



# American Bakers Association

*Serving the Baking Industry Since 1897*

August 25, 2017

United States Department of Agriculture  
Agricultural Marketing Service  
1400 Independence Ave  
Washington DC 20250

Dear Sir or Madam:

ABA provides the following comments in response to some of the 30 questions posted by USDA's Agricultural Marketing Service (AMS) on its website as "Proposed Rule Questions Under Consideration."

ABA is the Washington D.C.-based voice of the wholesale baking industry. Since 1897, ABA has represented the interests of bakers before the U.S. Congress, federal agencies, and international regulatory authorities. ABA advocates on behalf of more than 1000 baking facilities and baking company suppliers. ABA members produce bread, rolls, crackers, bagels, sweet goods, tortillas and many other wholesome, nutritious, baked products for America's families. The baking industry generates more than \$102 billion in direct annual economic activity and employs over 706,000 highly-skilled people. ABA appreciates this opportunity to submit these comments on USDA AMS's proposed rule questions addressing the issue of the National Bioengineered Food Disclosure Standard (the "disclosure standard").

## **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.

**ABA response:** ABA believes that the statute and legislative history contemplate that only limited terms, if any, might be interchangeable with "bioengineering" and made an express distinction that "genetic engineering" was broader than "bioengineering":

- The disclosure standard should be limited to "Bioengineering" and "BE" (and "biotech" and "biotechnology," where applicable). The Senate Report states in several instances that "the definition of bioengineering is set in statute and establishes the scope of the disclosure standard."<sup>1</sup> The Senate Report refers to "biotech" interchangeably with "bioengineering" and ABA does not object to use of this term (or to "biotechnology"), where appropriate.

---

<sup>1</sup> Senate Report, "S. 2609, RELATED TO ROBERTS SENATE AMENDMENT #4935 TO S. 764, A NATIONAL BIOENGINEERING LABELING DISCLOSURE STANDARD," Senate Committee on Agriculture, Nutrition, and Forestry at 2, 4 (Dec. 9, 2016), available at <https://www.congress.gov/114/crpt/srpt403/CRPT-114srpt403.pdf> [hereinafter Senate Report].

- For purposes of the definition of “bioengineering” in section 291(1), “genetic engineering” (“GE”) should NOT be used interchangeably with “bioengineering.” The Senate Report clearly explains that Congress intentionally drafted the statute to expressly distinguish between “bioengineering” and “genetic engineering” and that “genetic engineering” as used in the preemption provision in section 295 is a broader term than “bioengineering.”<sup>2</sup> Section 295, and its use of “genetic engineering” instead of “bioengineering” was intended to establish broad federal preemption of other disclosure requirements related to any labeling of whether a food or seed is genetically engineered or was developed or produced using genetic engineering.
- For purposes of the terms used in the text of the disclosure statement, the textual disclosure statement should be consistent with [FDA’s Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants](#) and should not use terms like GMO.<sup>3</sup> The Senate Report states that Congress expects AMS, “In considering definitions of terms . . . and similar decisions . . . to ensure consistency with other federal requirements and definitions.”<sup>4</sup> ABA incorporates by reference into these comments, FDA’s Guidance document, because it provides clear guidance why terms like “not genetically modified,” “non-genetically modified,” “GMO,” and similar claims are NOT interchangeable with terms like “bioengineering” and “biotechnology” and may be misleading.

ABA is clearly aware that consumers, food manufacturers, and others use the term “GMO” ubiquitously, particularly in voluntary “Non-GMO” claims. The statutory mandatory biotech disclosure standard, however, is expressly NOT a voluntary program and expressly prohibits the use of a “non-GMO” claim on a food simply because the food might not be subject to the mandatory disclosure. ABA believes that over time, consumers who are concerned about whether their food is bioengineered, will become familiar with this term and industry will undoubtedly assist in educating consumers on what bioengineering means. If AMS chooses to use a term related to “GMO,” ABA suggests the common term “GM,” but not GMO, because “organism” is not accurate or truthful.

---

<sup>2</sup> *Id.* at 7 (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>3</sup> FDA issued its Guidance in November of 2015. The Guidance is available at <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm059098.htm>.

<sup>4</sup> Senate Report at 4.

