August 25, 2017

Mr. Bruce Summers
Acting Administrator
Agricultural Marketing Service
United States Department of Agriculture
1400 Independence Avenue, SW
Room 3069 South Building
Washington, DC 20250

Submitted via GMOlabeling@ams.usda.gov

RE: Proposed Rule Questions Under Consideration (Posted June 26, 2017)

Dear Mr. Summers:

The Coalition for Safe, Affordable Food ("the Coalition") thanks the U.S. Department of Agriculture's (USDA) Agricultural Marketing Service (AMS) for the opportunity to provide feedback on questions being considered in connection with the development of a rule implementing the National Bioengineered Food Disclosure Law. The Coalition is comprised of members representing the entire American agriculture food supply chain – from farm to fork – and is committed to increasing the public's understanding about the science and safety of bioengineered foods and advocating for science-based policies that keep food affordable for every American. The Coalition was actively engaged in support of the Bioengineered Food Disclosure Law, which calls for the establishment of a uniform national disclosure standard for bioengineered food and prevents a patchwork of state-by-state or other governmental subdivision food labeling requirements that would have driven up food costs for consumers.

The Coalition has carefully studied the questions posed by USDA-AMS and is pleased to present responses demonstrating a strong consensus on a broad range of topics critical to the successful implementation of the law. The Coalition's responses are aimed at assisting USDA-AMS with fulfilling the multiple goals of the law, shared by the Coalition, which include fostering consumers' access to information about the food they eat; providing consumers with continued access to an abundant, safe, affordable and sustainable food supply; ensuring that farmers and ranchers have access to the technologies they need to feed a growing world population; providing food manufacturers with certainty in the supply chain; and respecting the strong scientific consensus on the safety of bioengineered food and, relatedly, preserving Congress' intention that the agency implement a disclosure standard for marketing purposes, and not based on health, safety, or nutrition. Because the

Coalition represents all segments of the U.S. food value chain with a broad range of interests, individual Coalition members will offer USDA-AMS recommendations on how to address certain questions.

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

Sincerely,

Agricultural Retailers Association
American Beverage Association
American Farm Bureau Federation
American Feed Industry Association
American Frozen Food Institute
American Seed Trade Association
American Soybean Association
American Sugarbeet Growers Association
Biotechnology Innovation Organization
Corn Refiners Association
CropLife America
Enzyme Technical Association
Food Marketing Institute
Grocery Manufacturers Association
Infant Nutrition Council of America
Institute of Shortening and Edible Oils
International Dairy Foods Association
National Association of State Departments of Agriculture
National Association of Manufacturers
National Black Growers Council
National Corn Growers Association
National Cotton Council
National Council of Farmer Cooperatives
National Grain and Feed Association
National Grocers Association
National Milk Producers Federation
National Oilseed Processors Association
National Potato Council
National Seasoning Manufacturers Association
North American Millers' Association
Pet Food Institute
SNAC International
U.S. Beet Sugar Association
U.S. Canola Association

ATTACHMENT

Response of the Coalition for Safe, Affordable Food to USDA-AMS Questions Under Consideration

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

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

Coalition Response

Because the Coalition represents all segments of the U.S. food value chain with a broad range of interests and perspectives, individual Coalition members will offer USDA-AMS recommendations on how to address Question 1.

Question 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.

Coalition Response

"Conventional breeding" should encompass breeding methods that use the organism's gene pool and other methods that enable efficient movement of native genes from unadapted to elite organisms. As reflected in the bipartisan Senate Report on the Law,[1] this approach is consistent with Congress's direction that the USDA-AMS mandatory marketing disclosure program "be technology neutral and reflect technological changes over time." (Senate Report). The concept of "conventional breeding" does not apply to most microorganisms, but many other forms of genetic modification have been applied to microbes for decades. As is true of plants and animals, if the genetic modification could have been obtained by these well-established microbial genetic modification techniques, the resulting food product should not be subject to disclosure in the USDA-AMS mandatory marketing disclosure program.

Additional information*: Plant and animal breeding encompasses an evolving set of scientific disciplines and enabling methods in order to ensure the availability of effective breeding outcomes on an ongoing basis. Any discussion of breeding techniques that would constitute "conventional breeding" should recognize this evolution. USDA-AMS should avoid a static listing of breeding techniques because any such list would ignore this evolution and hinder development of future enabling technologies that make the improvement of our food supply more efficient to accomplish.*

Regarding microbes, the concepts of "breeding techniques" and "conventional breeding" have limited applicability, especially with respect to methods for genetically modifying microbes that are food, that produce molecular substances added to food, or that carry out biological processes used in food production and processing. Over many decades, a wide array of methodologies, all derived from or based

[1] S. Rep. No. 114-403 (2016) (Senate Report).

upon natural microbial methods of genetic modification, have been used to change the prokaryotic and eukaryotic microbes used in the manufacture of food and food ingredients. We view these methodologies as "conventional" because of their long history of safe use in many common foods. Over time, these methods have been altered and improved, and this evolution will continue as more is learned about microbial molecular genetics. Each of these methods should be considered "conventional breeding" under the law and products resulting from these techniques would not be subject to mandatory disclosure.

Question 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.

Coalition Response

The relevant statutory text in the definition is "contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques and for which the modification could not be otherwise … found in nature." In vitro recombinant DNA techniques can be used to recreate many molecular changes that occur naturally. However, in vitro recombinant DNA techniques also allow scientists to use enzymes to assemble combinations of genetic elements into genetic constructs that are not found in nature. When in vitro recombinant DNA techniques are used to create combinations of genetic elements that would not be found in nature, food products containing these constructs would be subject to disclosure within the USDA-AMS mandatory marketing disclosure program.

Additional Information: *In vitro recombinant DNA techniques rely on the use of laboratory methods and exogenous enzymes to create genetic constructs composed of genetic components derived from any organism, irrespective of its taxonomic relationship to the recipient organism. While any single element of the genetic construct may be capable of moving into the recipient by horizontal gene transfer, the odds of the recipient naturally containing all of the genetic elements arranged in a linear fashion, immediately adjacent to one another, are so remote it is inappropriate to view the inserted genetic construct as something that could be found in nature. Lateral or horizontal gene transfer is the acquisition of genetic material from another organism without being its offspring, although it frequently refers to transfer from organisms belonging to another species. It contrasts with vertical gene transfer, which is the acquisition of genetic material from an ancestor.*

In vitro recombinant DNA techniques can also be used to "mimic" the end points of various types of changes to genes that occur in nature, independent of human intervention, including: gene deletions, duplications, additions; nucleotide deletions, duplications, additions, substitutions; transposon insertion, and horizontal transfer of genetic material. However, in vitro recombinant DNA techniques rely on the use of a combination of purified, exogenous enzymes, isolated from various sources, to construct a linear assemblage of genetic elements that would not occur naturally.

