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Submitted Electronically via GMOLabeling@ams.usda.gov

Comments Re: National Bioengineered Food Disclosure Standard – USDA AMS Proposed Rule
Questions Under Consideration

I. Executive Summary

Campbell Soup Company (“Campbell”) is driven and inspired by our Purpose, “Real food that matters for life’s moments.” We make a range of high-quality soups and simple meals, beverages, snacks and packaged fresh foods. For generations, people have trusted Campbell to provide authentic, flavorful and readily available foods and beverages that connect them to each other, to warm memories and to what’s important today.

Campbell’s diverse portfolio spans both the center store and the perimeter, with shelf-stable and packaged-fresh refrigerated offerings that run the spectrum from organic baby food, fresh carrots, and super-premium beverages to canned soups, sauces, frozen products, and a variety of snacks, cookies and breads. This broad range of differing foods and drinks provides our Company with a unique perspective within the industry to comment on proposals related to food ingredients, their use and how they are named.

Our purpose has had a profound impact on Campbell. Today, everyone at Campbell is thinking, talking and acting differently about our food—from how it’s grown to how it’s made in our plants. We strive to be open and honest about what’s in our food, and we believe transparency builds trust. Viewing GMOs through this transparency lens has caused us to think differently and changed our perspective on GMO labeling.

In January 2016, Campbell became the first major U.S. food company to support national mandatory GMO labeling on foods. We committed to print clear and simple language about GMO content on the labels of our U.S. products that contain GMOs because we believe consumers have a right to know how their food is grown and made. We always put consumers at the center of everything we do – and have done so for nearly 150 years.

Campbell Soup Company to USDA Agricultural Marketing Service
“Comments Re: National Bioengineered Food Disclosure Standard – USDA AMS Proposed Rule Questions Under Consideration”
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Campbell continues to recognize that the GMO ingredients it uses are safe, and the science shows that foods derived from crops grown using genetically modified seeds are not nutritionally different from other foods. The company also believes that this technology does and will continue to play a crucial role in feeding the world’s population.

In 2016, we sought a label statement that would provide consumers the information they wanted. We talked to thousands of consumers and learned a number of their wants, including simple and familiar language and for specific GMO ingredients to be identified on labels.

1. Simple and Familiar Language: Language that is direct, to the point and understandable; language that uses familiar terms such as “GMO” instead of “genetic engineering.” Consumers found technical terms confusing and less transparent.
2. Ingredients to Be Identified: Consumers want to know the specific ingredients that are from modified crops, like soy, corn, canola and sugar.

Incorporating those principles, our current label statement reads:

THE INGREDIENTS FROM CORN / SOY / CANOLA / SUGAR IN THIS PRODUCT COME FROM GENETICALLY MODIFIED CROPS.

This meets consumers’ needs – it’s clear, simple, and familiar, and it points out the specific GMO ingredients.

In 2016, as we were developing our statement, we had discussions with both FDA and USDA about the consumer research we conducted. Another element consumers indicated they were interested in was a statement of safety on the label. We discussed that with those agencies at that time and continue to work with FDA and USDA on how that information can appear on a label.

After conducting consumer research, developing disclosure statement options, and working with the federal agencies in 2016, Campbell began printing the above GMO statement on U.S. products that contain genetically modified ingredients in April 2017. We expect that it will take up to two years to implement this labeling across our U.S. products.

Families of all kinds use our products throughout the day and every day. They rely on us to present accurate and understandable information about the food and beverages we make. Our comments¹ reflect our commitment to transparency, to provide consumers with truthful, accurate and easily understood information about the foods we make and they eat.

¹ As of the date of this letter, Campbell Soup Company is a member of the American Bakers Association (ABA) and the Grocery Manufacturers of America (GMA). ABA, GMA, and a coalition of food industry trade associations to which GMA belongs, are submitting separate comments to USDA on this topic. Campbell is not joining in ABA’s, GMA’s or the coalition’s comments.

II. Questions

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.

Campbell Response: Campbell recommends that for the purposes of the labeling disclosure the following terms be interchangeable with “bioengineering” or “bioengineered food”, depending on whether the term is describing the technology applied to the food² or the food itself:

- genetically modified
- GMO
- genetic engineering
- GE
- genetically engineered
- Other terms that truthfully and accurately describe the activity of bioengineering or the bioengineered food;

Campbell recognizes that the phrases “genetically modified” and “GMO” may be broad when viewed literally, and could encompass historical plant breeding techniques as US FDA has stated previously.³ However, consumer and industry use of the term for more than a decade has made the term synonymous with how the term “bioengineering” is defined in the National Bioengineered Food Disclosure Standard. Not including genetically modified and GMO as permitted synonyms to “bioengineered food” would likely confuse some consumers.

