



August 25, 2017

Submitted Electronically via [GMOLabeling@ams.usda.gov](mailto:GMOLabeling@ams.usda.gov)

**Re: AMS Questions on Bioengineered Food Disclosure Law**

Dear Sir or Madam:

The Grocery Manufacturers Association (GMA) appreciates the opportunity to provide comments to the U.S. Department of Agriculture's (USDA's) Agricultural Marketing Service (AMS) regarding the National Bioengineered Food Disclosure Standard (the "disclosure standard").

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 has facilities in 30,000 communities, generates \$1 trillion in sales annually, contributes \$415 billion in added value to the economy every year, and is the single largest U.S. manufacturing industry with 1.7 million manufacturing workers. 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](http://gmaonline.org).

GMA and its members advocated for and strongly support the establishment of a uniform national standard for the disclosure of bioengineered foods. We applaud AMS for seeking stakeholder input as the agency works to implement the standard via rulemaking. Below we respond to the questions posed by AMS. We have separated our responses by topic, including issues related to the scope of the standard (questions 1, 4, 5-11), the required disclosure (questions 12-18, 23-25), recordkeeping (questions 26-29), and imported foods (question 30). For that reason our responses are not ordered numerically but are arranged by topic.

**Scope**

**Question 1. What terms should AMS consider interchangeable with 'bioengineering'? (Sec. 291(1))**

**Context:** The disclosure standard would be a mechanism to inform consumers about their food. AMS is considering the advantages and disadvantages of allowing the use of other terms to provide for disclosure.

**GMA Response:**

No terms other than "bioengineering" should be considered interchangeable with "bioengineering" for the purposes of section 291(1), as the term bioengineering was specifically defined by Congress, whereas other terms were not.

However, this does not preclude the use of a different term in the required disclosure text. The definition of “bioengineering” in section 291(1) is a separate issue from the language to be used in the disclosure text (e.g., “bioengineered,” “genetically engineered,” “GMO,” etc.). Terms that are permitted to be used in the disclosure text, therefore, should not necessarily be considered interchangeable with the term “bioengineering” under section 291. For example, to the extent that AMS permits or requires the term “genetically engineered” or “genetic engineering” to be used in the disclosure text, we ask that the agency clarify that this term is not considered interchangeable with “bioengineering” under section 291 and that the ability to use this term in the disclosure text has no impact on the meaning of “genetic engineering” as that term is used in section 295 of the law. Section 295 establishes broad federal preemption related to any requirement relating to the labeling of whether a food or seed is genetically engineered or was developed or produced using genetic engineering.

AMS should also clarify that the term “genetic engineering” as used in section 295 is broader than the term “bioengineering” in section 291(1). This request is consistent with Congressional intent and would help to clarify the broad scope of the preemption provision in 295. The Senate Committee Report makes clear that the term genetic engineering is intended to be interpreted more broadly than bioengineering:

Congress recognizes the importance of having a uniform national standard for the disclosure of whether a food is or may be genetically engineered to prevent a patchwork of state, tribal, and local requirements. The preemption provision in Section 295 applies to all disclosure requirements regarding whether a food or seed is genetically engineered. **Congress selected the term “genetically engineered” food or seed, rather than “bioengineering,” 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.** The intended goal is national uniformity and avoiding the confusion and disputes that would arise if a jurisdiction could require disclosure relying on one or more other terms that might be used to refer in various ways to genetic engineering, biotechnology, or breeding techniques, now or in the future.<sup>1</sup>

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” under the law.

**Question 4. Will AMS require disclosure for food that contains highly refined products, such as oils or sugars derived from bioengineered crops? (Sec. 291(1)(A))**

**Context:** Many processed foods may contain ingredients derived from bioengineered crops, such as highly refined oils or sugars that contain undetectable levels of bioengineered genetic material such that they are indistinguishable from their non-engineered counterparts. AMS is considering whether to require disclosure for foods containing those derived ingredients that may be undetectable as bioengineered.

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<sup>1</sup> 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) (emphasis added).

### GMA Response:

GMA supports the inclusion of highly refined ingredients (HRI) 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 HRI disclosure is grounded in our industry’s commitment to transparency and to building consumer trust in the use of bioengineered ingredients and foods. 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 HRIs 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 HRI that come from these products. We expect that excluding HRIs from the scope of the mandatory disclosure standard would result in roughly 80 percent fewer products being disclosed under the federal law. While GMA members are committed to continuing to disclose these ingredients and foods regardless of the eventual requirements, we urge AMS to include them on a mandatory basis.

AMS has clear legal authority to require disclosure of HRI and foods containing HRI 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 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 fairly 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 HRI 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 although HRI may not “contain” rDNA, “bioengineered substances” – i.e., ingredients derived from bioengineered crops – are present in these foods or ingredients.

Under the landmark U.S. Supreme Court case *Chevron USA v. National Resources Defense Council (NRDC)*,<sup>2</sup> 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

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<sup>2</sup> 467 U.S. 637 (1984).

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 fairly broad discretion to which courts will defer. For these reasons, we do not interpret the statute as prohibiting USDA from including HRI 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 HRI:

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 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 HRI 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 HRI are considered to be bioengineered foods would be consistent with reasonable consumer expectations. 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 Food and Drug Administration’s (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.<sup>3</sup> 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.

As noted above, if HRIs are not included in the mandatory standard, many manufacturers will continue to disclose them voluntarily. Our industry prefers, however, to have a single mandatory standard to avoid consumer confusion. A clear, simple, and consistent mandatory disclosure standard that includes

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<sup>3</sup> 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>.

HRI will assist manufacturers in educating consumers about biotechnology as a safe and beneficial method of plant breeding.

Including HRI within the scope of the standard will also simplify compliance. It will be more practical for manufacturers to comply with a standard based on traceability rather than testing for a number of reasons. As FDA has recognized in its final guidance to industry on voluntary labeling, it is difficult to differentiate through validated test methods between plant-derived foods developed through bioengineering vs. those developed using traditional breeding methods. Tests tend to be less useful in demonstrating the absence of bioengineered material in foods, particularly for HRI. 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 standard based on traceability would be consistent with how industry currently keeps records to substantiate voluntary labeling statements regarding foods that are not bioengineered.

For these reasons, GMA favors the inclusion of HRI derived from bioengineered crops within the mandatory disclosure standard.

**Question 5. Although the Law states that the definition of bioengineering shall not affect any other definition, program, rule, or regulation of the Federal government, could there be potential areas of confusion between the definition of bioengineering as used in the Law and others similar terms used by the Federal government? If so, what are the potential remedies that could be added to this regulation to alleviate any confusion between this definition and others by the Federal government? (Sec. 292(b))**

**Context:** AMS recognizes that other Federal agencies have different terms to describe organisms created through recombinant DNA techniques. AMS is considering areas of potential overlap or confusion over terms, as well as potential language to add to this regulation to ensure the term bioengineering does not affect any other definition, program, rule, or regulation.

**GMA Response:**

The statute directs the agency to consider establishing consistency between the National Bioengineered Food Disclosure Standard and the Organic Foods Production Act of 1990 and its implementing regulations (the “organic standards”). GMA supports such consistency, where appropriate, to help reduce consumer confusion. To this end, we offer several guiding principles that should inform AMS’s efforts to establish consistency between the two standards.