Finally, additional forms of genetic modification that occur in nature include the genetic recombinations achieved by crossing over in meiosis and sexual reproduction; microbial conjugation, transformation and transduction; and spontaneous gene mutations in somatic and germline cells. Naturally occurring mutations include: (i) point mutations that delete, add, duplicate or substitute nucleotides and/or genes; (ii) chromosomal mutations, such as duplication, deletions, translocations, inversions; and (iii) random

insertions of transposons. Some, but not all, of these naturally occurring genetic modifications would be very difficult, or even impossible, to create with current recombinant DNA techniques, because those modifications can involve large amounts of genetic material.

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

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

Coalition Response

USDA-AMS is incorrectly using the term "highly refined products" to refer to food products, such as sugar and oils. Rather, the more appropriate term is simply "refined ingredients." The terms "highly processed" or "highly refined" ingredients typically refer to multi-ingredient mixtures processed to the extent that they are no longer recognizable as their original plant/animal source, e.g., candy, tomato sauce, ice cream, etc. In contrast, when a single isolated food component, such as sugar or oil, is obtained by extraction or purification using physical or chemical processes, it is typically referred to as "refined."[2] For these reasons, we urge USDA-AMS henceforth to use the accurate term "refined ingredients" when referring to single food components, such as sugar and oils. We also note that Question 4 is directed toward "bioengineered crops," but USDA-AMS should be mindful that the precise definition of "food" is not limited to plant-derived foods, but also includes a subset of foods from animals; the agency should take that fact into account generally throughout rulemaking.

Because the Coalition represents all segments of the U.S. food value chain with a broad range of interests and perspectives, individual Coalition members will offer USDA-AMS recommendations on how to address other aspects of Question 4.

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

[2] *See, e.g.*, Poti, J.M., et al., Is the degree of food processing and convenience linked with the nutritional quality of foods purchased by US households?, 101 Am. J. Clin. Nutr. 1251-1262 (June 2015). *See also*, Monteiro, CA, *et al.*, A new classification of foods based on the extent and purpose of their processing, 11 Cad Saude Publica, 2039049 (Nov. 2010) (describing three categories of processed foods: (1) minimally processed foods (physical processes applied to single basic foods such as cleaning, chilling, etc.; (2) processed foods (extraction of one specific component of a single basic food, such as oils and fats, sugar, high fructose corn syrup, and milk and soy proteins); and (3) ultra-processed foods (processing of several foodstuffs, including ingredients from group 2 and unprocessed or minimally processed basic foods from group (1).

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.

Coalition Response

When addressing any potential areas of confusion between the definition of "bioengineering" in the Law and other similar terms used by the Federal government, USDA-AMS should reinforce the fact that the bioengineered food disclosure standard is a marketing standard, and not a health, safety, or nutrition standard.

The Law directs USDA-AMS to consider establishing consistency between the eventual National Bioengineered Food Disclosure Standard and the Organic Foods Production Act of 1990. The Coalition supports consistency, where appropriate, to help reduce consumer confusion. Additional comments in this regard follow.

- *The disclosure rulemaking should not impact the organic standards.*
    - *The Law does not, and future regulations should not, impact the authorities or obligations under the Organic Foods Production Act and no modifications should be made to the USDA Organic rules solely as a result of bioengineered food disclosure rulemaking.*
    - *Consistent with USDA's September 2016 Policy Memo, no certified organic products should require disclosure as a bioengineered food.*
    - *The Coalition further supports, as the Law outlines, that foods certified under the National Organic Program are considered sufficient to continue making claims about the absence and exclusion of bioengineering.*
- *The Organic standard may inform some aspects of the disclosure rulemaking, where appropriate, but it should not dictate them.*
    - *USDA's Organic regulations have their own definition of recombinant DNA techniques. We interpret the parts of the current definition for the Organic standard's excluded methods of genetically modified organisms that refer to "recombinant DNA technology" that result in products "that are not possible under natural conditions" and which "do not include the use of traditional breeding" to already be similar to the definition of "bioengineering" in the Law. While we are aligned with these principles, we refer USDA-AMS to the more technically precise information we have provided in response to Questions 2 and 3.*
- *The Coalition supports consistency between the two standards, where appropriate.*

Question 6. Meat, poultry, and egg products are only subject to a bioengineered disclosure if the most predominant ingredient, or the second most predominant ingredient if the first is broth, stock, water,

or similar solution, is subject to the labeling requirements under 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.

Coalition Response

The Coalition urges USDA-AMS to use the ingredient declaration on the product label to evaluate predominance of ingredients to determine how the Law will apply to multi-ingredient food products. As described in 21 C.F.R. § 101.4(a), 9 C.F.R. § 317.2(f)(1), 9 C.F.R. § 381.118(a) and A Guide to Federal Food Labeling Requirements for Meat, Poultry and Egg Products[3], the ingredients are required to be declared on the label of a food by common or usual name in descending order of predominance by weight.

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

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

Coalition Response

Per the statutory provision in Section 293(b)(2)(A), a food derived from an animal is not considered bioengineered solely because the animal consumed feed produced from, containing, or consisting of a bioengineered substance. USDA-AMS must acknowledge the clear statutory intent that food is not subject to the mandatory disclosure requirement solely because it is derived from animals fed bioengineered substances. It would be appropriate for USDA-AMS to adopt via regulation the language in Section 293(b)(2)(A). As to invertebrates, the Coalition refers the agency to its response to Question 11, below.

***Additional information**: Consistent with the statutory definition of "food" in Section 291(2) as being limited to food solely "intended for human consumption," the bipartisan Senate Report states, "[i]t is the intent of Congress that the mandatory disclosure provisions not apply to animal feed, pet food, or ingredients used in animal feed or pet food. The language prohibits the Secretary from considering any food product derived from an animal to be bioengineered solely because the animal may have eaten bioengineered feed." We support the Congress' conclusion.*

[3] A Guide to Federal Food Labeling Requirements for Meat, Poultry and Egg Products, https://www.fsis.usda.gov/wps/wcm/connect/f4af7c74-2b9f-4484-bb16-fd8f9820012d/Labeling_Requirements_Guide.pdf?MOD=AJPERES, 43-43 (2007) (last visited July 24, 2017).