2. Which breeding techniques should AMS consider 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.

Campbell Response: Campbell recommends AMS adopt rules that establish a distinction between products of genetic engineering and those that are not by defining “conventional breeding” and citing examples of plant breeding techniques currently in use which are and are not included within the definition. In general, we have observed that principles can be applied to make this distinction based on whether the breeding results in expression of characteristics which are already present within a species and whether a process of selection is used to proceed.

² The use of the term “food” in this comment also includes food ingredients, unless otherwise noted.

³ Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants, Office of Nutrition, Labeling and Dietary Supplements in the Center for Food Safety and Applied Nutrition and the Office of Surveillance and Compliance in the Center for Veterinary Medicine at the U.S. Food and Drug Administration, November 2016.

An approach like this is described in Canada’s “National Standard of Canada Voluntary Labelling and Advertising of Foods That Are and Are Not Products of Genetic Engineering”.⁴ The standard describes certain plant breeding techniques which are outside the scope of genetic engineering and therefore from disclosure because they are considered “conventional” (based on current plant breeding techniques):

1. *in vitro* fertilization
2. conjugation, transduction, transformation, or any other natural process
3. polyploidy induction
4. mutagenesis
5. cell fusion* (including protoplast fusion) or hybridization techniques where the donor cells/protoplasts fall within the same taxonomic family.

*Campbell notes that cell fusion, regardless of whether the fusion is within or between taxonomic families, is not a permitted method under USDA Organic requirements. See our response to Question 3.

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.

Campbell Response: Campbell recommends use of the distinctions described in the National Organic Program under the regulation for “allowed and prohibited substances, methods and ingredients ...”⁵. This would to ensure program alignment between this disclosure standard and the National Organic Program. If changes are made to the National Organic Program in this section (205), either to include or exclude certain methods of plant breeding, we propose that these same changes be proposed through rulemaking under the National Bioengineered Foods Disclosure Standard.

Presently, the National Organic Program lists “excluded methods” that could be used by AMS to address the question of what could be found in nature. These excluded methods presently encompass a variety of methods used to genetically modify organisms or influence their growth by means that are not possible under natural conditions or processes that are not considered compatible with organic productions.⁶ Two excluded methods are specifically noted: cell fusion and recombinant DNA technology. Per this regulation, recombinant DNA technology includes “gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology.” Methods that are not “excluded methods” and which are therefore suitable for organic

⁴ The National Standard of Canada Voluntary Labelling and Advertising of Foods That Are and Are Not Products of Genetic Engineering, Canadian General Standards Board—CAN/CGSB-32.315-2004 Reaffirmed 2016, Section 3.1.

⁵ 7CFR §205.105, Allowed and prohibited substances, methods, and ingredients in organic production and handling.

⁶ 7CFR §205.2 Terms defined, Excluded methods. “A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, *in vitro* fertilization, or tissue culture.

as natural processes include: traditional breeding, conjugation, fermentation, hybridization, *in vitro* fertilization, or tissue culture.

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.

Campbell Response: Campbell notes that the statute states “‘bioengineering’ ...with respect to a food, refers to a food (A) that contains genetic material that has been modified...”. Sec. 291(1)(A) (emphasis added). However, Campbell recommends that AMS require disclosure for food even when it contains highly refined products such as oils or sugars derived from bioengineered crops in order to address consumers’ interest in knowing about all ingredients derived from genetically engineered crops, regardless of whether the genetic material that would allow for the identification of genetic engineering has been processed out or to the point where it is no longer identifiable. The purpose of the law was to “establish a mandatory uniform national disclosure standard for human food that is or may be bioengineered.” Senate Report 114-403 at 1. Highly refined foods originate from bioengineered crop or seed. Prior to processing, highly refined foods contained genetic material (or may still contain genetic material after processing, just material that is no longer identifiable). In other words, testing the processed product is not the determining factor. Instead, it is whether the source material (the crop or seed, in the case of plants) meets the definition of a bioengineered food. It is not consistent with the purpose of the law to allow refining or other processing to eliminate the requirement of disclosure. AMS’s regulatory standards should permit manufacturers to explain to consumers in their disclosure about the highly refined products and their lack of (or lack of testable) genetic material. At a minimum, however, AMS should require the minimum disclosure (see response to Question 12) when highly refined GMOs are present.