First, the disclosure standard should not impact the organic standards in any way. The bioengineered food disclosure statute does not, and any implementing regulations should not, impact the authorities or obligations under the Organic Foods Production Act and no modifications should be made to the organic standards solely as a result of the bioengineered food disclosure rulemaking. GMA supports the statement in AMS’s September 2016 Policy Memo that “No proposed rules for bioengineered food disclosure will require that modifications be made to the USDA organic regulations.”<sup>4</sup> Similarly, the final

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<sup>4</sup> Memorandum from Elanor Starmer, Administrator, AMS, to AMS Deputy Administrators re: Consistency between Bioengineered Disclosure and National Organic Program, Sept. 19, 2016.

regulations implementing the bioengineered food disclosure law should not require modifications to the organic standards.

Second, consistent with the statutory language stating that certified organic products may be represented as “non-GMO” or “not bioengineered” solely on the basis of organic certification, no certified organic products should require disclosure as a bioengineered food. This approach is also consistent with USDA’s September 2016 Policy Memo, which states that “No certified organic products will require disclosure as bioengineered.”<sup>5</sup>

Third, the organic standards may appropriately inform some aspects of the disclosure rulemaking, where appropriate, but should not be viewed as binding in any way. For example, the USDA organic regulations define “recombinant DNA technology” (i.e., bioengineering) as an “excluded method.”<sup>6</sup> The definition of “excluded methods” under the organic standards refers to “recombinant DNA technology” that modifies organisms or influences their growth and development “by means that are not possible under natural conditions or processes,” which does “not include the use of traditional breeding” techniques. While we view these portions from the definition of “excluded methods” under the organic standards as similar to the definition of “bioengineering” in the bioengineered food disclosure statute, there are a number of potential inconsistencies between the two definitions. We therefore encourage AMS to establish a new definition of the term “bioengineering” that is specific to the disclosure standard and reflects the statutory language.

Fourth, GMA supports continued consistency between the two definitions, as appropriate. However, any future changes to the organic standards should not automatically result in changes to the bioengineered food disclosure standard. Furthermore, any proposals affecting the definition of bioengineered food for the purposes of the disclosure standard must be considered under the notice-and-comment rulemaking process.

**Question 6. Meat, poultry, and egg products are only subject to a bioengineered disclosure if the most predominant ingredient, or the second most predominant ingredient if the first is broth, stock, water, or similar solution, is subject to the labeling requirements under FFDC. How will AMS determine the predominance of ingredients? (Sec. 292(c))**

**Context:** AMS is considering how to evaluate predominance to determine how the Law will apply to multi-ingredient food products.

**GMA Response:**

In evaluating the predominance of ingredients to determine how the law will apply to multi-ingredient foods, AMS should rely upon the ingredient declaration on the product label. As described in FDA<sup>7</sup> and

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<https://www.ams.usda.gov/sites/default/files/media/Policy%20Memo%20GMO%20Disclosure-NOP%20Consistency.pdf>.

<sup>5</sup> *Id.*

<sup>6</sup> 7 C.F.R. § 205.2.

<sup>7</sup> 21 C.F.R. § 101.4(a).

USDA<sup>8</sup> regulations, the ingredients are required to be listed on the food label by common or usual name and in descending order of predominance by weight. AMS should look to the first ingredient declared in the ingredient statement. If the first ingredient is a meat, poultry, or egg product, the food should not be subject to the disclosure standard, regardless of whether the first ingredient is a single-ingredient food (e.g., “beef”) or a multi-ingredient food (e.g., “chicken tenders (chicken breast with rib meat, water, whole wheat flour, corn starch, salt)” or “beef fritters (bread crumbs (wheat flour, salt, yeast), beef)”). If the first ingredient is broth, stock, water, or a similar solution, but the second most predominant ingredient is a meat, egg, or poultry product, the food similarly should not be subject to the disclosure standard.

**Question 7. How should AMS craft language in the regulations acknowledging that animals consuming bioengineered feed are exempt from the disclosure requirements as bioengineered solely because they fed on bioengineered feed? (Sec. 293(b)(2)(A))**

**Context:** AMS is considering regulatory language similar to the wording in the Law and if the Agency should provide clarity that food derived from any animal, including invertebrates such as crickets or bee products, would not require disclosure as a bioengineered food solely because their nutrition came from food with bioengineered ingredients.

**GMA Response:**

To respond to the specific question posed by AMS in the “context” section, we encourage AMS to expand upon the language of the law. In addition to clarifying that foods and ingredients from animals that grow or feed on a bioengineered crop are not considered bioengineered on that basis, we encourage AMS to clarify that food derived from any animal, 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.

Consistent with the statutory language stating that a food is not considered bioengineered solely because it was derived from an animal that consumed bioengineered feed, the following foods and ingredients should be excluded from the mandatory disclosure standard:

- Those derived from animals, insects, or microorganisms which grow or feed on a bioengineered crop or ingredient directly derived from such a crop.
  - Examples include milk and eggs from animals that consumed bioengineered feed; honey from bees that may have fed on pollen from bioengineered plants; and fermentation products developed using a bioengineered substrate that is consumed during the fermentation process, such as alcohol, amino acids, enzymes, citric acid, and vinegar.

Like bioengineered feed or pollen consumed 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. In particular, the microorganism uses the substrate as a food source to grow, consuming it as part of the fermentation process.

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<sup>8</sup> 9 C.F.R. §§ 317.2(f)(1); 381.118(a).



- Those derived from animals that have been treated with drugs and pharmaceuticals produced from, containing, or consisting of a bioengineered substance.

It would be consistent with the statutory exemption for AMS to clarify that the treatment of an animal with drugs or pharmaceuticals produced from, containing, or consisting of a bioengineered substance does not result in the food derived from such an animal being considered a bioengineered food. In both cases the consumption of or treatment with a bioengineered substance does not result in the animal being considered a “bioengineered animal” and so should not result in a food derived from that animal being considered a bioengineered food.

**Question 8. What is the amount of a bioengineered substance present in a food that should make it be considered bioengineered? (Sec. 293(b)(2)(B))**

**Context:** The Law authorizes the Secretary to determine the amount of a bioengineered substance present in food in order for the food to be disclosed as a bioengineered food. The amounts of a bioengineered substance that may be present in food in order for the food to be a bioengineered food might be determined in a variety of ways: if a bioengineered substance is near the top of the list of ingredients, by determining the percentage of bioengineered ingredients in a food product, or by listing any ingredient that was produced through bioengineering, among others. AMS is considering how to determine the amount of bioengineered food or ingredient needed for a product to require a bioengineered disclosure, as well as the advantages and disadvantages of various methods.

**GMA Response:**

In establishing a threshold for the amount of a bioengineered substance in a food that should make it be considered bioengineered, GMA recommends that AMS consider two separate issues: (1) the low levels of adventitious presence in the agricultural supply; and (2) the amount of a bioengineered substance that makes a food bioengineered.