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

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

Coalition Response

When determining any threshold or amount of a bioengineered substance present in food that triggers mandatory disclosure, USDA-AMS should reinforce that the bioengineered food disclosure standard is a marketing standard, and not a health, safety, or nutrition standard. In addition, the regulations should make clear that, whatever threshold or amount of a bioengineered substance triggers mandatory disclosure, voluntary disclosure below that level is permissible provided that the disclosure is truthful and not misleading.

Additional information: *When determining the amounts of a bioengineered substance that may be present in food, or the threshold requirement, USDA-AMS should adhere to the Congress' instruction in the bipartisan Senate Report to "minimize the impacts on all aspects of the domestic and international value chain." USDA-AMS should also consider that while there are multiple international thresholds pertaining to presence of a bioengineered substance, no single international standard or consensus exists.*

USDA-AMS should also ensure that the rule is consistent with Section 293(b)(3), which provides that "a bioengineered food that has successfully completed the pre-market Federal regulatory review process shall not be treated as safer than, or not as safe as, a non-bioengineered counterpart of the food solely because the food is bioengineered or produced or developed with the use of bioengineering." USDA-AMS must also ensure thresholds or amounts triggering mandatory disclosure do not imply, directly or indirectly, that a bioengineered substance is a contaminant or stigmatize foods with such substances. Furthermore, USDA-AMS should consider a threshold that supports continued use of bioengineered ingredients or substances, recognizing their contribution to a safe, affordable, abundant, and sustainable food supply. USDA-AMS should also take into account consumers' interest in information about their food and the impact of mandatory bioengineered food disclosure on costs to the consumer, food processor, supply chain, and food producer when determining what, if any, threshold or amount of bioengineered substances in a food triggers mandatory disclosure.

Because the Coalition represents all segments of the U.S. food value chain with a broad range of interests and perspectives, individual Coalition members will offer USDA-AMS additional recommendations on how to address Question 8.

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

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

Coalition Response

The Law creates two categories of mandatory disclosure within the USDA-AMS marketing program: food that is "bioengineered" and food that "may be bioengineered."

***Additional information**: The Law requires the Secretary to establish through rulemaking a mandatory uniform national disclosure standard for human food that is or may be bioengineered, a point which is confirmed throughout the bipartisan Senate Report. The Secretary has authority, as outlined in Section 293, to generate requirements and procedures to carry out the mandatory marketing disclosure program via USDA-AMS. Those requirements and procedures may inform USDA-AMS thinking on how to best elaborate on disclosure categories. See our responses to Questions 10 and 11 for more information about the Coalition's recommendations related to requirements and procedures.*

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

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

Coalition Response

Any determinations made under Section 293(b)(2)(C) must take into account the statutory definition in Section 291. See our response to Question 11 for more information related to Section 293(b)(2)(C).

Question 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.

Coalition Response

Yes, and as stated in our answer to Question 10, any determinations made under Section 293(b)(2)(C) must take into account the statutory definition in Section 291. So, consistent with the statutory definition, USDA-AMS is required by the Congress to establish requirements and determinations that guide the agency in developing the mandatory marketing disclosure program. Such requirements and determinations could include, for example, the establishment of a threshold under which a food is not considered bioengineered (see Question 8) or the exemption of certain classes of food or ingredients from mandatory disclosure. USDA-AMS should be transparent in this process and consider providing information on its website to help the public and developers of bioengineered food or ingredients understand if their products are bioengineered and thereby subject to mandatory disclosure. Any exemption from the mandatory program should be based on criteria that are clear and scientifically and legally justified.

***Additional information**: According to the bipartisan Senate Report, "Congress intends the Secretary to provide exemptions and other determinations under which a food is not considered bioengineered." The Report noted examples of exemptions provided by various states to their labeling mandates, including for food products that (i) may include enzymes, additives, and processing aids; and (ii) have medicinal and supplementary applications. We agree with the Congressional interpretation and urge USDA-AMS to provide exemptions for products (i) made using enzymes, additives, and processing aids or (ii) that have medicinal and supplementary applications, to the extent those products would otherwise be subject to mandatory disclosure. We also urge USDA-AMS to use this provision of the Law to ensure the following do not trigger mandatory disclosure, to the extent those products would otherwise be subject to mandatory disclosure, solely because of the below-described characteristics:*

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

- *Food derived from animals treated with bioengineered animal drugs and pharmaceuticals.*

- *Food ingredients derived by the chemical transformation of materials directly obtained from a bioengineered crop (examples include caramel flavoring and color, vitamin C, and sugar alcohols).*

- *Food produced with microbially-derived products, including fermentation products. Such products used in food include ingredients, e.g., vitamins and amino acids, and processing aides.*

- *A processing aid, incidental additive, or secondary direct food additive that may be from a bioengineered source material. Examples include carriers for flavor components and substances that have a functional role in ingredients but no function in the final product. By their very*

definition, processing aids and incidental additives are present at insignificant levels in the finished food and have no technical or functional effect in that food.[4] For that reason, FDA regulations do not require the declaration of processing aids or incidental additives in the ingredient statement on food labels.[5] Therefore, their use in processing is not material to whether the finished food is bioengineered. Indeed, the EU recognizes that processing aids are outside of the scope of the GMO disclosure regulation.[6] Similar to processing aids and incidental additives, a secondary direct food additive has a technical effect in food during processing, but not in the finished food.

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

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

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

Coalition Response

The term "may" should be permitted given that food manufacturers may intermittently alternate between using both bioengineered and non-bioengineered ingredients in the same product throughout the year. There may be other instances in which the term "may" is appropriate, such as where a manufacturer is unsure of the source of an ingredient for which bioengineered and non-bioengineered versions are available.

USDA-AMS should also consider providing flexibility for unpackaged raw agricultural commodities intended for direct human consumption and not for further processing, as well as other single-ingredient foods, such as papaya, that are otherwise subject to the mandatory disclosure standard, to be identified using a different term, such as "bioengineered product." Similar flexibility should be provided for foods or ingredients that are not from a bioengineered crop but instead are or contain an ingredient from a bioengineered animal, like salmon.

The agency should establish a compliance date that provides sufficient time for companies to revise their labels to comply with the new mandatory disclosure requirement. USDA-AMS should also consider

[4] 21 C.F.R. § 101.100(a)(3).
[5] *Id.*
[6] Regulation (EC) No 1829/2003 of the European Parliament & of the Council on Genetically Modified Food & Feed, cl. 16, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:268:0001:0023:EN:PDF.

harmonizing the compliance date with other relevant labeling changes required by new Federal regulations.