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.

Campbell Response: We acknowledge that there are precedents for different definitions of terms across different federal agencies. However, the definitions within the regulations applicable to this Act should apply solely to the obligation for disclosure of bioengineered food, provided that they are consistent with the Organic Foods Production Act of 1990 as required per Section 293(f).

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 FFDCA. 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.

Campbell Response: Campbell supports disclosure of all ingredients derived from bioengineering in multi-ingredient foods, not only for those where the most predominant or second most predominant ingredient (when the first ingredient is broth, stock, water or a similar solution) in a food, based on descending order of predominance in the ingredient statement, are subject to the Federal Food, Drug and Cosmetic Act. The effect of Section 292(c) would be to exempt foods where amenable levels of meat and/or poultry ingredients are present but not predominant, as is often the case in multi-ingredient foods such as soups. Because the law directs the Secretary to determine the application of this standard, Campbell requests that voluntary disclosure be permitted in instances where a product is subject to inspection⁷ but meets the exemption criteria of Section 292(c).

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.

Campbell Response: Campbell agrees that the term “animal” used in the law be interpreted broadly as the context above suggests. AMS regulation should state that consumption of bioengineered ingredients as food or feed does not result in an organism becoming genetically engineered.

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: 1) if a bioengineered substance is near the top of the list of ingredients, 2) by determining the percentage of bioengineered ingredients in a food product, or 3) 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.

Campbell Response: Campbell recommends listing or identifying any ingredient that was produced through bioengineering (3rd scenario) using the ingredient listing on the product label as the basis for

⁷ Inspection refers to foods subject to the labeling requirements under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products S. 764—2 Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.).

what ingredients may be subject to the disclosure. This could be accomplished by either a) using the existing allergen labeling formats as a model to identify ingredients with a parenthetical or through a footnote statement, or b) identifying ingredients using an asterisk or dagger. Identifying specific ingredients provides consumers both with information about which ingredients were derived from bioengineering and the relative amount of the ingredient in the food.

We interpret the 2nd scenario as a proposal for a threshold where products with x percentage of genetically engineered ingredients would require disclosure and those with less than that amount would be exempt. Campbell recommends use of this approach in combination with our comments on the 3rd scenario described above, provided the threshold is established in a way that any bioengineered ingredient subject to labeling is subject to the mandatory disclosure. In other words, if a consumer is on notice that an ingredient is present in a product because it is on the food label’s ingredient list or in a mandatory allergen disclosure statement under the FDCA, then that ingredient is subject to the mandatory disclosure regulation if it is bioengineered.

Campbell does not recommend using the order of predominance approach (1st scenario), where a determination is made based only on the ingredients near the top of the ingredient list. We have reviewed a wide range of products to determine whether genetically engineered ingredients are present or not and have found that when those ingredients are present, they are rarely the most predominant, characterizing ingredients. This is because the most common GM ingredients tend to be starches, sweeteners and oils, functional in multi-ingredient foods at moderate to low levels (from an order of predominance perspective). A determination based on the most predominant ingredients would result in infrequent disclosures on the multi-ingredient foods that widely use them. This would conflict with what consumers expect from the transparency that is the intent of the law.

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.

Campbell Response: For Campbell, as a provider of multi-ingredient foods, a tiered approach based on the degree of transformation of an ingredient from farm to food would not be meaningful because most multi-ingredient foods would be in category (c); they contain some ingredients *derived* from bioengineered crops.

However, we share the agency’s observation that changes in sourcing for part of the year could affect a manufacturer’s ability to maintain accurate disclosure statements, especially if specific ingredients are identified in the disclosure approach. There are many commodity crops which change their sourcing year-on-year and sometimes during a single crop year. We would support a means for disclosing that some ingredients are GE from time to time depending on availability. Any such disclosure language would need to be enduring so that labels did not need to be changed to match the crop supply in use at

that time. Recurring label changes to the same product due to crop variability of GMO content would be costly to manufacturers and potentially confusing to customers. This is another reason, as explained in Campbell’s responses to 1 and 12, why AMS’ disclosure standard should set a minimum but otherwise allow manufacturers to be truthful and not misleading on their labels about their product’s GMO content. In this scenario of seasonal variability, manufacturers may wish to explain this information to consumers about particular ingredients’ seasonality. AMS’ regulations should allow for that.

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.