*Low levels of adventitious presence in the agricultural supply:* As discussed in our response to question 4, ingredients that are derived from a bioengineered crop, such as high fructose corn syrup from bioengineered corn or canola oil from bioengineered canola, should be considered bioengineered foods subject to the disclosure. When ingredients are derived from either a source for which there is no bioengineered version commercially available, or from a non-bioengineered or identity preserved source, they should not be subject to the disclosure even if there may be low levels of bioengineered material in the ingredient due to adventitious presence. The amount of permissible adventitious presence of a bioengineered substance should be consistent with existing agricultural practices in the U.S., such as those reflected in the U.S. Grain Commodity standards. We also encourage AMS to consider the USDA organic regulations, where the presence of adventitious levels of bioengineered material does not adversely impact the organic designation when the farmer has documentation demonstrating compliance with the organic requirements. The USDA organic standards do not set any upper limit as to the amount of permissible adventitious presence of bioengineered material.

*The amount of a bioengineered substance that makes a food bioengineered:* Beyond adventitious presence due to commingling or agricultural practices, 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. In order to comment on the appropriate level for this threshold, GMA will need to have a better understanding of AMS's proposed approach for processing aids, minor ingredients, and other substances discussed in our response to question 10. We encourage AMS to consider the threshold together with the issue of which exemptions are granted.

#### **Question 9. Should AMS consider more than one disclosure category? (Sec. 293(b)(2)(D))**

**Context:** AMS is considering if it should develop various categories for disclosure and if it should differentiate between those products that a) are bioengineered, b) contain ingredients that are bioengineered, or c) contain ingredients derived from bioengineered crops or animals. Additionally, AMS is considering the creation of a set of disclosures for a category of bioengineered foods for those products that, due to changes in sourcing, include bioengineered ingredients for part of the year, and non-bioengineered ingredients for other parts of the year. AMS is considering the advantages and disadvantages, based on cost, clarity, and other factors, of using a single disclosure category or multiple disclosure categories.

#### **GMA Response:**

With respect to the number of disclosure categories, AMS should provide an option for the disclosure of products where the origin of the disclosed ingredient 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 beet (largely bioengineered); and
- Blends of oils, where FDA ingredient labeling regulations permit the use of the term "and/or" with a listing of the specific oils,<sup>9</sup> some of which may be derived from bioengineered crops (e.g. corn oil) and others from non-bioengineered crops (e.g. sunflower oil).

In such cases, if the sugar or oil(s) is the only potentially bioengineered food or ingredient in the product, AMS should provide an option where the disclosure language conveys that the product may be sourced from bioengineered crops. Use of this type of qualifying language should be voluntary 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. We discuss the specific language for the disclosure text in our response to question 12.

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<sup>9</sup> 21 C.F.R. 101.4(b)(14).

**Question 10. What other factors or conditions should AMS consider under which a food is considered a bioengineered food? (Sec. 293(b)(2)(C))**

**Context:** AMS must develop a process to help stakeholders determine whether a food is subject to bioengineered disclosure. AMS anticipates the process would include considering factors such as these: whether a food contains a substance that has been modified using recombinant in vitro DNA techniques (Sec. 291(1)(A)), and for which the modification could not be obtained through conventional breeding or found in nature (Sec. 291(1)(B); [Question 2 and 3](#)), , and whether a food requires disclosure based on the predominance of ingredients (Sec. 292(c), [Question 6](#)), among others. The outcomes of these determination requests might be publicly posted on a Web site. The process to implement Sec. 293(b)(2)(C) is not intended to be an investigation or enforcement process (see [Questions 26-29](#)); instead, the implementation would likely be framed for manufacturers or developers of bioengineered food or ingredients who have a question on whether their food is subject to disclosure. AMS is considering the factors to be considered, the way to inform the public about the outcome of the requests, and ideas regarding the process to be used to make the determination.

**GMA Response:**

As discussed above under our response to question 4, AMS should determine via the rulemaking process that HRI are subject to the disclosure standard due to “other factors and conditions.”

In addition, a food should not be considered a bioengineered food solely because it contains or is:

- An ingredient currently authorized for use in certified organic foods, including those on the National List of Allowed Substances. Providing such an exception will establish consistency with the National Organic Program, as AMS is required to consider doing under the law.
- An incidental additive, including processing aids, or a secondary direct additive, that may be from a bioengineered source material. Examples include carriers (e.g. those used for flavor components) 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.<sup>10</sup> For that reason, FDA regulations do not require the declaration of incidental additives in the ingredient statement on food labels.<sup>11</sup> 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 GMO disclosure regulation.<sup>12</sup> Similar to incidental additives, a secondary direct food additive has a technical effect in food during processing, but not in the finished food.<sup>13</sup>
- Fermentation products produced using bioengineered microorganisms, such as vitamin B2 and B12 as long as the microorganism is no longer present in the ingredient or food. Bioengineered

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<sup>10</sup> 21 C.F.R. § 101.100(a)(3)(i) and (ii).

<sup>11</sup> *Id.*

<sup>12</sup> Regulation (EC) No 1829/2003 (clause (16)), <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:268:0001:0023:EN:PDF>.

<sup>13</sup> 21 C.F.R. § 173

microorganisms used in fermentation are considered processing aids, and should not result in the fermentation product being considered bioengineered for the same reasons discussed above with respect to processing aids. Furthermore, the source of the feedstocks for these fermentation processes should also not result in an ingredient or food being considered bioengineered.

- Ingredients isolated from bioengineered microorganisms to the extent possible. If the microorganism is present in the ingredient or food, the microorganism is being consumed as the food.

### Disclosure

#### **Question 12: If a manufacturer chooses to use text to disclose a bioengineered food, what text should AMS require for a text disclosure? (Sec. 293(b)(2)(D))**

**Context:** Currently, some food manufacturers use language compliant with the Consumer Protection Rule 121 from the State of Vermont to identify their food products as bioengineered (“Produced with Genetic Engineering,” “Partially Produced with Genetic Engineering,” or “May be Produced with Genetic Engineering”). AMS is considering whether to allow manufacturers to continue using these disclosures under the new national bioengineered disclosure standard and if their language is appropriate. Further, AMS is considering what phrases could be used as a text disclosure for bioengineered food that consumers would find informative, truthful, and not misleading.

AMS is also considering whether there should be one standard text disclosure language, or whether manufacturers should be allowed flexibility to choose from more than one acceptable phrase and where the bioengineered food disclosure should be placed on food packages.

#### **GMA Response:**

GMA recognizes that there are numerous terms used today to disclose that a food is bioengineered. We support the use of consistent language in the mandatory disclosure text to avoid consumer confusion while also maintaining continuity with existing labeling practices. Specifically, GMA supports use of the term “bioengineered” in the disclosure text and suggests that AMS consider the following two options for the mandatory disclosure:

- Ingredients sourced from bioengineered crop(s) (or animal as appropriate)
- Ingredients may be sourced from bioengineered crop(s) (or animal as appropriate)

It would also be appropriate for AMS to provide flexibility to disclose the name of the specific crop (e.g., “corn”) instead of using the term “crop.”

Additionally, some manufacturers currently use disclosure language that complies with Vermont Act 120, which went into effect last July 2016 before being preempted by passage of the National Bioengineered Disclosure Standard. GMA requests that AMS establish a “grandfathering” provision that allows continued use of disclosure language that complies with the requirements of Vermont Act 120 and Vermont Consumer Protection Rule 121 (i.e., “[Partially] [May Be] Produced with Genetic

Engineering”). The grandfathering provision we are proposing would only permit manufacturers that labeled products to comply with the Vermont law to continue to use those labels and to continue to use this disclosure text for future product labels.

