

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: Stakeholder Input on Questions Regarding the Establishment of a National Bioengineered Food Disclosure Standard

Dear Mr. Summers:

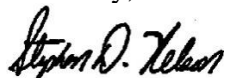
On behalf of the Nebraska Farm Bureau Federation (NEFB) and our over 61,000 member families, I want to thank you for this opportunity to provide feedback on questions being considered in connection with the development of a rule implementing the National Bioengineered Food Disclosure Law.

The state of Nebraska is a very diverse state agriculturally, and NEFB members produce an array of agricultural products. From sugar beets and dry edible beans in the western Panhandle, cattle in the Nebraska Sandhills, to corn, soybeans, wheat, hogs, fruit and vegetables all help make Nebraska an important world leader in food, fiber and fuel production. To remain internationally competitive and lead the world in achieving the productivity and efficiency gains required to meet the food, fiber and fuel demands and environmental challenges of the twenty-first century, U.S. agriculture must stay on the cutting edge of technology.

With the use of bioengineered seeds, our members produce safe foods, and raise healthier and more productive crops, while providing a broad array of environmental benefits to help meet long-term sustainability objectives. We understand and support the consumer's desire to know what is in their food. However, our concerns have always been that any mandated disclosures must not disparage biotechnology, impose undue regulatory burdens, or create market discrimination when there are no material differences between conventional foods and foods derived from biotechnology. We worked with Congress in drafting the National Bioengineered Food Disclosure Standard and support it because it strikes the correct balance between transparency, accuracy, and fairness and it prevents a state-by-state patchwork of food labeling requirements that would have driven up food costs for consumers.

We appreciate your thoughtful consideration of our submission and stand ready to answer further questions or supplement additional details should you request them.

Sincerely,



Stephen D. Nelson
President

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.*

No terms other than “bioengineering” should be considered interchangeable with “bioengineering” for the purposes of the Act. Use of a single term for purposes of the mandatory disclosure standard would be simplest for consumers.

The legislative history of the Act makes clear that the purpose of the legislation is to “establish a mandatory uniform national disclosure standard for human food that is or may be bioengineered.” We therefore discourage use of any other words or terms within the context of this AMS mandatory marketing program.

Use of a single term for purposes of mandatory disclosure does not preclude the use of a different term in additional voluntary statements about foods. Additional descriptive terms used in voluntary statements, therefore, should not be considered interchangeable with the term “bioengineering” under section 291. For example, to the extent that AMS permits the term “genetically engineered” or “genetic engineering” to be used in additional voluntary statements that are truthful and not misleading, the agency should clarify that these terms are not considered interchangeable with “bioengineering” under section 291 and that the ability to use this term in the voluntary disclosure text has no impact on the meaning of “genetic engineering” as that term is used in section 295 of the Law.”

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.*

“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.

¹ S. Rep. 114-403 (2016).

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 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.*

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 otherwise ... be found in nature.” 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.*

USDA 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 to use the term “refined ingredients” when referring to single food components such as sugar and oils.

Requiring disclosure for foods containing undetectable levels of genetic material would contravene Congressional intent and would exceed AMS’s authority

The National Bioengineered Disclosure Standard, Pub. L. 114-216, (the “Disclosure Standard” or Act”) is *unambiguous*; Congress required disclosure only for foods that *contain bioengineered genetic materials*. Congress thoughtfully, deliberately and intentionally did not extend the scope of the Act to include ingredients derived from bioengineered plants that after the refining process do not contain bioengineered genetic materials. Congress further directed the Secretary to “determine the amounts of a bioengineered substance that may be present in food, as appropriate, in order for that food to be a bioengineered food.” § 293(b)(2)(B). Thus, any food that does not contain the level of genetic material the Secretary determines to be appropriate for being considered a bioengineered food, cannot be considered a bioengineered food. The Act’s legislative history reinforces the plain language of the statute:

“The Secretary of Agriculture is directed to establish a mandatory uniform national disclosure standard for human food that is or may be bioengineered. For this purpose, *the definition of bioengineering is set in statute and establishes the scope of the disclosure standard*. Congress intends an item of food to be subject to the definition if it contains genetic material that has been modified through in vitro

² See e.g., Poti, J.M., et al., Is the degree of food processing and convenience linked with the quality of food 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).

recombinant deoxyribonucleic acid (DNA) techniques and this same modification could not be otherwise obtained through conventional plant breeding or found in nature.”³

Refined food products that do not contain genetic material *do not* meet the statutory definition of a bioengineered food.