Campbell Response: Campbell recommends that the Agency replicate current, successful programs within the Department of Agriculture for ways to enable manufacturers or developers of bioengineered foods to make their own determinations or ask questions related to determinations. We cite three examples to consider:

- 1) FSIS’s “askFSIS”⁸ website is a service provided for manufacturers and developers of products under labeling jurisdiction of FSIS. This system provides a means for posting inquiries which can be answered by competent agency staff. Questions and answers are posted publicly (after removing the requestor’s name/affiliation) to enable others to learn and thereby reduce redundancy of inquiries within the same company, across companies and within the agency. Inspection staff also benefits from understanding the intent of the agency staff who manage the program.
- 2) The USDA-FSIS Compliance Guideline for Label Approval, last updated August 2017, provides (inspected) establishments with guidance to meet FSIS regulations for labeling. This guideline document reflects current thinking and incorporates answers to frequently asked questions. It can be updated without rulemaking to allow timely adjustments based on stakeholders needs.
- 3) The National Organic Program Handbook⁹ is the result of a click on “Want to Become Certified Organic?”. This program book, now all electronic, allows stakeholders to access up to date

⁸ <https://askfsis.custhelp.com/>

⁹ <https://www.ams.usda.gov/rules-regulations/organic/handbook>

guidance and instructions. This approach also allows for updates without rulemaking although changes to the handbook follow a more formal than the other two examples provided.

Campbell is not requesting that AMS create a label preapproval process like FSIS’ or a certification process like the National Organic Program’s. The National Bioengineering Labeling Disclosure Standard does not authorize the creation of either. Instead, Campbell references the above resources as resources for manufacturers and others in industry to understand AMS’ regulations.

Campbell also requests that AMS not prohibit third party service providers, such as “The Non-GMO Project”, that provide a consumer-facing label statement or symbol that the labeled product meets either a standard that the provider has developed or, in the future, is consistent with AMS’ regulations.

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 AMS could exclude certain food types such as medical food and dietary supplements, among others from requiring disclosure as bioengineered.

Campbell Response: The subsection allows AMS to make determinations on certain types of food per the Act. Campbell recommends AMS applies its regulations to all foods (as defined per the FDCA). That is consistent with the purpose of the law, providing consumers with the transparency the law intends.

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.

Campbell Response: We support use of truthful and not misleading text for disclosure of bioengineered foods. We recommend that AMS set a minimum standard but allow manufacturers to label their products to provide information to consumers that goes beyond the minimum standard such as if the manufacturer wishes to describe which ingredients are GMO, the technique used for the genetic modification, the purpose of the genetic modification, processing that relates to the genetic material, seasonal variations that affects whether an ingredient may or may not be GMO in the food and other truthful and accurate information. In this regard, we recommend establishment of a set of principles to guide manufacturers across all forms of food, at the heart of which is the requirement that the disclosure be truthful and not misleading.

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.

Campbell Response: Campbell consumer research has shown that consumers prefer disclosures using words and statements to those with symbols. Symbols are unlikely to provide consumers with the level of detail that our research shows they want. However, Campbell recommends that any symbol be clear and easily understood by consumers. We concur with the criteria AMS describes for development of a symbol for disclosure. Consistent with our response to 12, manufacturers should have the option to label their products with additional truthful not misleading information about the food’s GM content when using a symbol.

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.

Campbell Response: Campbell does not recommend the use of digital or electronic links for satisfying the law’s disclosure requirements for several reasons. The primary reason is that our consumer research found that consumers significantly preferred use of text or a symbol for disclosure of GM information. In addition, the very difficulties that USDA acknowledges in these proposed rule questions concerning the evolving nature of technology rendering some quickly obsolete, as well as technology surpassing regulations, show the weakness in relying solely on digital or electronic links at the point of sale on labels as the consumer’s only source of information about the presence of GM content in food they are considering purchasing.

Campbell recommends that AMS require all products that meet the requirements for bioengineered disclosure to have text that at a minimum discloses that the food has GM content, even if the manufacturer chooses also to use an electronic or digital link on their label. Consumers that do not have access to the particular technology used on a label will not know whether their food is bioengineered, which would undermine the purpose of the law. Use of a link alone does not enable all consumers to be informed about bioengineered food at the point of sale, particularly in a brick and mortar setting.

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.

Campbell Response: This concern is one of the reasons exactly why Campbell does not recommend that AMS allow manufacturers to rely solely on digital or electronic disclosures to satisfy the law, as stated in response to Question 14. As stated in the previous section, AMS should require a minimal text disclosure on the product label in addition to the use of digital or electronic methods.

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.