**2. Which breeding techniques should AMS consider as conventional breeding? (Sec. 291(1)(B))**

**Context:** AMS is considering what would be defined as modifications that could otherwise be obtained through conventional breeding because these modifications would be exempt from mandatory disclosure.

**3. Which modifications should AMS consider to be found in nature? (Sec. 291(1)(B))**

**Context:** AMS is considering what would be defined as modifications that could otherwise be found in nature because these modifications would be exempt from mandatory disclosure.

**ABA response to questions 2 and 3:** AMS should not foreclose technologies that are akin to conventional breeding or found in nature. There is a whole range of new genetic manipulation techniques such as CRISPR being studied with a focus on increasing yield, higher protein levels, and other benefits to feed the world population. AMS should add clarity and ensure that the disclosure requirement does not encompass innovative breeding techniques that may be a modern form of traditional breeding or are modifications that are akin to those found in nature.

**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.

**ABA response:** The language of the statute clearly states that a disclosure is required for food “that contains genetic material” from biotechnology. The plain language of the statute suggests that Congress did not intend highly refined ingredients that do not “contain genetic material” to be encompassed in the mandatory disclosure. Even so, ABA recognizes that consumers who are concerned about bioengineered crops may have concerns beyond what actually ends up in the food. ABA could support a disclosure standard that encompassed some if not all highly refined ingredients if AMS addressed the compliance and enforcement challenges related to a disclosure standard that includes highly refined ingredients.

For example, because highly refined ingredients do not contain any or at least any detectable amounts of biotech material, compliance and enforcement could not rely on product testing, but would depend on records that document traceability across the supply chain. For certain ingredients, not even exclusively highly refined ingredients, the complexity of the supply chain makes it practically impossible to determine with absolute certainty whether certain ingredients are derived from a biotech crop/animal. If AMS includes highly refined ingredients in the disclosure standard, ABA suggests that AMS consider whether certain highly refined ingredients should be exempt, such as beet sugar, corn syrups, and soybean oil. Congress specifically stated

that it intends USDA to provide exemptions and other determinations under which a food is not considered bioengineered.<sup>5</sup>

Moreover, if AMS incorporates some or all highly refined ingredients in the disclosure standard, the amount of biotech material that triggers disclosure should be set at 5% (see additional discussion below).

**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 other 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.

**ABA response:** ABA agrees that the definition of bioengineering for purposes of the mandatory disclosure should not create confusion with other regulations, such as the National Organic Program, but if AMS proceeds to harmonize definitions across regulations, it should not revise the statutory definition of bioengineering for the mandatory disclosure.

**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 the Federal Food, Drug, and Cosmetic Act. 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.

**ABA response:** Predominance of ingredients should be determined based on the ingredient statement provided on the food label, presuming that the ingredients are listed in descending order of predominance in compliance with FDA's regulations (e.g., do not include inappropriate collective groupings of ingredients).

**7. How should AMS craft language in the regulations acknowledging that the Law prohibits animal products from being considered bioengineered solely because the animal consumed feed products from, containing, or consisting of a bioengineered substance? (Sec. 293(b)(2)(A))**

---

<sup>5</sup> *Id.* at 3.

**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.

**ABA response:** AMS should use the language provided in the statute and also make clear that Congress intended that meat, milk, eggs, and other human food products derived from animals that consume bioengineered feed or feed ingredients are not considered to be bioengineered food subject to the mandatory disclosure.<sup>6</sup> ABA agrees that such products include food derived from any organism, including invertebrates (crickets and bee products) and microorganisms, which may feed or grow on a bioengineered crop or ingredient derived from a bioengineered crop. Additional examples of such products include honey from bees that may have fed on bioengineered plants and fermentation products derived from organisms consuming a bioengineered substrate (products include alcohol, amino acids, enzymes, citric acid, vinegar, etc.).

In addition, AMS should clarify that this exemption includes products derived from animals that have been treated with drugs and pharmaceuticals produced from, containing, or consisting of a bioengineered substance. Treatment of animals with such products does not, on its own, result in a bioengineered food.

#### **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.

**ABA response:** The amount of biotech material in food should be in a meaningful amount, given that the disclosure is mandatory and given that companies who want to differentiate their food products from biotech food can make voluntary claims that such foods are “Non-GMO.” This is particularly true if AMS chooses to include some or all highly refined ingredients in the disclosure standard even though such ingredients do not contain any bioengineered genetic material.