Some are making the argument that Congress defined “bioengineering” in § 291(1) of the Act and gave the Secretary discretion in § 293(a) to define a bioengineered food, which is based largely on floor statements made by Members during debate and with a memo from USDA’s General Counsel, which has been incorrectly described as a legal opinion. NEFB believes that those advancing this argument are reading Member statements and the memo out of context. Nevertheless, Member statements and an agency memo cannot supplant the plain language of the Act. As the Supreme Court has repeatedly made clear the “plain language” of a statute is the “primary guide” to Congress’ preferred policy.” *Sandoz, Inc. v. Amgen, Inc.*, 137 S. Ct. 1664, 1678 (2017) (quoting *McFarland v. Scott*, 512 U.S. 849, 865 (1994)). Here, the plain language makes clear that “bioengineering . . . with respect to a food, refers to a food . . . that contains genetic material.” § 291(1). It further directs the Secretary to set the threshold above which a food is considered a bioengineered food. § 293(a)(2)(B). There is no provision in the Act where Congress gave the Secretary the discretion to rewrite the definition of a bioengineered food from a food that itself contains genetic material to any food derived from bioengineering, a definition Congress expressly rejected. NEFB urges AMS to reject all attempts to broaden the definition of a bioengineered food.

AMS should not assume that refined products produced from bioengineered crops that do not contain detectable levels of genetic material nevertheless contain genetic material

NEFB is further concerned that the way in which Question 4 is framed, AMS appears to assume that even if a refined food product does not contain “detectable” amounts of bioengineered genetic material, it may nevertheless contain bioengineered genetic material and therefore should be subject to the Disclosure Standard. To take this approach would render superfluous Congress’s direction that the Secretary “determine the *amounts* of a bioengineered substance” that may be present in food to be considered a bioengineered food because AMS is not specifying a threshold. Rather, AMS would be incorrectly assuming that any food derived from bioengineering must contain bioengineered genetic material even if the material cannot be detected through validated scientific methods.

In addition, such an approach would be inconsistent with international precedence. Japan, China, Australia, New Zealand, Thailand, Indonesia, Malaysia, and S. Korea have strict labeling regimes, but do not require the labeling of several products refined from bioengineered crops because they do not contain transgenic DNA or protein. Indeed, Japan’s labeling laws do not apply to corn oil, corn starch, dextrin, starch syrup, hydrolyzed protein derived from bioengineered corn; soy sauce, soybean sprout, margarine, hydrolyzed protein derived from bioengineered soy; canola oil derived from bioengineered canola; or sugar derived from bioengineered sugarbeets because they “do not contain traces of DNA.”⁴ Similarly, refined foods such as sugars and oils produced from bioengineered crops are not included in Australia or New Zealand’s mandatory GMO labeling laws because of the absence of DNA and protein

³ Legislative History at 3.

⁴ See Gain Report, Japan

https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Tokyo_Japan_7-13-2015.pdf;

in the refined product and “because the composition and characteristics of these foods are exactly the same as the non-GM food.”⁵

Indonesia’s food registration procedures require labeling for food containing genetically modified potatoes, soybeans, corn, and their derivative products. However, product derivatives which have undergone further refining processes to the point where the genetic material cannot be identified (to include but not limited to oils, fats, sucrose, and starch) do not require any GMO statements.⁶ In Malaysia refined foods, defined as those where processing has removed all novel DNA and protein, are not included in the labeling requirements (refined oil, sugar, corn syrup, honey and dextrin).⁷ Finally, South Korea recently expanded their labeling law but still does not include several refined products.⁸

Requiring disclosure for refined foods that do not contain genetic material is false and misleading, not supported by the evidence before the Agency, and will only lead to consumer confusion

Requiring all refined products produced from bioengineered crops to be labeled as a “bioengineered” food would be false and misleading. *Importantly, it represents to consumers that the refined products produced from bioengineered crops are somehow different, less safe, and less desirable than refined products produced from non-bioengineered crops even though “the composition and characteristics of these foods is exactly the same as the non-GM food.”*⁹

AMS should not pursue this approach because: (1) it runs counter to the scientific evidence, (2) it contravenes Congress’s intent that “USDA’s implementing regulations treat the safety of a bioengineered food the same as its non-bioengineered counterpart,” and (3) *misbrands* the food within the meaning of the Food, Drug and Cosmetic Act, when the Act prohibits the disclosure standard from affecting any other federal definition, program, rule, or regulation.¹⁰ *See Motor Vehicle Mfrs. Ass’n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (an agency’s decision is arbitrary or capricious if it runs counter to the evidence before the agency, relies on factors which Congress did not

⁵ Genetically modified (GM) food labeling, Food Standards-Australia and New Zealand, <http://www.foodstandards.gov.au/consumer/gmfood/labelling/Pages/default.aspx>

⁶ See USDA GAIN Report No. 1526, Indonesian National Biosafety Commission for Genetically Engineered Products, available at https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Jakarta_Indonesia_7-14-2015.pdf.