Campbell Response: AMS should follow applicable precedent in other food labeling requirements for each of these points of sale. For example, vending machine foods have on-the-pack labeling for all applicable labeling requirements. No additional labeling on the machine is mandated by federal law for that purpose. There is no reason that the application of this law to vending machine foods should be any different.

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 area available to bear labeling.

Campbell Response: Campbell agrees that alignment of requirements for on-pack disclosure statements with FDA and USDA¹⁰ requirements for nutrition labeling based on available label space would be appropriate so that determinations on overall label content and label design can be approached using a single criterion applicable to multiple aspects of labeling. The applicable reference will necessarily be based on whether the food, as a whole, is under FDA or USDA jurisdiction.

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

¹⁰ Refer to (FDA) 21 CFR 101.9 (j)(13) Small and intermediate packages. (FDA) 21 CFR 101.9 (j)(13)(i) Foods in small packages that have a total surface area available to bear labeling of less than 12 square inches; (FDA) 21 CFR 101.9 (j)(13)(ii) Foods in packages that have a total surface area available to bear labeling of 40 or less square inches; and (USDA) 9 CFR 317.309 (g) and 9 CFR 381.409 (g) – which does not use the term “small package” but defines same modifications under less than 12 square inch and 40 or less square inches similarly.

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?

Campbell Response: Campbell agrees that extending the alignment with FDA nutrition labeling provisions for small and very small packages¹¹ would allow abbreviated requirements for the disclosure text in addition to a method for consumers to obtain additional information.

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 businesses 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.

Campbell Response: Campbell recommends defining small businesses with respect to disclosure based on the jurisdiction of the food and its associated small business exemption for nutrition labeling. By aligning with existing labeling regulations in this way the disclosure can be applied in a way that is consistent for the affected business.

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.

¹¹ (FDA) 21 CFR 101.9 (i)Exemptions and Special Labeling Provisions, Foods in packages with available label space of less than 12 square inches (e.g. pack of gum), provided that the label provides a means for consumers to obtain nutrition information (e.g., address, phone number).

Campbell Response: Campbell requests that AMS require a truthful and not misleading statement that the food contains GMO ingredients (or other applicable statement) and that the contact information will provide consumers with more information about the GM content of the food.

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 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.

Campbell Response: Campbell recommends AMS adopt the NOP definition¹² of a retail food establishment to address the requirement in Sec. 293 to exclude “food served in a restaurant or similar retail food establishment”. The NOP definition for the purposes of exemption include, “A restaurant; delicatessen; bakery; grocery store; or any retail outlet with an in-store restaurant, delicatessen, bakery, salad bar, or other eat-in or carry-out service of processed or prepared raw and ready-to-eat-food.”

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.

Campbell Response: Consistent with its response to Question 19, Campbell recommends defining very small businesses with respect to disclosure based on the jurisdiction of the food and its associated very small business exemption for nutrition labeling. By aligning with existing labeling regulations in this way the disclosure can be applied in a way that is consistent for the affected business.

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))

¹² 7 CFR §205.2

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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.

Campbell Response: The phrase “scan here for more information” alone does not give consumers notice that the food has GM content. Campbell does not recommend that AMS allow that statement alone to be used with a link or other electronic or digital disclosure method as it does not satisfy the intent of the law.

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.

Campbell Response: As stated above, Campbell recommends that at a minimum a product label have a disclosure that the product has GM content even if the manufacturer uses an electronic or digital disclosure for more information. AMS’ regulations should specify that all disclosures regardless of type be conspicuous. For consistent location, the regulation could specify the location of the disclosure. Campbell recommends that the disclosure, regardless of type, appear on the information panel immediately following, or contiguous to, the ingredient statement.

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.

Campbell Response: As stated above in response to Question 14, these kinds of technical difficulties are exactly why AMS should not permit an electronic or digital disclosure alone to be effective in satisfying the disclosure requirement. AMS should require, at a minimum, a brief text statement informing the consumer that there is GM content in the food.

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.

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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.

Campbell Response: Campbell concurs with AMS’ suggestion to model record-keeping requirements after existing FSIS regulations, including the 2-year maintenance period. Products that are shelf-stable could be in commerce for as long as two years.

The types of records to be maintained would be those records that are substantial evidence that the food is or is not GMO. That evidence may include, but is not limited to, the following:

- documentation provided by suppliers of ingredients who have direct knowledge of the source of the crop;
- genetic testing for the recognized markers of recombinant DNA techniques for the applicable organism;
- chain of custody records from the supply chain of the food from seed (or the animal) to the finished food; or
- other analytical testing method recognized by industry or testing experts that would enable applicable experts in the field to determine whether a food is or is not GMO.