Because the Coalition represents all segments of the U.S. food value chain with a broad range of interests and perspectives, individual Coalition members will offer USDA-AMS additional recommendations on how to address Question 12.

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

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

Coalition Response

The symbol designed for compliance with the bioengineered disclosure standard must be non-disparaging of the technology. USDA-AMS should not be overly prescriptive in specifying the location, color or size of the symbol.

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

Context: See Questions 23-25.

Coalition Response

The mandatory text provided in the online disclosure statement should be the same as that required for the on-package disclosure text (discussed in our response to question 12). Beyond the required language, USDA-AMS should make clear that nothing in the Law or regulations prohibits companies from communicating additional information that is truthful and not misleading, such as adding a statement noting that ingredients from bioengineered crops are commonly known as GMOs, using a complete sentence that includes the mandatory text, or adding a statement to ensure that the mandatory text is not misleading (e.g., "No significant difference has been shown between ingredients derived from bioengineering and ingredients derived without bioengineering" or "the ingredient is the same as one produced from a conventionally or organically produced product").

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

Context: AMS recognizes that disclosure technologies may quickly surpass regulations. AMS is considering what terms will ensure the regulations keep pace with technological changes and how AMS

can notify stakeholders about changes in technology as they occur. AMS is also considering what the most appropriate electronic or digital disclosure technologies are currently and how to deal with obsolete technologies.

Coalition Response

The regulation should not identify a specific carrier, but suggest that a reference to a QR code as an example is appropriate. Addressing emerging or obsolete technology is best managed by implementing a set of guidelines or principles. These principles should start with (see our response to Question 14) definitions / terms of reference for a Digital Link and a Carrier.

The digital link should include a Uniform Resource Locator (URL). The URL, like HTML code, is an internet protocol that will likely not change for a long time. However, the regulation should include a proviso that digital link capability will be reviewed and adjusted if and when internet technologies change.

The technologies that will change are the carriers capable of embedding a URL. As those technologies change, smart device reading capabilities will also evolve.

The following set of guidelines or principles should be used when addressing emerging or obsolete capabilities:

• A compliant carrier:

• Must be able to contain a URL.

- *The carrier must be open-sourced technology. The USDA must ensure rules do not confine companies to single-point (for-profit) providers or create intellectual property issues. As mentioned in our response to Question 14, QR codes, DataMatrix, DataBar, RFID and some forms of Digital Watermarking meet this requirement.*

• Must be broadly read by consumer devices (see our response to Question 14) through the camera function on the devices or other functions that allow consumers to gain access to the information via the carrier.

- *Today, only QR codes meet this requirement. Data Matrix and DataBar are not consumer-facing tools. They are business-to-business and production-management tools. Digital Watermarking has consumer-facing promise but today, few apps are available and no utilities have this reading capability.*

• Must be easily recognized by consumers as a carrier to be scanned by a Smart Device.
QR codes are the only vehicle that meets these requirements today. These principles provide the flexibility to leverage emerging technologies like Digital Watermarking if and when that technology meets the stated guideline above.

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

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

Coalition Response

Disclosure information required under this Act should be sufficient disclosure for items sold through vending machines.

USDA-AMS recognizes that certain foods should be treated differently, and that USDA and other agencies consistently provide modified requirements for these foods. In particular, FDA has recognized that labeling certain foods is impractical and, as such, provided for a number of exemptions for traditional nutrition facts panel (NFP) labeling under 21 C.F.R. § 101.9 ("Nutrition labeling of food"). Although the mandatory disclosure standard is directed to marketing and not safety, health, or nutrition, it is our position that USDA-AMS should, for consistency, similarly recognize that foods exempt from traditional labeling under 21 C.F.R. § 101.9 should be exempt from the mandatory disclosure requirement where not inconsistent with the Law. So, for example, this would include recognition of the exemption in 21 C.F.R. § 101.9(j)(10) for raw fruits and vegetables subject to section 403(q)(4) of the Federal Food, Drug, and Cosmetic Act (FFDCA). Unpackaged foods are not subject to the mandatory disclosure requirement. The Senate Report specifically states:

> *"Unpackaged foods and food processed or prepared in a restaurant or similar retail food establishment are also excluded from the scope of the disclosure requirement"*

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

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

a. In 21 *C.F.R. §* 101.9(j)(13)(i)(B), FDA defines small packages as those with less than 12 square inches in total surface area available to bear labeling.

b. FDA also has allowances for packages that have less than 40 square inches of total surface are available to bear labeling.

Coalition Response

Although the mandatory disclosure standard is directed to marketing and not safety, health, or nutrition, USDA should, for consistency, define small and very small food packages using some of the principles that FDA applies when determining the appropriate format for nutrition labeling information or to determine that available labeling space is too small to accommodate nutrition facts information. Although FDA does not have a definition for very small package, small packages are defined as "hav[ing]

a total surface area available to bear labeling of less than 12 square inches . . . .”[7] USDA should align the definition for small packages with FDA’s “small package” definition. FDA has also recognized that food packages with more than 12 square inches, but less than 40 square inches of available labeling space require smaller modified “tabular format” for nutrition facts information. It would be appropriate for USDA to permit flexibility in terms of the size of text and placement of a disclosure statement for packages that are larger than the above defined “small package” but have less than 40 square inches of available labeling space.

If a package meets the small package definition proposed above, the following accommodations should be made. USDA should provide flexibility about the form of disclosure for small packages. Small packages should have options on the size of the disclosure, as the space available will determine the size of the text or symbol that can be placed on the label. Additionally, manufacturers of food in small packages should be allowed to list a phone number with language such as “For nutrition information or other food facts, call 1-800-XXX-XXXX” or “For nutrition information or bioengineered food facts, call 1-800-XXX-XXXX” so that consumers have access to the disclosure information. Alternatively, small packages should be provided additional flexibility and be allowed to only provide a web address maintained by the manufacturer that provides information consistent with the electronic disclosure requirement about the bioengineered content of the food. Although we have not provided a recommendation for the definition of “very small packages” we would assume this size of package would have proportionally less available labeling space than the proposed 12 square inches or less for a “small package.” Therefore, due to the extremely limited labeling space on very small packages, USDA should not require disclosure in any form on very small packages.