⁷ See USDA GAIN Report No. MY6005, Malaysia Biosafety Law, the National Biosafety Board, available at https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Kuala%20Lumpur_Malaysia_9-2-2016.pdf.

⁸ See USDA GAIN Report No. KS1716, Korea’s New Biotech Labeling Requirements, available at https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Update%20to%20Korea's%20New%20Biotech%20Labeling%20Requirements_Seoul_Korea%20-%20Republic%20of_6-23-2017.pdf.

⁹ Genetically modified (GM) food labeling, Food Standards-Australia and New Zealand, <http://www.foodstandards.gov.au/consumer/gmfood/labelling/Pages/default.aspx>

¹⁰ Under the Food, Drug and Cosmetic Act a food is misbranded if “its labeling is false or misleading in any particular.” 21 U.S.C. § 343(a). *See also* Legislative History at 6 (“Congress does not intend the legislation to impact the authorities or obligations under the Federal Food, Drug, and Cosmetic Act, . . .”).

intend, and/or is not otherwise the product of reasoned decision making.). AMS must remember the Disclosure Standard is a marketing standard, not a health, safety, or nutrition standard, which the general public is unlikely to understand. Therefore, AMS must be extremely cautious to avoid any mandated disclosures that imply differences between foods when none exist.

Requiring refined products produced from bioengineered crops to be labeled as a bioengineered food when they do not contain genetic material imposes unnecessary regulatory burdens resulting in less competition and higher consumer prices and harms the American farmer

The legislative history of the Act makes clear that “the Secretary, when determining the amounts of a bioengineered substance that may be present in food, or the threshold requirement, shall *minimize the impacts on all aspects of the domestic and international value chain.*”¹¹ Moreover, the Act “is not intended to increase the costs of food manufacturing or changes in distribution or handling.” Congress’s intent that the Disclosure Standard not disrupt domestic and international supply chains is reinforced by E.O. 13777, which established a federal policy to alleviate unnecessary regulatory burdens. The Department of Agriculture recently requested public comment on how its Task Force, required by E.O. 13777, can reduce the regulatory burdens of existing regulations, particularly regulations that are unnecessary, impose costs that exceed benefits, or eliminate jobs. 82 Fed. Reg. 32649 (July 17, 2017). The same principles apply to new regulations.

Requiring refined food products produced from bioengineered crops to be labeled as bioengineered foods when they do not contain genetic material exacerbates the impacts on the domestic and international value chain. First, it discriminates against refined products derived from biotechnology by implying to consumers that they are different or less desirable than their conventional counterparts, when they may in fact be identical. This leads to price differentiation, with premiums imposed for the “more desirable” conventional products and aggressive marketing to gain market share. Second, any time identical products are differentiated in the market it causes food manufacturers and retailers to restrict their supply chain thereby reducing competition and driving up costs which are eventually passed onto consumers. This was clearly evidenced in 2015-2016 as food manufacturers began to constrict their supply chains in order to comply with the Vermont law. Third, for retailers that source refined products from multiple suppliers, often interchangeably, requiring refined products derived from biotechnology to be disclosed would require different labels for identical products leading to increased costs and further disruption in the supply chain.

Finally, disruption in the supply chain and disparagement of the technology harms the American farmer because demand for genetically engineered crops will decline, even though they improve crop yields and are more environmentally sustainable than conventional crops.¹² Indeed, when the Vermont law was enacted many farmers faced uncertainty regarding the future viability of their bioengineered crops. AMS should be mindful that in enacting the Disclosure Standard Congress made “every effort . . . to ensure that farmers have access to seed technology and not limit the options available to agricultural

¹¹Legislative History at 3.