Related to this request, we refer back to our response to question 1 and ask AMS to clarify that the term used in the disclosure has no impact on the scope of the term “bioengineering” in section 291(1) nor does it affect the definition of the term “genetic engineering” used in section 295.

**Question 13. If a manufacturer chooses to use a symbol to disclose a bioengineered food, what symbol should AMS require for disclosure? (Sec. 293(b)(2)(D))**

**Context:** AMS needs to ensure that the symbol designed for the bioengineered disclosure is not disparaging toward bioengineering. As with the text disclosure, AMS must develop criteria for placement of the symbol to ensure consumers can readily locate the symbol, the symbol is scalable for different sized packages, and the symbol is a meaningful representation of bioengineered foods. AMS is considering what the symbol should look like and guidance on its use.

**GMA Response:**

GMA recommends that AMS observe the following guiding principles when designing the disclosure symbol:

- The symbol should not be disparaging of biotechnology in any way. As an example, the symbol should not expressly or by implication convey a “warning” statement.
- The symbol should be required to be displayed in a prominent and conspicuous manner. We recommend that AMS adopt requirements that are no more prescriptive than those for other symbols currently managed by USDA, such as the USDA organic seal, which must appear “legibly and conspicuously” with certain requirements related to the contrast of the symbol and its background.<sup>14</sup> If text is required as part of the symbol, the text should be displayed in a type size no smaller than 1/16<sup>th</sup> inch, which is the minimum type size requirement for the ingredient statement under FDA regulations<sup>15</sup>
- AMS should provide flexibility to use either a black and white, or color version of the symbol, as is permitted for the USDA organic seal.
- AMS should provide flexibility on the placement of the symbol on packaging, including on the front, side, or back panels, as long as it does not conflict with other regulatory requirements for placement of mandatory labeling elements such as the ingredient statement and nutrition information.

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<sup>14</sup> 7 C.F.R. § 205.311.

<sup>15</sup> 21 C.F.R. § 101.2(c).

- AMS should consider testing the proposed symbol with consumers to ensure it is easily understandable, not disparaging, and sufficiently prominent. Furthermore, AMS could consider using the symbol to help communicate some of the benefits of the technology.

**Question 14: If a manufacturer chooses to use an electronic or digital link to disclose a bioengineered food, what requirements should AMS implement for an electronic or digital link disclosure? (Sec. 293(b)(2)(D))**

**Context:** [See Questions 23-25.](#)

**GMA Response:**

With respect to the specific language used for the disclosure provided via the electronic or digital link, AMS should adopt requirements that reflect the following principles.

- The disclosure language for the electronic or digital link should be consistent with the language used for the on-label disclosure text option.
- GMA supports the use of the following statement for the electronic or digital link, “This product includes ingredients sourced from bioengineered (BE) crops, commonly known as GMOs.” This is the language currently used by many companies under the SmartLabel™ program and should be permitted to serve as the disclosure statement.
- GMA requests that AMS permit the use of additional information to supplement the disclosure text so long as the information is truthful and non-misleading. For example, the standard should permit additional information to accompany the required disclosure text to explain that ingredients sourced from bioengineered crops are “commonly known as GMOs.”
- AMS should provide flexibility on the placement of the electronic or digital link on packaging, including on the front, side, or back panels, as long as it does not conflict with other regulatory requirements for placement of mandatory labeling elements such as the ingredient statement and nutrition information.

With respect to the mechanics of the electronic or digital link disclosure, GMA believes that AMS should not identify specific electronic or digital disclosure methods by regulation as technologies rapidly become obsolete. Instead, AMS should establish criteria for the disclosure method including requirements for (1) the **digital link** and (2) the **carrier** for the digital link. Below we provide background information on what is meant by each of these two terms, and then outline proposed criteria for each.

The electronic or digital “link” should be defined as a Uniform Resource Locator (URL). This technology is the foundation of most of the internet protocol. It is the string of alpha-numeric letters or numbers (i.e., www.URLaddress.com) that web browsers use to bring the user to the desired webpage. GMA does not expect this foundational element to change for a long period of time.

The URL requires a “carrier.” A “carrier” is a barcode or other technology that can embed the URL on a package label. As brief background, today there are a number of technologies that can do this (DataBar,

DataMatrix, Electronic Product Code (EPC / Radio Frequency Identification (RFID), Digital Watermarking, QR code). UPC codes do not have this capability.

With respect to the regulatory definitions of these terms, the “**digital link**” should be defined as a URL embedded in an on-package carrier. The URL must be embedded in a carrier because section 293(b)(2)(D) of the Law states that the use of “Uniform Resource Locators not embedded in the link” do not satisfy the requirements for an electronic or digital disclosure. Additionally, without the carrier, the consumer would need to type in an average of 26-42 characters on their device, which could lead to errors or frustration. (We note, however, that it may be appropriate to allow use of a URL address not embedded within a carrier as a reasonable alternative disclosure option for small food manufacturers under section 293(b)(2)(F)(i)(ii) of the Law.)

A compliant on-package “**carrier**” must:

- (1) Be able to contain or embed a URL.
- (2) AMS must ensure that its regulations encourage open-sourced technology but that they do not require the use of single-point (for-profit) providers or create intellectual property issues.
- (3) Allow the embedded digital link (the URL) to be broadly read by consumers via free apps or other smart device (e.g., smart phones, tablets) technology that has the capability to read the URL. Today, this is accomplished through the camera function on the devices but regulations must enable any other functions that allow consumers to gain access to the information via the carrier.<sup>16</sup>
- (4) Be easily understood by consumers as a carrier (such as a barcode, icon, or other technology) that can be read by a Smart Device.

In sum, the consumer would scan the carrier; the device would read the URL embedded in the carrier, and the consumer would be brought to a webpage containing the required disclosure information.

**Question 15. Should AMS specify in the regulations the type of electronic or digital disclosure manufacturers, e.g. QR code, can use to disclose bioengineered food? What steps should AMS take if an electronic or digital disclosure method becomes obsolete? (Sec. 293(b)(2)(D))**

**Context:** AMS recognizes that disclosure technologies may quickly surpass regulations. AMS is considering what terms will ensure the regulations keep pace with technological changes and how AMS can notify stakeholders about changes in technology as they occur. AMS is also considering what the most appropriate electronic or digital disclosure technologies are currently and how to deal with obsolete technologies.

**GMA Response:**

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<sup>16</sup> Today, smart devices can read UPC and QR codes via hundreds of apps (over 400 alone in each app store). In the past six months, Google Chrome (Feb 2017) and Apple (June 2017) announced that their next release would include a QR code reader as a standard utility within the camera function, eliminating even the need to have an app.

In order to accommodate current and future technology and to ensure the regulations do not become obsolete as technology advances, GMA recommends that AMS not identify specific electronic or digital disclosure methods by regulation. Instead, and as discussed above in our response to question 14, AMS should establish a set of criteria for the disclosure method, including principles for (1) a **digital link**, and (2) a **carrier**. The regulations should refer to use of a Quick Response (QR) code as an example of an appropriate carrier.

Digital Link: With respect to the criteria for the digital link, we believe that it is sufficient for the regulations to specify that the digital link must include a URL. The URL, like HTML code, is an internet protocol that will likely not change in the near future. However, GMA suggests that the regulation include a proviso that the requirements for the digital link will be reviewed and adjusted if and when internet technologies change.