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

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

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

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

Coalition Response

Similar to the provision described in 21 C.F.R. § 101.9(j)(13)(i)(A), USDA-AMS should allow products in small and very small packages to be exempt from disclosure provided the manufacturer, packer or distributor provides on the food label a telephone number or web address (website) that a consumer can use to obtain the required disclosure information.

Excerpt from 21 C.F.R. § 101.9(j)(13)(i)(A):

[7] 21 C.F.R. § 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, Provided, That the labels for these foods bear no nutrition claims or other nutrition information in any context on the label or in labeling or advertising . . . . Claims or other nutrition information . . . subject the food to the provisions of this section."

Foods in packages subject to requirements of paragraphs (j)(13)(ii)(A)(1) and (2) of this section do not require the information in paragraphs (d)(9) and (f)(5) related to the footnote, however the abbreviated footnote statement "% DV = % Daily Value" may be used.

"(A) The manufacturer, packer, or distributor shall provide on the label of packages that qualify for and use this exemption an address or telephone number that a consumer can use to obtain the required nutrition information (e.g., ''For nutrition information, call 1–800–123–4567'')."

Question 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 C.F.R. § 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 C.F.R. §§ 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 C.F.R. §§ 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 C.F.R. §§ 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.

Coalition Response

Although the mandatory disclosure standard is directed to marketing and not safety, health, or nutrition, for consistency's sake, the term "small food manufacturer" should be defined in the same way it is defined under the FDA's Food Safety Modernization Act (FSMA) final rules, subject to notice and comment rulemaking, on preventive controls for human food, international adulteration of foods, and sanitary transportation of foods. All three of these rules define a small business as "a business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees." 21 C.F.R. § 117.3; 21 C.F.R. § 121.3; 21 C.F.R. § 1.904. The term "full-time equivalent employee" is also defined at 21 C.F.R. § 117.3.

This standard is appropriate to use for the purposes of the bioengineered food disclosure standard because it reflects FDA's recent consideration of which food manufacturers are considered small businesses. The standard is also based on the Small Business Administration's (SBA's) definition of small business.

Question 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.

Coalition Response

The Law provides flexibility as to the language used to indicate that a phone number provides access to additional information. In particular, section 293(b)(2)(F)(ii)(I) states that the phone number must be accompanied by "appropriate language to indicate that the phone number provides access to additional information." Under this standard, appropriate language could include:

- *"For more information, call …"; or*
- *"Call for more food information" (mirroring the language used for electronic or digital disclosures; "Scan here for more food information").*

USDA-AMS should provide small food manufacturers with flexibility to use either of these language options when a phone number is used to make the disclosure.

Question 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.

Coalition Response

Grocery stores offer a large variety of products, from large national brands of manufactured foods to unique local and seasonal offerings. While many of these products are traditional grocery items, others are offered for sale in diverse ways and in varying packaging formats. These might include made-to-order sandwiches packed by a store clerk in food-grade paper, a salad assembled by the customer and eaten on site in a reusable bowl, pasta salad sold by weight and packed into a plastic container, unpackaged bulk apples sourced from a farm down the road, and many more. We appreciate Congress' recognition that unpackaged foods and items prepared in the grocery stores are exempt from the

mandatory disclosure requirement and further appreciate the opportunity to comment on how USDA-AMS should define various terms in order to properly preserve this exemption.

As noted above, the Law excludes foods served in restaurants and similar retail food establishments from the mandatory disclosure requirement. USDA-AMS notes that food retailers and restaurants are treated differently from traditional human food manufacturing facilities under USDA, FDA and the National Organic Program (NOP). For example, restaurants and retail food establishments are not required to register with the Food and Drug Administration under the Bioterrorism Act because they are selling foods directly to consumers. Addressing the food itself, the Senate Report specifically states that "[u]npackaged foods and food processed or prepared in a restaurant or similar retail food establishment are also excluded from the scope of the disclosure requirement." Historically, FDA has also provided exemptions for unique foods and those that are processed and prepared in restaurants and similar retail food establishments. For example, FDA has created numerous exemptions to traditional labeling for packaged foods under the nutrition facts panel rule. Therefore, the Coalition supports a two-pronged approach to the exemption and its definitions, addressing both the establishments (i.e., restaurants and similar retail food establishments) and the foods sold.

First, USDA-AMS should look to the type of establishment.

Although the mandatory disclosure standard is directed to marketing and not safety, health, or nutrition, the Coalition supports, for familiarity and consistency purposes, utilizing FDA's definition of "retail food establishment" in 21 C.F.R. § 1.227 (i.e., Registration of Food Facilities) in defining "similar retail food establishment" for the disclosure rule. Specifically, Section 1.227 defines retail food establishment as follows:

> *Retail food establishment means an establishment that sells food products directly to consumers as its primary function. A retail food establishment [may] manufacture/process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufactures/processes, packs, or holds, directly to consumers. A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. The term "consumers" does not include businesses. A "retail food establishment" includes grocery stores, convenience stores, and vending machine locations.*

Clearly, it is the intent of the Law to ensure that the manufacturer of a packaged food product, and not the retailer selling the food product, is the entity responsible for compliance with the disclosure regulations. The above definition clearly addresses this distinction. Disclosure information required under this Act should be sufficient disclosure for items sold through vending machines.

Second, USDA-AMS should also define the types of foods that are exempt from the mandatory disclosure requirement.

As noted above, the Senate Report specifically states that "[u]npackaged foods and food processed or prepared in a restaurant or similar retail food establishment are also excluded from the scope of the disclosure requirement." In keeping with Congressional intent, the consistency principle outlined above, and agency recognition of unique foods, any foods exempt from the labeling requirements under the Nutrition Facts regulation, Federal Meat Inspection Act, Poultry Products Inspection Act, or Egg Products Inspection Act should similarly be exempt from the bioengineered food disclosure standard where not

inconsistent with the Law. In particular, those foods exempt from the requirements under 21 C.F.R. § 101.9 ("Nutrition labeling of food") are critical to carrying out legislative intent. As such, the Coalition emphasizes that, subject to the requirement for disclosure of packaged raw foods, the following exemptions from Section 101.9 should also be included in the National Bioengineered Food Disclosure Standard.