---

<sup>6</sup> *Id.*

Regardless of the amount that triggers the disclosure, the amount should be based on the food as packaged and not on any other basis. It is the packaged food in its packaged form that is required to bear the mandatory disclosure, so it should be the food as packaged that should be used to calculate the amount of biotech material in the food.

Moreover, as stated above, Congress specifically stated that it intends USDA to provide exemptions and other determinations under which a food is not considered bioengineered.<sup>7</sup> Examples Congress provided include foods sold online, enzymes, additives, processing aids, medical foods, dietary supplements. Congress expressly stated that “when determining the amounts of a bioengineered substance that may be present in food, or the threshold requirement” USDA “shall minimize the impacts on all aspects of the domestic and international value chain.”

In the disclosure standard, AMS should distinguish between adventitious levels of bioengineered material in a food versus non-adventitious bioengineered material. Adventitious bioengineered material should not be included in the amount of bioengineered material that triggers the mandatory disclosure.

ABA objects to a threshold set at 0.9%, which is the standard used by several organizations to substantiate “Non-GMO” claims. The statute expressly states that simply because a food is not subject to the mandatory disclosure does not mean it can make a “Non-GMO” claim. Setting a threshold as low as 0.9% is almost akin to creating a “Non-GMO” standard for foods that do not trigger the disclosure standard, particularly if the standard includes some or all highly refined ingredients.

ABA would support a threshold of 5% if AMS chooses to include some or all highly refined ingredients in the disclosure standard. Several standards exist that AMS can rely on to determine what amount of biotech material should trigger the disclosure. The National Organic Program permits “Organic” foods to contain 5% content that is not organic, even after excluding water and salt. If AMS chooses to exempt some but not all highly refined ingredients from the disclosure standard, another threshold option would be 2%, which would be supported by several FDA regulations that conclude that amounts below 2% are “insignificant.” Regardless, whatever threshold is ultimately used, it would not prevent companies from setting lower disclosure thresholds for their products.

#### **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

---

<sup>7</sup> *Id.*

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.

**ABA response:** Most likely yes, but ABA’s answer to this question depends in part on whether AMS includes some or all highly refined ingredients in the disclosure standard, whether AMS relies on product testing or traceability for compliance, and what amount of biotech material triggers the disclosure. Given the difficulties of traceability in the supply chain and the practical reality in the variability of sources for ingredients, AMS should use more than one disclosure category, such as “may contain . . .” This category, however, should not be limited to ingredients or ingredients derived from crops subject to seasonal variation, but should broadly apply to supply chain disruptions/variations in general.

In addition, AMS should provide categories that distinguish products based on the ingredient, such as disclosures directed at BE crops, e.g., “Bioengineered corn” and disclosures directed at ingredients derived from BE crops, e.g., “ingredients derived from bioengineered corn.” For products subject to supply chain variability, AMS should use disclosures such as, “may contain ingredients derived from a bioengineered crop” or “may contain ingredients derived from bioengineered corn.”

#### **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: whether a food contains a substance that has been modified using recombinant in vitro DNA techniques (Sec. 291(1)(A)), whether 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.

**ABA response:** 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. This would be consistent with the requirements of the National Organic Program.

- An incidental additive, such as processing aids or secondary direct additives 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 regulation, incidental additives must be present at insignificant levels in the finished food and have no technical or functional effect in that food, and if so, they are not required to be declared in the ingredient statement on food labels.<sup>8</sup> The EU recognizes that processing aids are outside of the scope of its disclosure regulation.<sup>9</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>10</sup>
- Fermentation products produced using bioengineered microorganisms, including vitamins and other ingredients, so long as the microorganism is no longer present in the ingredient or food. Bioengineered 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 fact that a fermentation feedstock is bioengineered, should not on its own, result in an ingredient or food being bioengineered.

**11. Could AMS consider whether a type of food is considered a bioengineered food under the determination process? (Sec. 293(b)(2)(C))**

**Context:** AMS is considering if it could exclude certain food types such as medical food and dietary supplements, among others from requiring disclosure as bioengineered.

ABA has no response to this question at this time.

**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.

---

<sup>8</sup> 21 CFR 101.100(a)(3)(i) and (ii).