Carrier: The technologies used for the carrier, i.e., the technology capable of embedding a URL, are more likely to change. As those technologies change, smart device reading capabilities will also evolve. The following criteria should be used when addressing emerging or obsolete capabilities. As discussed above, a compliant carrier must:

- (1) Be able to contain or embed a URL.
- (2) AMS must ensure that its regulations encourage open-sourced technology but that they do not require the use of single-point (for-profit) providers or create intellectual property issues.
  - As mentioned in our response to question 14, a number of carriers currently meet this requirement: QR codes, DataMatrix, DataBar, RFID, and some forms of digital watermarking.
- (3) Allow the embedded digital link (the URL) to be broadly accessible to consumers via free apps or other smart device (e.g., smart phones, tablets) technology that has the capability to read the URL. Today, this is accomplished through the camera function on the devices but regulations must enable any other functions that allow consumers to gain access to the information via the carrier.
- (4) Be easily understood by consumers as a carrier (such as a barcode, icon, or other technology) that can be read by a Smart Device.

Today, QR codes are one carrier that meets these four requirements.

GMA does not foresee the QR code becoming obsolete in the near future. Use of QR codes is actually growing. They give the brand owner control over where the consumer goes when they scan the carrier and a QR code can be multi-purposed to bring the consumer to one location while using the coding in the carrier for a completely different purpose in the manufacturing and production (business application) environments. Google and Apple have just recently announced that QR readers will be standard utilities within the camera function on the next releases and we can foresee carriers like Digital Watermarking emerging. It is therefore important that the rules be written based on the concepts of a digital link and a consumer-usable carrier.

These principles provide the flexibility to leverage emerging technologies like digital watermarking in the future if and when that technology meets the stated guideline above.



**Question 16. What kind of text, symbol, or electronic or digital disclosure should AMS require for bioengineered food that is not purchased from a grocery store shelf, such as food for sale in bulk (such as fresh produce in a bin or fresh seafood at a fish counter), in a vending machine, or online? (Sec. 293(b)(2)(D))**

**Context:** In some situations, disclosures may not be easily located when such products are on display for sale. AMS is considering disclosure practices for these and other non-conventional purchasing or packaging scenarios.

**GMA Response:**

The statute does not require that consumers be provided with access to the disclosure information prior to purchase, as was the case under the vending and menu calorie labeling provisions of the Affordable Care Act. For that reason, the information provided on the packaged food label itself should be considered sufficient disclosure to meet the requirements of the law. AMS should not require separate signage in, on, or near the vending machine, as there is no requirement in the law that consumers be provide access to the disclosure other than via the food package itself. Nor should AMS require any additional disclosure requirements when foods are sold online, other than the need for the packaged food itself to provide access to the disclosure. This would also ensure that packaged foods are subject to a single set of labeling requirements, regardless of the channel through which they are sold (i.e., vending, online grocery retail, or traditional brick-and-mortar grocery retail). GMA expects that information will be readily available to consumers online via SmartLabel™ and other emerging technologies and online retailer practices.

For food sold in bulk such as fresh produce, GMA suggests that AMS consider adopting FDA’s approach for voluntary nutrition labeling of such items in 21 C.F.R. § 101.45, whereby the information can be provided on the bulk produce bin, or via materials such as shelf-labels, signs, posters, brochures, notebooks, or leaflets. AMS should also permit the disclosure to be provided through digital disclosure, similar to the requirements for packaged foods.

**Question 17. The Law offers special provisions for disclosure on small or very small packages. How should AMS define very small or small packages? (Sec. 293(b)(2)(E))**

**Context:** AMS is considering if it should mirror FDA’s treatment of very small and small packages for nutrition labeling.

- a. In 21 CFR 101.9(j)(13)(i)(B), FDA defines small packages as those with less than 12 square inches in total surface area available to bear labeling.
- b. FDA also has allowances for packages that have less than 40 square inches of total surface are available to bear labeling.

### GMA Response:

The statute requires USDA, in its implementing regulations, to “provide alternative reasonable disclosure options for food contained in small or very small packages.” In implementing this requirement and defining the terms small and very small packages, GMA recommends that AMS look to the principles FDA uses to determine the appropriate format for nutrition labeling and to calculate the total space available for labeling.

FDA has not established a definition for “very small packages,” but has defined the term “small package” for the purposes of nutrition labeling in 21 C.F.R. § 101.9(j)(13)(i). This definition covers foods in packages with a total surface area of less than 12 squares inches in total surface area available to bear labeling. Although we are not providing a recommendation for the definition of “very small packages,” we expect a “very small package” would have proportionally smaller amounts of space available to bear labeling than one that meets the FDA definition of “small package.”

Additionally, FDA provides flexibility to use a smaller Nutrition Facts Panel format for those packages with a total surface area available to bear labeling of 40 or less square inches. 21 C.F.R. § 101.9(j)(13)(i)(A). GMA recommends AMS similarly provide flexibility in the disclosure requirements for packages with less than 40 square inches of space available for labeling. Appropriate options could include a reduced minimum type size, abbreviated text, or additional placement options to allow manufacturers more flexibility to fit the disclosure (i.e., text, symbol, or digital/electronic) within available space for labeling on the package.

Relatedly, we ask AMS to consider establishing 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).

### **Question 18. What are the reasonable disclosure options AMS should provide for food contained in very small or small packages? (Sec. 293 (b)(2)(E))**

**Context:** AMS is considering the disclosure standards for very small or small packages. FDA regulates nutrition labeling on very small or small packages differently. For example:

- a. Could disclosure requirements for very small packages be met by providing an address or phone number where consumers could obtain the information?
- b. Could disclosure requirements for small packages be met by providing abbreviated text disclosure or a Web site address where consumers could obtain disclosure information?

### **GMA Response:**

In addition to the standard disclosure options – i.e., text disclosure, electronic or digital link, or symbol – it would be appropriate for AMS to allow products in small and very small packages to meet the disclosure requirements using any of the following reasonable alternative disclosure methods:

- (1) Providing an address or phone number where the consumers could obtain the disclosure information. When a phone number is used, it would be appropriate to use the language specified in Sec. 293 (d)(1)(B): “Call for more food information” or “Call for more information.” Similarly, when an address is used, AMS could require the address to be accompanied by the language “Write for more food information” or “Write for more information.”
- (2) Providing a URL or website address that is not embedded in the digital or electronic link. For example: “For more food information, visit <http://www.example.com>,” where the URL is not embedded in a carrier.
- (3) Using one of the standard disclosure methods (i.e., text disclosure, electronic or digital link, or symbol), but providing for a reduced minimum type size, abbreviated text, or additional placement options to provide more flexibility to fit the disclosure (in whatever form the manufacturer selects) within the available space.

### **Question 23. Is there other equivalent on-package language that AMS should consider to accompany an electronic or digital disclosure besides “Scan here for more food information”? (Sec. 293(d)(1)(A))**

**Context:** The word ‘scan’ may or may not be relevant for each type of electronic or digital disclosure in the present or in the future. AMS is considering if it should issue guidance to identify equivalent language as technology changes and what that equivalent language would be.