> *"(j) The following foods are exempt from this section or are subject to special labeling requirements: . . .*
>
> *(2) Except as provided in §101.11, food products that are: . . .*
>
> *(i) Served in restaurants, Provided, That the food bears no nutrition claims or other nutrition information in any context on the label or in labeling or advertising claims or other nutrition information subject the food to the provisions of this section,*
>
> *(ii) Served in other establishments in which food is served for immediate human consumption (e.g., institutional food service establishments, such as schools, hospitals, and cafeterias; transportation carriers, such as trains and airplanes; bakeries, delicatessens, and retail confectionery stores where there are facilities for immediate consumption on the premises; food service vendors, such as lunch wagons,[8] ice cream shops, mall cookie counters, vending machines, and sidewalk carts where foods are generally consumed immediately where purchased or while the consumer is walking away, including similar foods sold from convenience stores; and food delivery systems or establishments where ready-to-eat foods are delivered to homes or offices), . . .;*
>
> *(iii) Sold only in such facilities, . . .;*
>
> *(iv) Used only in such facilities and not served to the consumer in the package in which they are received (e.g., foods that are not packaged in individual serving containers); or. . .*
>
> *(3) Except as provided in §101.11, food products that" meet each of the following criteria:*
>
> *"(i) Of the type of food described in paragraphs (j)(2)(i) and (j)(2)(ii) of this section,*
>
> *(ii) Ready for human consumption,*
>
> *(iii) Offered for sale to consumers but not for immediate human consumption,*
>
> *(iv) Processed and prepared primarily in a retail establishment, and*
>
> *(v) Not offered for sale outside of that establishment (e.g., ready-to-eat foods that are processed and prepared on-site and sold by independent delicatessens, bakeries, or retail confectionery stores where there are no facilities for immediate human consumption; by in-store delicatessen, bakery, or candy departments; or at self-service food bars such as salad bars), . . .*

[8] USDA-AMS should use the preamble and/or guidance associated with the bioengineered disclosure rule to make clear that terms such as "lunch wagon" include food trucks.

(9) Food products shipped in bulk form that are not for distribution to consumers in such form and that are for use solely in the manufacture of other foods or that are to be processed, labeled, or repacked at a site other than where originally processed or packed.

(10) Raw fruits, vegetables, and fish subject to section 403(q)(4) of the act, except that the labeling of such foods should adhere to guidelines in §101.45 . . . .

In summary, exemption under the bioengineered disclosure standards should address two prongs, as follows:

1. USDA-AMS should maintain the exemption for "similar retail food establishment," and should adopt the definition of "retail food establishments" in 21 C.F.R. § 1.227 when defining such.

2. USDA-AMS should clearly exempt foods that are also exempt from the labeling requirements under the Nutrition Facts regulation, Federal Meat Inspection Act, Poultry Products Inspection Act, or Egg Products Inspection Act. In particular, USDA-AMS should make clear the exemption under the bioengineered disclosure standard for foods processed and prepared in a retail establishment, and unpackaged foods, including unpackaged raw produce and unpackaged bulk foods.

Disclosure information required under this Act should be sufficient disclosure for items sold through vending.

Question 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.

Coalition Response

Although the mandatory disclosure standard is directed to marketing and not safety, health, or nutrition, the term "very small food manufacturer" should, for consistency, be defined in the same way it is defined under the FSMA final rule on preventive controls for human food, as adjusted for inflation. That rule defines very small business as "a business (including any subsidiaries and affiliates) averaging less than $1,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee)." 21 C.F.R. § 117.3. This standard is appropriate to use for the purposes of the bioengineered food disclosure standard because it has been promulgated through notice and comment rulemaking and is based on FDA's recent consideration of which food manufacturers are considered very small businesses, reflecting the current state of the industry.

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

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

Coalition Response

"Scan" will likely be a ubiquitous call-to-action for a long time so we believe that verb is acceptable. If another technology presents itself that meets the principles set forth in answers to questions 14 and 15, and it is readily apparent that the term "scan" is no longer an appropriate verb to describe how a consumer may know to access information from that technology, then USDA-AMS should have flexibility to provide companies with the option to use different terminology. However, given the ubiquitous nature of "scan here for more information" and consumer awareness of that phrase, the Coalition would not encourage USDA-AMS to consider other terminology until there is a specific example of technology that meets the criteria set forth in questions and 14 and 15 coupled with a compelling case that "scan here for more information" is no longer the best method to inform the consumer how to access information.

The on-package call-to-action should read "Scan here for more food information." In addition, USDA-AMS should also permit "Scan here for more information." Eliminating the word "food" opens up digital disclosure capability far beyond this specific Law. Digital disclosure goes far beyond "food" and can provide information on ingredients, allergens, product source, social compliance, sustainability and more. There is also a likelihood that digital disclosure will be a compliant disclosure tool for State nonfood regulations (e.g. personal care, cosmetics, cleaning product ingredient and safety information). Using "scan here for more information" helps make consumer education easier.

Digital disclosure goes far beyond what could ever fit on a label and can/will be used to address consumer/interest group concerns well beyond this single issue.

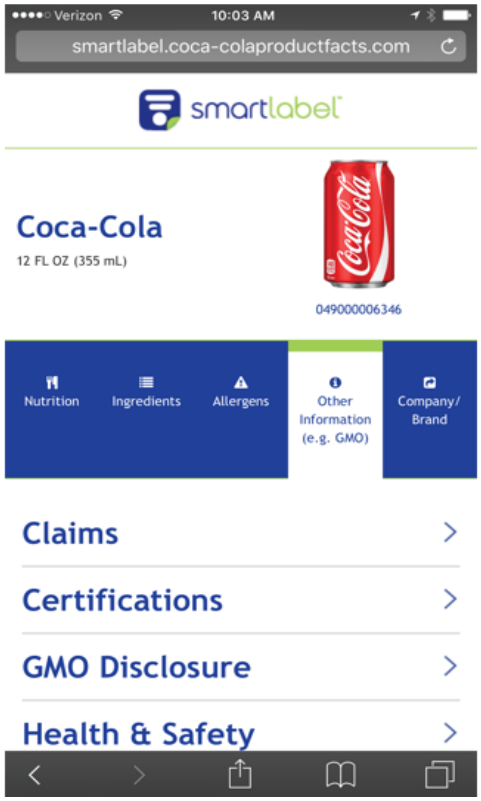
Question 24: How should AMS ensure that bioengineered food information is located in a consistent and conspicuous manner when consumers use an electronic or digital disclosure? (Sec. 293(d)(2))

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

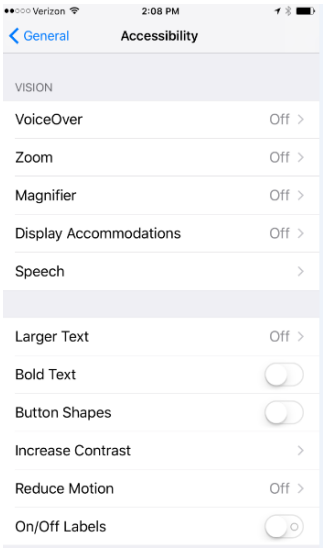
Coalition Response

As shown in the examples below, consumers must be able to locate the "GMO" information from the URL driven webpage in 2-clicks or less. The "2-click" requirement is necessary to accommodate potential device/consumer interface options. Two examples, both California's SB258 and New York's Household Cleansing Product Information Disclosure Program recognize this multi-click need.