<sup>9</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>10</sup> 21 CFR 173



**ABA response:** Congress recognized the use of voluntary disclosures and did not intend to prevent food manufacturers from voluntarily disclosing information prior to or after USDA establishes the mandatory disclosure standard up until the compliance date, but Congress expects companies to use the disclosure when the compliance dates are effective.

ABA supports the use of voluntary disclosures, including those mandated by Vermont, at least until there is a uniform federal disclosure standard. The Vermont disclosures were based on an entirely different statutory requirement, including a different definition of bioengineering and calculation requirements--requirements that likely will not be identical to the requirements of the federal mandatory disclosure standard. The intent of the federal disclosure standard is to provide a uniform disclosure standard conveyed through uniform statements. Hence, if the federal disclosure standard is not the same as the Vermont disclosure standard and therefore the Vermont text disclosures would not accurately reflect the federal standard, then such textual disclosures should be phased out prior to the compliance date of the federal standard.

ABA's examples above of textual disclosures include: "Bioengineered corn" (for disclosures directed at a bioengineered crop/animal); "Ingredients derived from bioengineered corn" (for disclosures directed at ingredients derived from bioengineered crops); and "may contain ingredients derived from a bioengineered crop" or "may contain ingredients derived from bioengineered corn."

**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.

**ABA response:** ABA advocates for a simple symbol disclosure, like a circle that encloses the letters "BE." As AMS knows, regardless of whether the disclosure is through text, a symbol, or digital link, the disclosure must not disparage biotech crops/animals and foods derived from biotech crops/animals.

**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.](#)

**ABA response:** Congress intends the federal standard to be a uniform disclosure, so whatever content is provided on the link should, at a minimum, be the same as the textual disclosure or symbol disclosure.

**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.

**ABA response:** No, AMS should not specify types of electronic or digital disclosure manufacturers can use, but, instead have language that allows the manufacturers flexibility when it comes to the use of utilizing digital disclosure statements. This is especially relevant when dealing with vending and bulk items.

**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.

ABA has no response to this question at this time.

**17. The Law offers special provisions for disclosure on very small or 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 area available to bear labeling.

ABA has no response to this question at this time.

**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?

**ABA response:** AMS should allow small and very small packages reasonable alternative disclosures in addition to the standard disclosures (text, electronic or digital link, or symbol). Examples of reasonable alternatives could include:

- Using the standard disclosures, but allowing reduced type size, abbreviations, and/or placement options, depending on available space. This is the approach FDA takes in the examples it has provided for the new nutrition facts labels permitted on small and very small packages.
- An address or phone number where consumers could obtain disclosure information. When a phone number is used, section 293 (d)(1)(B) provides options such as “Call for more food information” or “Call for more information.” When an address is used, it could be accompanied by the language “Write for more food information” or “Write for more information.”
- A URL/website address that is not embedded in a digital or electronic link, e.g., “For more food information, visit <http://www.example.com>” where the URL is not embedded in a carrier.

#### **19. How should AMS define small food manufacturers? (Sec. 293(b)(2)(F))**

**Context:** AMS is considering using regulatory language similar to that of other Federal government agencies that already define small businesses. For example:

- a. FSIS considers small businesses to be those with 500 or fewer employees and that produces 100,000 pounds or less of annual production of a single product, including single forms of meat such as sausage, bulk, patties, links, consumer product, etc., when determining exemptions from nutrition facts labeling (9 CFR 317.400 (a)(1)(ii)).
- b. FDA has several small business definitions with respect to food labeling rules, such as: i) retailers with total annual gross sales of \$500,000 or less, 21 CFR 101.9(j)(1) and (18); ii) food and dietary retailers with annual gross sales of foods or dietary supplement products of \$50,000 or less, 21 CFR 101.9(j)(1) and 101.36(h)(1); and iii) businesses that employ fewer than 100 full-time workers that produce a product that sells fewer than 100,000 units throughout the United States in a 12-month period, 21 CFR 101.9(j)(18) and 101.36(h)(2).

AMS is considering the advantages or disadvantages of these definitions of small food manufacturers for the bioengineered food disclosure regulations.

ABA has no response to this question at this time.

#### **20. For disclosures by small food manufacturers, what is the appropriate language indicating that a phone number provides access to additional information? (Sec. 293(b)(2)(F)(ii)(I))**

**Context:** AMS is considering using language in Sec. 293(d)(1)(B) of the Law.

ABA has no response to this question at this time.