### **GMA Response:**

With respect to the specific verb used to accompany the electronic or digital disclosure, we expect the term “scan” will appropriately describe how the electronic or digital disclosure can be accessed for the foreseeable future. Scan is an appropriate and relevant term to accompany the electronic or digital disclosure. Manufacturers should be provided with additional flexibility to identify the appropriate reference link. Therefore, the term “Scan here...” could be replaced with terms such as “Scan this icon...”, “Scan this logo...”, or “Scan this image...” AMS should provide flexibility for alternatives to the term “here” in on-package language to accompany electronic or digital disclosures.

If another technology becomes available and meets the principles set forth in our responses to questions 14 and 15, and it is readily apparent that the term “scan here” is no longer an appropriate action to describe how a consumer may know to access information from that technology, then AMS would have the authority under the statute to provide companies with the option to use a different verb that better reflects how that technology provides access to the disclosure. However, given the ubiquitous use of the term “scan” to provide access to electronic or digital information on food labels, and the resulting consumer understanding of that phrase, we would not encourage the consideration of other terminology until there is a specific example of technology that meets the criteria set forth in our

responses to questions and 14 and 15, coupled with a compelling case that the term “scan here” is no longer the best method to inform the consumer how to access the disclosure.

In addition to the language specified in the statute to accompany the digital or electronic link (“Scan here for more food information”), AMS should also permit the language “Scan here for more information” to be used. Permitting a statement that does not refer specifically to “food” information helps to accommodate uses of digital disclosure technology beyond the scope of the bioengineered food disclosure law. Digital disclosure goes far beyond information on the “food” and can provide information on ingredients, allergens, source or origin, social responsibility, sustainability, and more. We expect digital disclosure will also be used to comply with state regulations requiring disclosures for non-food items (e.g., ingredient and safety disclosure requirements for personal care, cosmetics, and cleanings). Permitting use of the language “Scan here for more information” facilitates use of a single statement to provide access to digital disclosures used for a wide range of products and to provide a wide variety of information not limited to the food itself. This consistency in language also helps to facilitate consumer education on digital disclosures. Omitting the term “food” does not materially change the meaning of the statement as the consumer is still informed that more information can be found by scanning the digital or electronic link.

**Question 24. How should AMS ensure that bioengineered food information is located in a consistent and conspicuous manner when consumers use an electronic or digital disclosure? (Sec. 293(d)(2))**

**Context:** AMS is considering requiring the same information associated with the text disclosure as the requirement language for an electronic or digital disclosure ([See Question 12](#)). Further, AMS is trying to determine how various disclosure options affect the amount and type of information available to consumers. AMS is also determining if there should be requirements or guidance on what size text would ensure the information is conspicuous to ensure the food information is located in a consistent and conspicuous manner when electronic or digital disclosure is accessed.

**Proposed GMA Response:**

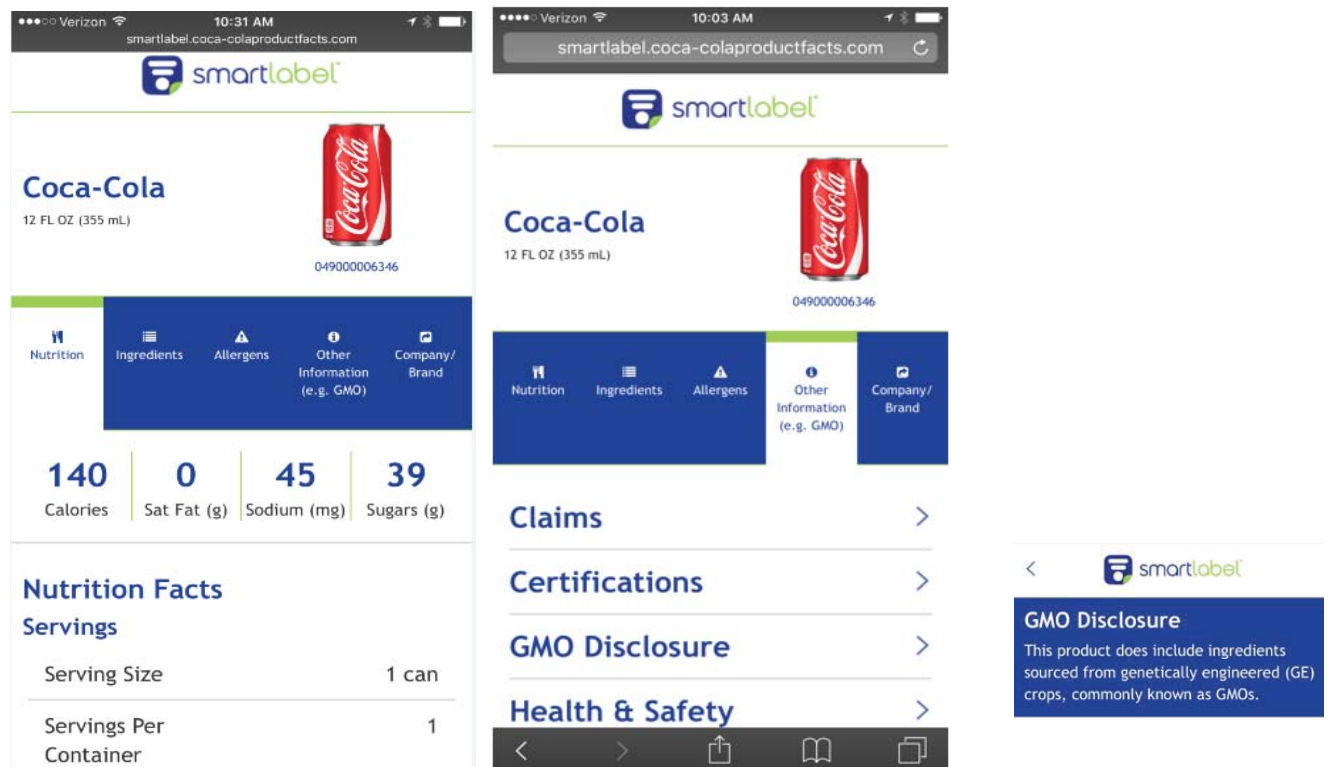
The required language used in the text disclosure and that used in the information associated with the electronic or digital disclosure should be the same. Please see our responses to question 12 for the precise language that should be used.

With respect to ensuring that the disclosure information is located in a consistent and conspicuous manner when consumers use an electronic or digital disclosure, the statute provides the following: “the electronic or digital link will provide access to the bioengineering disclosure located, in a clear 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.”

GMA believes that consumers must be able to locate the bioengineered food disclosure from the URL-driven landing page in one click or less, consistent with the statutory language requiring that access to the disclosure must be provided on the first product information page that appears, but that AMS should also accommodate use of a carrier that requires an additional “click” to initially reach the landing page – for a total of two clicks or less after scanning. As an example, some QR codes will prompt the

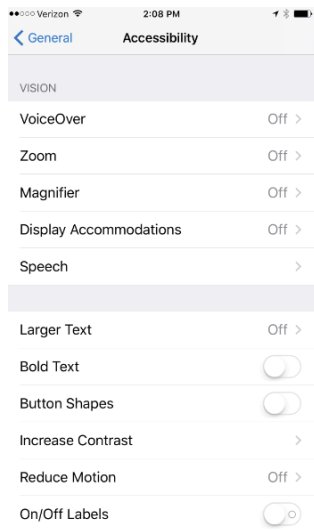
user upon scanning to respond to a question such as “Do you want to open up this URL?” before the user reaches the landing page. Some users may even require their device to prompt them in this way before opening the link. Others may allow the user to select which information page they would like to view in a situation where the QR code is used for multiple types of disclosures (e.g., “Do you want to see “SmartLabel™ information or California’s Prop 65 warning?”). From there, the user will reach the landing page or product information page and will need to click once more to select the bioengineered food disclosure. We ask AMS to accommodate systems with “two clicks or less” – i.e., one click to reach the landing page and one click from the landing page to reach the disclosure – so that the standard is both consistent with the statutory language and provides flexibility to use a single QR code for multiple types of disclosures. Without this flexibility, different disclosure requirements could each require a separate QR code on the label.