This SmartLabel™ example demonstrates the capability. When a consumer scans the QR code on a 12oz can of Coca-Cola the picture to the left is the default URL Landing Page. The "GMO" call-out within the Other Information tab is a requirement within SmartLabel™ and a demonstration of consistent and conspicuous disclosure. Consumers get to this view on the first click. Clicking on the tab with the "GMO" call-out and selecting "GMO" brings the consumer to the "GMO" disclosure.



Text size should not be defined because this is configurable by consumer/by device. Font size on a cell phone, on a tablet or on a desk top will be different.



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

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

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

Coalition Response

The manufacturer should be responsible for ensuring that the disclosure can be easily and effectively scanned. There are existing standards and industry will leverage those standards to ensure the electronic or digital link is effectively scanned. For example, specifications have been written to drive effective use of barcodes throughout the entire supply chain. from reading codes on high-speed production lines to cashier read rates in a grocery store checkout lane. Additionally, Figure 1 below shows the specifications written for QR code usage within the SmartLabel™ context. These specifications deliver a "First Time Read Rate" of 2 seconds or less.

The starting point for ease and effectiveness should be the guidelines / principles descried in Q-14.

The electronic or digital link and its carrier:

- *Must be broadly read by consumer devices (see response to Q-14) through the camera function on their devices.*
- *Must be easily recognized by consumers as a carrier to be scanned by a Smart Device.*

For perspective, QR codes leverage 2-dimentional capability while the UPC code utilizes just one-dimension. QR codes leverage the camera (image) technology while UPC codes require a laser scanner. This produces two distinct advantages:

1. *QR codes can be more effective at much smaller sizes. As little as ¼ inch.*
2. *There is much greater tolerance for printing variation. QR code printing does not need to be as exacting as a UPC code so it is a much more effective tool.*

FIGURE 1: QR Code Specification

Glossary of Terms

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

1. QR Code Guidelines

a. Compliance with ISO/IEC 18004 QR Code 2005 specification.

b. Module width "X" value nominal size of .020".

- *GS1 recommends a module width "X" value of 1.5 times greater than the "X" value for a comparably sized UPC/EAN symbol.*
  - *QR Code X value scales from .015" to .040" (although with 600 DPI or higher resolution, module width could be as little as .014" but should not go below).*

c. Error correction is Level M (medium level allowing recovery of 15% of embedded information). d. Quiet zone is 4X (4 module widths). This is a region 4X wide which shall be free of all other markings, surrounding the symbol on all four sides.

e. Encoding inside the barcode of a URL leading consumers to a page related to the product the barcode is printed on.

- *URL combines a domain name (e.g. GMA uses gmaonline.org) and a unique product reference (e.g. 1njcih) to form* http://gmaonline.org/forms
- *Domain name shall be encoded as following "http://smtlb.org" and be as short as possible, ideally 10 characters or shorter (not counting http://).*
- *Domain name can be either the ones proposed by code publisher or one selected by the brand if the code publisher allows for it.*
- *Embedded URLs will be determined by the brand in liaison with its selected code publisher. f. Use of Version 2 (up to 26 characters) or Version 3 (up to 42 characters) QR barcodes:*

To create smaller size barcodes or provide the best scanning experience, Version 2 (in liaison with your code publisher) is recommended.

g. Adjust barcode width reduction (BWR) to printer specifications to ensure the best scanning experience.

2. Recommended QR Code Sizes

Parameters	***Version 1***	***Version 2***	***Version 3***
Number of Modules (excluding quiet zone)	*21X*	*25X*	*29X*
Quiet Zone (Number of Modules)	*4X*	*4X*	*4X*
Maximum Number of Encoded Characters	*14*	*26*	*42*

		QR Size Including Quiet Zone (*)		
Module Width Size (**)	*.015" (80% - UPC "X"= .0104")*	*.44"*	*.50"*	*.56"*
	.018" (90% - UPC "X"=.0117")	*.52"*	*.59"*	*.67"*
	.020" (100% - UPC "X"=.0130")	*.58"*	*.66"*	*.74"*
	.025" (125% - UPC "X"=.0163")	*.73"*	*.83"*	*.93"*
	.030 (150% - UPC "X"= .0195")	*.87"*	*.99"*	*1.11"*
	.035 (175% - UPC "X"= .0228")	*1.02"*	*1.16"*	*1.30"*
	.040" (200% - UPC "X"=.0260")	*1.16"*	*1.32"*	*1.48"*

(*) QR size rounded up two digits after decimal

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

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

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

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

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

Coalition Response

As USDA-AMS considers how best to implement Sec. 293(g)(2) of the Law, the Coalition asks the agency to be mindful of the following key principles:

First, this rule should reflect the reality that there has been an overwhelming adoption, through utilizing a proven, safe technology, of bioengineered food ingredients in the United States providing an abundant and affordable food supply, many environmental benefits, and greater sustainability.

Second, the Law states that those subject to the mandatory disclosure requirement must maintain records that the Secretary of Agriculture "determines to be customary or reasonable in the food industry," to demonstrate compliance. Keeping in mind that every single regulatory requirement adds time and cost for producers, the supply chain, food manufacturers, retailers, and, ultimately, consumers, it would be unreasonable to impose new recordkeeping burdens or systems on stakeholders to whom the mandatory disclosure requirement applies. We strongly recommend that those impacted by this requirement be allowed to utilize existing practices and mechanisms used in the normal course of business to demonstrate compliance. For example, to the extent that compliance could be achieved

through commonly used paperwork, such as specification sheets, bills of lading, contracts, etc., USDA-AMS would be adhering to the "customary or reasonable" letter of the Law. The Coalition further recommends that the rule expressly authorize recordkeepers to maintain records in electronic form.