**21. The Law excludes restaurants and similar retail food establishments from disclosure requirements. How should AMS define similar retail food establishment to exclude these establishments from the requirements of the regulation? (Sec. 293(b)(2)(G)(i))**

**Context:** AMS is considering how to treat establishments that sell food ready for human consumption, such as institutional food service, delicatessens, or catering businesses. In its regulations for Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments (21 CFR 101.11), FDA defines restaurant or similar retail food establishment and restaurant-type food

For FSIS, the Federal Meat Inspection Act (FMIA) provides for the mandatory inspection of commercial meat and meat products. The FMIA and implementing regulations do, however, provide exemptions from the continuous inspection provisions for retail operations and restaurants (9 CFR 303.1(d)(2)).

NOP also defines retail food establishment in its regulations (7 CFR 205.2).

AMS is using this information as it considers definitions for restaurants and similar retail establishments, with the understanding that these definitions will be used to determine what types of retail establishments are excluded from the requirements of the Law.

ABA has no response to this question at this time.

**22. How should AMS define very small food manufacturers to exclude these manufacturers from the requirements of the regulation? (Sec. 293(b)(2)(G)(ii))**

**Context:** [See Question 19](#). AMS could use definitions similar to how other Federal agencies define very small businesses, and is considering definitions to distinguish small food manufacturers (Question 19) and very small food manufacturers, with understanding that very small food manufacturers would be excluded from the requirements of the Law.

ABA has no response to this question at this time.

**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.

**ABA response:** It is impossible to foresee future technologies and the terms that might be used to describe them. The standard should be flexible enough to accommodate terms that might apply to future technologies, presuming that at some point in the future, the term “scan” might not be accurate.

**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.

**ABA response:** If AMS requires text to accompany an electronic or digital disclosure, the text should be consistent with the textual disclosure, examples of which ABA provides above.

With respect to placement, under FDA’s regulations, additional information on ingredients is generally found on the “information panel,” which is defined as the panel immediately contiguous and to the right of the PDP.<sup>11</sup> In addition, FDA regulations require mandatory information to be in a font size no less than one-sixteenth of an inch in height, unless otherwise exempt.<sup>12</sup> FDA also requires the mandatory label information to be sufficiently conspicuous and prominent.<sup>13</sup>

ABA supports a flexible approach, given the variety of packaging needed to accommodate various foods. AMS should allow the disclosure--regardless of the format (textual, electronic, digital)--to appear on whatever panel can accommodate the disclosure and in a font size (for the textual disclosure) no less than one-sixteenth of an inch in height (unless otherwise exempt). The disclosure should be sufficiently conspicuous and prominent and should not appear under a fold or flap of the label or otherwise concealed and hard for the consumer to find.

**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.

---

<sup>11</sup> 21 CFR 101.2(a).

<sup>12</sup> 21 CFR 101.2(c).

<sup>13</sup> *Id.*

**ABA response:** The statutory requirement should be sufficient for the disclosure rule, “The electronic or digital link disclosure is of sufficient size to be easily and effectively scanned or read by a digital device.” The statutory language supports a flexible approach.

**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.

**ABA response:** ABA defers its response until the formal rulemaking process, but requests that AMS consider whether it is feasible to compile a list of acceptable test methods or test method parameters for certain bioengineered substances.

**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.

ABA has no response to this question at this time.

**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.

ABA has no response to this question at this time.

**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.

ABA has no response to this question at this time.

**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.

**ABA response:** Imported products should be subject to the same disclosure requirements as domestic products in the same way the imported food is now held to the same food safety standards as domestic foods. Otherwise, imported food may be permitted an unfair market advantage.

**Conclusion:**

We appreciate the opportunity to provide this input to the USDA's Agricultural Marketing Service (AMS) as it gathers input from stakeholders that will be used in drafting a proposed rule as required by The National Bioengineered Food Disclosure Standard. Should there be any questions or if additional information is needed please contact Lee Sanders at 202-789-0300 or at [lsanders@americanbakers.org](mailto:lsanders@americanbakers.org).

Sincerely,

Lee Sanders, CAE  
Senior Vice President  
Government Relations & Public Affairs