The following SmartLabel™ example demonstrates an appropriate means to provide access to the disclosure via a QR code. When a consumer scans the QR code on a 12oz can of Coca-Cola, the picture to the left is the default URL landing page. This first page provides access to the bioengineered food disclosure information, as required by the statute, when the consumer clicks on the tab “Other Information (e.g., GMO).” When the consumer clicks on the “GMO” tab (as demonstrated in the middle image), this selection will bring the consumer to the bioengineered food disclosure (shown in the right-most image). Although in this example only one “click” is needed from the landing page (without the need for an additional initial “click” to reach the landing page), for the reasons discussed above, we ask AMS to accommodate systems that provide the disclosure within “two clicks or less” after scanning.



AMS should not specify a required minimum text size because consumers can configure this specification on their individual device, as appropriate to a cell phone, tablet, laptop, or desktop

computer. The following image shows an example of how consumers can modify their text size settings using their individual device.



*Each consumer device allows customization via the “settings” capability. The picture on the left is one example. Consumers go to “settings / General” and are able to configure their device to: Zoom, Magnify, have larger text, bolder text and even to adjust the shapes of various buttons.*

**Question 25. How should AMS ensure that an electronic or digital disclosure can be easily and effectively scanned or read by a device? (Sec. 293(d)(5))**

**Context:** AMS is aware that electronic or digital disclosures need to be effective, that requirements will vary for each specific type of electronic or digital disclosure, and that the technology for electronic or digital disclosure may change faster than AMS will be able to update its regulations. AMS is determining how to address these issues given the variety of electronic or digital disclosures currently available in the marketplace, along with the specifications for these disclosures to be used effectively in a retail setting.

**Proposed GMA Response:**

With respect to ensuring that the electronic or digital disclosure can be easily and effectively scanned, the language in the statute is sufficient: “The electronic or digital link disclosure is of sufficient size to be easily and effectively scanned or read by a digital device.” This language provides flexibility while still ensuring the disclosure can be easily and effectively accessed. There are existing industry standards for ensuring the electronic or digital link is effectively scanned. For example, there are specifications to drive effective use of bar codes throughout the supply chain, from reading codes on high-speed production lines to cashier read rates in a grocery store checkout lane. We are also providing Attachment 1 as an example of these existing specifications for QR code usage. These specifications deliver a “First Time Read Rate” of two seconds or less, which supports that the disclosure can be easily and effectively scanned.

We also refer AMS to the principles described in our response to question 14. The electronic or digital link and its carrier must: (1) be broadly read by consumer devices through the camera or other

functions on their devices; and (2) be easily understood by consumers as a carrier to be scanned by a Smart Device.

For reference, QR codes satisfy both of these requirements. QR codes leverage two-dimensional capability, in contrast to UPC codes, which use one-dimension. QR codes also use camera or image technology, rather than requiring a laser scanner as needed for UPC codes. These two differences allow QR codes to be effectively scanned at much smaller sizes; as small as ¼ square inch. Additionally, QR codes can be easily and effectively scanned even where there is variation in the printing. The printed QR code need not be printed as precisely as a UPC code so it is a particularly effective tool.

### Record-Keeping

#### **Question 26. What types of records should AMS require to be maintained to establish compliance with the regulations? (Sec. 293(g)(2))**

**Context:** Each person or entity subject to the mandatory disclosure requirement would be required to maintain and make available to the Secretary records that establish compliance with the Law. Typically, record keeping requirements include those for the records required to be kept, the place of maintenance of such records, the record retention period, and what it means for AMS to have adequate access to and inspection of such records.

Under current FSIS regulations, records must be maintained at a place where business is conducted, except that if business is conducted at multiple places of business, then records may be maintained at a headquarters office. When the business is not in operation, records should be kept in accordance with good commercial practices. For FSIS, records are required to be maintained for a 2-year period. The maintenance time for FDA records vary from 6 months through up to 2 years.

AMS is considering what recordkeeping requirements for persons subject to the Law would be most appropriate.

#### **GMA Response:**

**Records Required to be Kept:** The recordkeeping requirements should be tailored to the definition of the term “bioengineered food,” because the definition of this term determines which foods are subject to the disclosure requirement and the types of records that would be appropriate to establish compliance with the Law. In general, for foods or ingredients derived from crops that are overwhelmingly produced using bioengineering in the country where they are grown, such as corn, canola, soy, and sugar beets grown in the U.S., AMS should apply a presumption that the ingredient is sourced from a bioengineered crop and is a bioengineered food, unless the manufacturer can obtain documentation showing that that is not the case, such as documentation showing the ingredient is certified organic or is identity preserved and not from a bioengineered crop or another traceability program is in place to assure the crop is not from a bioengineered seed. AMS should also establish recordkeeping provisions related to the threshold of a bioengineered substance established under section 293(b)(2)(B) of the Law and should make clear in the regulation that manufacturers are not required to disclose proprietary information such as recipes or formulations.



As required by the statutory language stating that the records that must be kept are limited to those that are “customary or reasonable in the food industry,” the recordkeeping provisions should not require manufacturers to keep additional records beyond those records customarily maintained. For example, to demonstrate that a food is not subject to the disclosure standard because meat or poultry is the first ingredient, a manufacturer could simply provide AMS with a copy of the label showing the USDA inspection legend and the ingredient statement listing the meat or poultry ingredient as the first ingredient. No additional records should be required to be kept.

*Place of Maintenance of Records:* AMS should recognize it is appropriate to store the required records off-site, such as at a central location or headquarters office, as long as the manufacturer provides the records within a reasonable period of time upon the request of AMS. In this context, a reasonable period of time would be similar to the period of time FDA provided for records that demonstrate compliance with the menu labeling requirements, i.e., 4-6 weeks. Because the bioengineered food disclosure standard is a disclosure standard, and not a safety standard, the menu labeling requirements are similar in nature and provide an appropriate precedent.

*Record Retention Period:* It would be appropriate to require that records be kept for two years after introduction or delivery for introduction of the food into interstate commerce. This is the same record retention period that is required in FDA’s nutrition labeling regulations for records supporting nutrient declarations.<sup>17</sup> Records to support that a food or ingredient is not bioengineered should be considered valid unless and until the supplier, ingredients, or formulation is changed in a way that changes the records needed to support the determination that a food or ingredient is not bioengineered.