¹² See also “Crop biotechnology has contributed to significantly reducing the release of greenhouse gas emissions from agricultural practices. This results from less fuel use and additional soil carbon storage from reduced tillage with GM crops. In 2012, this was equivalent to removing 27 billion kg of carbon dioxide from the atmosphere or equal to removing 11.9 million cars from the road for one year.” GM crops: global socio-economic and environmental impacts 1996-2012. PG Economics Ltd, UK, <http://www.pgeconomics.co.uk/page/36/-gm-crop-use-continues-to-benefit-the-environment-and-farmers>.

production” and directed USDA “to take every effort to minimize the impacts on growers.”¹³ Impacting the American farmer is also directly contrary to E.O. 13790, which established an interagency Task Force to “identify legislative, regulatory, and policy changes to promote in rural America agriculture, economic development, job growth, infrastructure improvements, technological innovation, energy security, and quality of life.”¹⁴ This includes advancing “the adoption of innovations and technology for agricultural production and long-term, sustainable rural development.” Biotechnology is at the forefront of agricultural innovation enabling farmers to produce more food on fewer acres using less energy and fewer pesticide applications. Any mandate that refined foods that do not contain genetic material be subject to the Disclosure Standard undermines the advancement of technology for agricultural production in direct contravention of E.O. 13790.

As the world leader in bioengineered crop production, the United States should send a strong message to all nations that bioengineered seeds have significant economic and environmental benefits; the U.S. should not create a Disclosure Standard that discriminates against the technology. Requiring disclosure of refined food products not containing genetic material would only perpetuate the misinformation activists have used for decades to distort the truth about biotechnology and instill fear in the general public when the global scientific community has repeatedly attested to its safety.¹⁵ Indeed, in making clear that the Disclosure Standard is a marketing standard, not a health, safety, or nutritional standard, Congress expressly recognized that “the comprehensive federal regulatory review process has determined that foods produced using bioengineering are safe and not materially different in any way from those made using other methods.”¹⁶

There is no legal or scientific basis for AMS to treat refined food products differently than fermentation products that are derived from bioengineering

As a member of the Coalition for Safe and Affordable Food, NEFB endorses the Coalition’s response to Question 11 identifying categories of foods that AMS should exempt from the Disclosure Standard. Each recommended exemption category can be legally and scientifically justified. In particular, the Coalition recommends that fermentation products, e.g., enzymes, processing aids, should not be subject to the Disclosure Standard solely because they are produced using a bioengineered microorganism when the bioengineered microorganism is not present in the food. This recommendation is legally justified because the food product would not meet the definition of a bioengineered food under the Act (one that contains genetic material) and is scientifically substantiated using validated scientific methods.

The same legal and scientific justification applies to many refined products. Refined food products that can substantiate the absence of genetic material in the food below the established threshold should similarly not be subject to the Disclosure Standard. There is no rational basis under the Act to exempt

¹³ Legislative History at 7.

¹⁴ See Executive Order 13790, “Promoting Agriculture and Rural Prosperity in America” <https://www.federalregister.gov/documents/2017/04/28/2017-08818/promoting-agriculture-and-rural-prosperity-in-america>;

¹⁵See e.g., National Academy of Sciences, The Royal Society of Medicine, WHO, OECD, the American Medical Association, Food and Agriculture Organization of the United States, American Diabetes Association, and the Society of Toxicology.

¹⁶ Legislative History at 4.

one category of foods because of the absence of genetic material but require disclosure for another category of food when those foods also do not contain genetic material.¹⁷

To be clear, NEFB is not recommending that AMS categorically exempt refined food products from the Disclosure Standard. Rather, we are urging AMS not to categorically mandate that refined food products are subject to the Disclosure Standard. This will allow those refined food products that can substantiate the absence of genetic material below the established threshold to be treated fairly under the Act.

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 other similar terms used by the Federal government? If so, what are the potential remedies that could be added to this regulation to alleviate any confusion between this definition and others by the Federal government? (Sec. 292(b))

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

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. NEFB 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.
 - NEFB 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

¹⁷ To justify the disparate treatment of fermentation products and refined products some may argue that fermentation products such as microbes and processing aids are not themselves food but refined products such as sugar and oils are food. That distinction is legally and scientifically unsupportable.

“bioengineering” in the Law. While we are aligned with these principles, we refer you to the more technically precise information we have provided in response to Questions 2 and 3.

- NEFB 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.*

NEFB 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 Products¹⁸, 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.*

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, NEFB 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, “it 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.

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))

¹⁸ 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, accessed 7/24/2017, pg. 43-45

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.*

In determining the amount of a bioengineered substance (referred to in the Act as “genetic material”), AMS identifies as one option “listing any ingredient that was produced through bioengineering.” This option would be wholly inconsistent with the Act because the Congress did **NOT** intend and the Act does **NOT** apply to food or ingredients produced *through* bioengineering. Rather, the Act only applies to a “bioengineered food” which “contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature.” Congress clearly recognized that there would be foods that are produced through bioengineering that would not be subject to the disclosure standard. Basing the trigger for disclosure on whether an ingredient was produced *through* bioengineering impermissibly rewrites the statutory definition of a bioengineered food and contravenes Congress’s intent.