Finally, in the context provided for this question, USDA-AMS references FDA record maintenance time. While FDA recordkeeping requirements would certainly be familiar to industry and demonstrate a consistent approach, the Coalition underscores that any recordkeeping requirements administered by USDA-AMS should be viewed through the lens and scope of market differentiation; and <u>not</u> food safety, health, or nutrition.

To be certain, there is no health, safety, or nutritional issue with bioengineering. At the October 2015 Senate Committee on Agriculture, Forestry and Nutrition hearing on biotechnology, the Associate Administrator of the USDA's Animal Plant Health Inspection Service (APHIS) testified, "We [APHIS] have great confidence in the safety of GE crops that have been approved under the current U.S. regulatory system." At that same hearing, FDA's Director of the Center for Food Safety and Applied Nutrition concluded, "As a result of these premarket consultations, we [FDA] are confident that foods derived from GE plants in the U.S. marketplace today are as safe as their conventional counterparts." These findings of safety by USDA and FDA are firmly buttressed as the consensus of scientists and scientific authorities all over the world, including the World Health Organization and the United Nations Food and Agriculture Organization. In addition, the National Academies of Science, Engineering and Medicine (NAS) engaged in a comprehensive analysis of two decades of data on biotechnology and found that GE crops are safe to eat and have the same nutrition and composition as non-GE crops.

Still, we understand that the agency will be under enormous pressure to craft a rule that seeks to cast away science in order to create doubt over the health and safety of this technology. One way to avoid this outcome is to craft recordkeeping requirements that do not equate marketing claims (AMS' mission) with food safety, health, or nutrition standards (FDA's mandate). Again, because bioengineering and bioengineered foods and food ingredients are safe, the recordkeeping requirements imposed for marketing purposes need not be as stringent as those required for food safety, health, or nutrition purposes. At the same time, USDA-AMS should endeavor to successfully implement the recordkeeping provisions in ways that are customary, reasonable and familiar to those in the industry.

With respect to place and maintenance of records, USDA-AMS should recognize that it is appropriate to store records off-site as long as the manufacturer provides records within a reasonable period of time upon request by USDA-AMS. The 4-6 week timeframe the FDA allows companies to demonstrate compliance with certain labeling requirements is appropriate in this context as well, once again stressing that disclosure is directed to marketing and not food safety, health, or nutrition standards.

With respect to adequate access to and inspection of records, as discussed above a 4-6 week turnaround time from date requested would be appropriate. The regulations should also make clear that USDA-AMS does not have access to proprietary information (such as recipes), nor does it have authority to make copies of records as such authority is not granted by the Law.

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.

Coalition Response

USDA-AMS should impose no new burdens on those who must comply with this mandatory requirement and the recordkeeping provisions should be not as stringent as those dealing with food safety, health, or nutrition.

As far as audit triggers and audit procedures are concerned, to our knowledge, the Country of Origin Labeling is the only other mandatory marketing program currently existing at USDA. As USDA-AMS examines other recordkeeping requirements and regimes used by other agencies, care should be taken to avoid equating marketing claims with food safety, health, or nutrition claims or imposing new burdens or additional work on those impacted by the rule.

For audit triggers, USDA-AMS should conduct a review of food disclosures and only initiate an inquiry if the food is generally understood to be a source of bioengineered content and bioengineered content is not disclosed. USDA-AMS should also conduct a review of other similar foods and see if those products disclose bioengineered content instead of requesting materials from companies prior to initiating the investigation.

If based upon its review of the disclosure, USDA-AMS reasonably believes a company is not in compliance with the disclosure standard, the agency can request to review a company's records kept to establish compliance. If USDA-AMS determines a company is not in compliance with the disclosure standard, it should issue a written notification of noncompliance to the food manufacturer.

To verify compliance with the disclosure requirement, USDA-AMS should primarily rely on records review as described above as opposed to analytical testing for recombinant DNA. To the extent that analytical testing results are available, and suggest recombinant DNA is present, USDA-AMS should give the manufacturer an opportunity to review and respond to both the testing results and methods used before issuing a notice of noncompliance.

Finally, the Law does not provide USDA-AMS the authority to conduct inspections. Therefore, the agency should not attempt to extend its authority to inspect farms, manufacturers, or retailers. The audit authority of USDA-AMS should be limited to requesting and inspecting records of the entity required to provide the disclosure for the food under the disclosure standard.

Question 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.

Coalition Response

USDA-AMS should impose no new burdens on those who must comply with this mandatory requirement and the recordkeeping provisions should be not as stringent as those dealing with food safety, health, or nutrition.

As USDA-AMS examines other recordkeeping requirements and regimes used by other agencies, care should be taken to avoid equating marketing claims with food safety, health, or nutrition claims or imposing new burdens or additional work on those impacted by the rule.

If USDA-AMS determines an entity is not in compliance with the disclosure standard, it should issue a written notification of noncompliance to the entity identified on the label. Such notification should provide:

1. *A description of each noncompliance;*
2. *The facts upon which the notification of noncompliance is based; and*
3. *The date by which the entity must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible.*

We offer the following recommendations concerning procedural matters regarding alleged findings of noncompliance. The affected entity should be given 30 days to respond with supporting documentation establishing compliance with the disclosure standard or corrective actions. The entity should be accorded the opportunity to request a meeting or informal administrative hearing with USDA-AMS during this 30-day period, and informed that failure to respond with supporting documentation in a timely manner will result in the entity being publicly identified as non-compliant by USDA-AMS on the agency's web site. USDA-AMS should commit to reviewing the response provided from the entity that addresses the finding of non-compliance. If USDA-AMS is not satisfied with the response it receives, the agency should determine if further administrative actions are necessary. If USDA-AMS is satisfied with the response, then the agency will issue a close out letter.

Question 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.

Coalition Response

USDA-AMS should maintain appropriate internal records of each examination, audit, or similar activity conducted by the agency, as well as the total number of audits performed and the details of the audits performed. If an entity is found to be out of compliance following exhaustion of the administrative process discussed in response to Question 28, it should be afforded the opportunity and time to work with USDA-AMS to address the issue to achieve compliance. If an entity is still found to be out of compliance after a reasonable amount of time to address the issue, USDA-AMS should use its web site to

make public a simple declaration of an entity being out of compliance for a period of six months, or until such time as the reason for the finding of noncompliance is corrected.

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

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

Coalition Response

Imported products must be required to follow the same disclosure requirement as products manufactured in the United States. The U.S. is obligated to apply any requirement in a nondiscriminatory way that is consistent with U.S. obligations under World Trade Organization and other international trade and investment agreements.