In no event should AMS require records to be kept for longer than two years. The Law states that the recordkeeping requirements must be consistent with those records that are “customary or reasonable in the food industry” and the Bioterrorism Act limits record retention requirements for persons who “manufacture, process, pack, transport, distribute, receive, hold, or import food...” to no longer than two years.<sup>18</sup>

*Adequate Access to and Inspection of Records:* As discussed above, AMS should establish that records must be provided within a reasonable period of time upon request of the Agency, where 4-6 weeks is considered a reasonable period of time. The regulations should make clear that AMS does not have legal authority to copy records because the statute does not expressly provide such authority.

## **27. How should AMS obtain information related to potential non-compliance with these regulations? Is there information USDA should request prior to conducting an examination of non-compliance? (Sec. 293(g))**

**Context:** AMS is considering what tools could be used to identify potential non-compliance and enforce compliance with the regulations. AMS is considering the types of information needed to verify compliance with the Law and the most optimal way to obtain such information.

### **GMA Response:**

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<sup>17</sup> 21 C.F.R. § 101.9(g)(11).

<sup>18</sup> 21 U.S.C. § 350c(b).

In verifying compliance with the disclosure standard, AMS should request and review the records kept to establish compliance as required by section 293(g)(2) of the statute. This could include either reviewing the records discussed above under our response to question 26, or records establishing that the product is certified organic under USDA's National Organic Program. AMS should not rely solely on analytical testing to support a determination of non-compliance with the standard. To the extent analytical testing results are available and indicate the presence of recombinant DNA, the agency should provide the manufacturer an opportunity to review the testing results and to the degree possible the detailed information on the specific analytical method used and to provide any additional records documenting compliance with the standard.

### **28. What are the rules of practice for a hearing? (Sec. 293(g)(3)(B))**

**Context:** AMS is considering the appropriate procedures for audits and other compliance actions, including opportunities for hearing. AMS is considering this aspect for the rules of practice and other options regarding a prospective hearing and internal adjudication process.

#### **GMA Response:**

It would be appropriate for AMS to follow the general hearing procedures outlined in 7 CFR Part 1, Subpart H, which apply to administrative hearings under the Organic Foods Production Act as well as other AMS-enforced laws and regulations. AMS has experience holding hearings under these procedures and the regulations provide flexibility with respect to a number of factors, such as the scheduling of the hearing date and whether the hearing is conducted by telephone or in person.

### **29. How should AMS make public the summary of any examination, audit, or similar activity? (Sec. 293(g)(3)(C))**

**Context:** AMS is considering if the results and findings of any examination, audit, or similar activity should be posted after the notice and opportunity for a hearing described under Sec. 293(g)(3)(B). AMS is also considering how it should make summaries of the examination, audit, or similar activity public.

#### **GMA Response:**

Section 293(g)(3)(C) of the Law requires that a summary of any examination, audit, or similar activity be made public after the notice and opportunity for hearing. Making the summary information "public" as required by statute could be accomplished by posting the information on the AMS website, similar to how AMS posts such information related to compliance with the National Organic Program (NOP) standards on its website at <https://www.ams.usda.gov/services/enforcement/organic/>. AMS should remove any summaries of compliance examinations, audits, or similar activities from the website after a period of six months, although the information could continue to be made available via Freedom of Information Act (FOIA) requests. Maintaining a website with only the most recent summary information would be consistent with the statutory requirement but would also recognize that after six months, the information has diminishing relevance. Additionally, AMS should ensure that any trade secrets or confidential commercial information is redacted before posting the summary information, as required under FOIA.

## Imported Foods

### **30. What should the requirements for imports into the United States of products covered by the Law/regulation be? (Sec. 294(a))**

**Context:** AMS is considering how the disclosure requirements should be applied to imported products.

#### **GMA Response:**

Imported products should be subject to the same disclosure requirements as products manufactured in the United States. The disclosure requirements should be applied to both domestically produced and imported foods in a nondiscriminatory way that is consistent with U.S. obligations under the World Trade Organization and other international trade and investment agreements. This is consistent with the way other U.S. laws and regulations are applied and enforced (see, e.g., The Federal, Food, Drug and Cosmetic Act). For example, nutrition labeling requirements apply equally to imported and domestic foods. The bioengineered food disclosure requirements should be no different. Quite simply, products that are intended for U.S. distribution and/or consumption must meet U.S. requirements, whether manufactured in the U.S. or in other countries. Without equal treatment for domestic and imported product, product produced domestically would be at an unfair competitive disadvantage. Furthermore, unequal treatment under the disclosure law for domestic and imported products would lead to consumer confusion in the marketplace.

## **ATTACHMENT 1: QR Code Specification**

### **Glossary of Terms**

- **Module:** QR codes are made up of black squares and white squares. Each of these squares is a module.
- **Quiet Zone:** The area surrounding the QR code that should remain free of any printing
- **HRI (Human Readable Interpretation):** The readable interpretation of the URL embedded in the QR code such that a user can type in the URL and get to the same destination as scanning the QR code.

### **1. QR Code Guidelines**

- a. Compliance with ISO/IEC 18004 QR Code 2005 specification.
- b. Module width “X” value nominal size of .020”.
  - i. GS1 recommends a module width “X” value of 1.5 times greater than the “X” value for a comparably sized UPC/EAN symbol.
  - ii. QR Code X value scales from .015” to .040” (although with 600 DPI or higher resolution, module width could be as little as .014” but should not go below).
- c. Error correction is Level M (medium level allowing recovery of 15% of embedded information).
- d. Quiet zone is 4X (4 module widths). This is a region 4X wide which shall be free of all other markings, surrounding the symbol on all four sides.
- e. Encoding inside the barcode of a URL leading consumers to a page related to the product the barcode is printed on.
  - i. URL combines a domain name (e.g. GMA uses gmaonline.org) and a unique product reference (e.g. 1njcih) to form <http://gmaonline.org/forms>
  - ii. Domain name shall be encoded as following “http://smtlb.org” and be as short as possible, ideally 10 characters or shorter (not counting http://).
  - iii. Domain name can be either the ones proposed by code publisher or one selected by the brand if the code publisher allows for it.
  - iv. Embedded URLs will be determined by the brand in liaison with its selected code publisher.
- f. Use of Version 2 (up to 26 characters) or Version 3 (up to 42 characters) QR barcodes: To create smaller size barcodes or provide the best scanning experience, Version 2 (in liaison with your code publisher) is recommended.
- g. Adjust barcode width reduction (BWR) to printer specifications to ensure the best scanning experience.

## 2. Recommended QR Code Sizes

Parameters		Version 1	Version 2	Version 3
Number of Modules (excluding quiet zone)		21X	25X	29X
Quiet Zone (Number of Modules)		4X	4X	4X
Maximum Number of Encoded Characters		14	26	42
		QR Size Including Quiet Zone (*)		
Module Width Size (**)	.015" (80% - UPC "X"=.0104")	.44"	.50"	.56"
	.018" (90% - UPC "X"=.0117")	.52"	.59"	.67"
	.020" (100% - UPC "X"=.0130")	.58"	.66"	.74"
	.025" (125% - UPC "X"=.0163")	.73"	.83"	.93"
	.030" (150% - UPC "X"=.0195")	.87"	.99"	1.11"
	.035" (175% - UPC "X"=.0228")	1.02"	1.16"	1.30"
	.040" (200% - UPC "X"=.0260")	1.16"	1.32"	1.48"

(\*) QR size rounded up two digits after decimal

(\*\*) Read as follow. Module Width Size =.015" –Comparable module width for 80% UPC = 0.0104"