional year after the compliance date established in the final rule. These manufacturers are already complying with the spirit of disclosure. Allowing them additional time ensures a more orderly transition to AMS' eventual final disclosure options.

V. Rulemaking Analyses and Notices

GMA appreciates the in-depth and detailed economic analysis contained within the AMS' Regulatory Impact Analysis. GMA agrees 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 a patchwork of state-by-state labeling requirements. GMA suggests AMS reconsider two key concepts presented in the rulemaking analysis; 'nesting' and 'shielding' when comparing the impact of Scope 1 (which is GMA's preferred scope) and Scope 2 (which excludes refined ingredients from mandatory disclosure).

Nesting

The "nesting" concept put forward by AMS correctly notes that most foods contain more than one ingredient. However, AMS suggests that if a food is not required to disclose due to the presence of a refined ingredient (e.g. sugar) it may contain another bioengineered ingredient that is not a refined ingredient. AMS used the example of a "breaded chicken product. The first few

ingredients listed on the product label include Salt, Spice, Sugars, Water, Onion Powder, Garlic Powder, Dextrose, and Modified Food Starch. The categorical exemption would apply to Sugars and Dextrose, but the product would still require disclosure to the presence of Spice and Modified Food Starch." AMS found that nesting is sufficiently widespread that there would be no noticeable difference in the number of labeled products resulting from a categorical exemption of oils and sugars.

This is in stark contrast to the assessment GMA conducted in 2017, which found the exclusion of refined ingredients would result in 78 percent fewer products being otherwise disclosed. In July 2017, GMA surveyed members to identify ingredients typically sourced from bioengineered crops that are common in the U.S. market including but not limited to corn, soy, canola, and sugar beets. Working from a database of manufactured products, GMA began by excluding products that would not be subject to mandatory disclosure, including single-ingredient milk, meat, poultry, and egg products as well as those certified as Organic or some form of 'non-GMO'. From there the list of commonly bioengineered ingredients was used to estimate the number of products that could be subject to mandatory disclosure if refined ingredients were included and if they were excluded. The impact of excluding refined ingredients from disclosure is significant.

GMA members are aware of many categories of food that only include refined ingredients from bioengineered sources and without any ingredients which "contain" modified genetic material. Exempting refined ingredients would result in significantly fewer products requiring disclosure than typical "GMO Labeling-type" requirements such as Vermont's law. Common examples of foods that only contain refined BE ingredients include but are not limited to: many jams, jellies, preserves and other fruit spreads; soybean, corn, canola and blended vegetable oils; breakfast syrups; relishes, pickles and other condiments; flavored and sweetened ready-to-drink coffees and teas; fortified fruit and vegetable juices; peanut butters; ice cream toppings; baking mixes; potato chips; and soft drinks. Given the many products that fall into these categories, we urge AMS to correct its assessment on the impact of refined ingredients as GMA believes the impact of excluding them from mandatory disclosure is much greater than AMS has documented.

Shielding

AMS found that the administrative costs associated with Scope 2 were slightly higher relative to scope one due to "shielding." According to AMS, "[s]hielding results from the fact that disclosure is a binary decision (you label or you don't). As such, the costs of deciding whether and how to label will be capped by the lowest administrative cost ingredient on a particular label. In other words, if you have BE corn flour, you will label the product before you need to worry about tracking down the BE status of your xanthan gum. To the extent that some of the oils and sugars are on the low administrative cost end of the spectrum, the administrative cost for an individual product could actually increase if the lower administrative cost ingredients are exempted." If an ingredient of high percentage is BE in a product and that scope should stop once the 0.9% intentional ingredient is met. For example, if >0.9% corn flour is present in the finished product then it is labeled BE and further ingredients will not necessarily need to be documented.

GMA appreciates that a manufacturer may only need to document BE status for a single ingredient or a small number in product that exceed the threshold, but each ingredient is well-documented before a disclosure determination is made. The 'shielding' concept as presented by AMS does not adequately reflect how and when a manufacturer determines the genetic modification status of foods and ingredients, and of the product development process. Manufacturers typically "track down" the genetic status of every single ingredient during the ingredient approval process, which is very early in the product development stage. Often, manufacturers incur cost due to delays in obtaining that information from ingredient suppliers. Manufacturers cannot wait until a product's label is developed to make determinations about the BE status of ingredients. Product developers need to know the genetic status (and all other ingredient attributes) of ingredients *before* a product can be created, especially if one of the criteria for the product being developed is to qualify for a non-GMO claim. Product developers then can choose ingredients from an entire approved ingredient portfolio that meet product criteria. The same ingredient might be used in multiple types of products. Later on, when the label is being developed, the BE status of the finished product is determined, based on BE status of each ingredient, taking into account any exemptions and thresholds that apply. In the shielding analysis, we ask that AMS recognize that determining the genetic status of all ingredients is a necessary part of the ingredient approval process, which happens well before, and unrelated to the process of evaluating a finished product to determine which BE statement is required. Again, the process of "tracking down" the BE status of all ingredients is not relieved during the process of making a BE determination of a finished product.

Sincerely,

Karin F.R. Moore
Senior Vice President & General Counsel
Grocery Manufacturers Association

[i] The Grocery Manufacturers Association (GMA) is the trade organization representing the world's leading food, beverage and consumer products companies and associated partners. The U.S. food, beverage and consumer packaged goods industry plays a unique role as the single largest U.S. manufacturing employment sector, with 2.1 million jobs in 30,000 communities across the country that deliver products vital to the wellbeing of people in our nation and around world. Founded in 1908, GMA has a primary focus on product safety, science-based public policies and industry initiatives that seek to empower people with the tools and information they need to make informed choices and lead healthier lives. For more information, visit gmaonline.org.