The records must be reviewed in the context of an established threshold determined by AMS (Sec. 293(b)(2)(B)) as part of the rulemaking process and the ingredients declared on the label.

This is likely to require the industry to maintain records that have not been customarily kept as GMO transparency is a new concept for the food industry. Requiring these records from manufacturers will have systemic effects on industry as they will affect the suppliers, processors, testing laboratories, and other third parties that are connected to the bioengineered food. The transparency requirements for the finished food will likely push that chain of connections to increase transparency for their role in the GM content in the food.

Campbell addresses access to those records in its response to the following question.

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.

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Campbell Response: Consistent with section 293(g)(3), AMS should obtain information related to potential non-compliance with these regulations and the law only through (1) routine audits (“not for cause”); (2) investigations initiated by a complaint from a third party that AMS reviews and determines to have merit sufficient to warrant use of AMS resources and is consistent with its authority under this law; and (3) investigations that AMS initiates.

AMS’ inquires pursuant to each of the scenarios above should begin with a written request to the manufacturer of the product containing the following information, at a minimum, to give the manufacturer sufficient notice of AMS’ activity concerning their product(s):

- i) whether the request is a routine audit or an investigation;
- ii) if the request is part of an investigation, whether the investigation arose from a third party complaint or was initiated by AMS;
 - (1) if the investigation arose from a complaint, provide a copy of the complaint (with identifying information of the complaining party redacted to protect their privacy as the law requires); and
 - (2) the specific aspects of the disclosure law or regulation that AMS suspects may be violated
- iii) identification of the specific product(s) that is/are the subject of the audit or investigation;
- iv) the deadline for the manufacturer’s response and necessary information to send the response to AMS either electronically or in paper form.

The time allowed for a manufacturer to respond to a written inquiry described above must be reasonable. The time to respond should be relative to the number of products that are the subject of the inquiry; however, audit inquiries should be limited in scope so that a manufacturer may respond without any effect on their day-to-day operations. Furthermore, AMS regulation should include a method by which manufacturers subject to an audit inquiry may object to the scope of the audit as unduly burdensome.

Campbell notes that section 293(g)(3), or even the National Bioengineering Standards Law itself, does not give the USDA the authority to arrive at a manufacturer’s place of business and conduct an inspection or audit on site.

Campbell also requests that AMS further state in regulation the timing for the review process of an audit or investigation such that AMS must provide the manufacturer with the results of the audit or investigation by a date certain from which AMS receives the manufacturer’s submission. AMS’ statement of results should include, at a minimum, AMS’ conclusion whether there has been a violation of law or regulation and, if so, the basis for that violation and the product at issue. The statement of results must also include notice to the manufacturer of the legal implications of the determination that a violation has occurred, if any, and the manufacturer’s right to a hearing on the results, consistent with section 293(g)(3)(B).

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.

Campbell Response: The general hearing regulations in 7 CFR Part 1, Subpart H, “Rules of Practice Governing Formal Adjudicatory Proceedings Instituted by the Secretary Under Various Statutes” should apply to a hearing under Sec. 293(g)(3)(B). To that end, 7 CFR §1.131 should be amended to include the National Bioengineered Food Disclosure Standard. Subpart H is intended to apply to adjudicatory proceedings under the jurisdiction of the Secretary and there is no reason why it should not apply in this case.

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.

Campbell Response: Campbell strongly encourages AMS to post on its website in an easily identifiable and searchable way the results and findings of any examination, audit or similar activity (after the notice and opportunity for a hearing under Sec. 293(g)(3)(B)) in addition to summaries of the same (collectively “results and findings”). Those results and findings are valuable information for consumers and industry to understand how AMS interprets and enforces this law. This law is a response to consumer interest in transparency so it is consistent with that transparency to make the results and findings under it easily accessible. Requiring a Freedom of Information Act request to gain access would unduly burden the agency and undermine the value of transparency. In addition, it is consistent with the Electronic Freedom of Information Act Amendments (EFOIA), 5 USC §552(a)(2)(D), to make this available in this way as there are likely to be multiple requests for the same information.

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.

Campbell Response: Imported products subject to U.S. labeling requirements under the jurisdiction of the USDA and/or FDA should also be subject to the requirements of the National Bioengineered Food Law Disclosure Standard and it implementing regulations. Section 292 does not have an exemption for imported products.