Other methods AMS may use to set the disclosure threshold are critically important and have direct implications as to how the technology is viewed by consumers and global trading partners. ***NEFB strongly urges AMS to set a 5% threshold because it supports biotechnology, appropriately balances disclosure, market dynamics, and international trade, and is consistent with other U.S. regulatory programs, including the USDA Organic Program that allows up to 5% of non-organically produced agricultural ingredients.***

It should be clearly understood that there is no international standard for bioengineered thresholds. Nor is there any scientific basis for the threshold percentages because biotechnology does not raise health, safety or nutrition concerns.¹⁹ Accordingly, thresholds are simply a tool to create a differentiation in the market place to provide a marketing advantage to non-bioengineered products. Thresholds are arbitrarily established mainly to drive consumers away from the technology and create non-tariff trade barriers to imported biotech commodities to protect domestic producers who do not have access to the

¹⁹ See e.g., USDA Foreign Agricultural Service, European Union 28, Agricultural Biotechnology Annual, December 6, 2016 at 20, 37 (noting that “the EC continues to pursue inconsistent and unpredictable approaches regulating the technology. Due to the strong emotional and ideological stance taken by EU consumers and nongovernmental organizations (NGOs) on biotechnology, born in many ways out of the misleading information provided by anti-biotechnology groups, legislation adopted by the EC as well as the process surrounding the approval for cultivation and use of GE crop varieties has suffered,” and further noting that “different types of civil society organizations have militated against agricultural biotechnology since it was first introduced in the 1990s. They are generally opposed to economic growth and globalization. They see more risks than opportunities in technical progress and campaign for a broad application of the precautionary principle. Some of them defend an ideal science that would focus solely on understanding phenomena, and not on developing useful and profitable applications; others reject or strongly criticize science and progress, in line with philosophers such as Hans Jonas and Bruno Latour. They are skeptical of new technologies, in general, and for biotechnology specifically they feel it is dangerous, of little public benefit, and developed by companies that seek private profit at the expense of the common good. As part of their political strategy, their actions include lobbying public authorities, acts of sabotage . . . and communication campaigns to heighten public fears.”), available at https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Paris_EU-28_12-6-2016.pdf;

technology.²⁰ As a world leader, and a leader in biotechnology, the U.S. must set its threshold standard on multiple justifications and not acquiesce to standards set by other countries that attempt to oppose or stigmatize the technology. It is also important to keep in mind that “Congress intend[ed] for the standard to be technology neutral.”²¹ Other countries are closely watching what the U.S. will do in these regulations and it will likely influence their internal discussions regarding acceptance and disclosure.

International thresholds for disclosure of bioengineered foods can be categorized into three groups: **Approach 1** is to treat bioengineered ingredients as no different from other ingredients and not have any mandatory labeling requirements. There are 116 countries (including neighboring trading partners, Canada and Mexico), representing 59% of the countries in the world and 24% of the world population, following this approach. This approach indicates support, trust, acceptance and fostering of bioengineering and bioengineered crop ingredients. This results in lower ingredient costs, greater savings to consumers, provides multiple environmental benefits, does not impact the domestic and international value chain, and is technology neutral. This should be the global standard. However, after two decades of activists maligning the technology and costly state-by-state labeling referendums, Congress responded by enacting the Disclosure Standard. Therefore, this approach is no longer available to the U.S.

Approach 2 is to treat bioengineered ingredients as a non-disparaged low-level presence ingredient. Some countries that follow this approach have a 5% threshold, including Japan, South Africa, Indonesia, Vietnam, and Thailand (collectively representing 8% of the world population). Canada has a voluntary 5% threshold.

Approach 3 is to treat bioengineered ingredients as contaminants. Countries (EU, China, Russia, etc.) following Approach 3 have thresholds that range from 4% to 0.0% and outright bans. For example, Nigeria has a 4% threshold;²² Malaysia and Taiwan (not recognized as a country) have a 3% threshold; Brazil, Australia, New Zealand, Saudi Arabia have a 1% threshold; 41 countries have a 0.9% threshold;²³ 21 countries representing 43% of the world population have a 0.0% threshold;²⁴ and Kenya, Morocco, Benin, Sri Lanka, and Serbia have outright bans.²⁵ It is important to note that there is clear

²⁰ “In September 2014, the government released remarks by President Xi Jinping affirming official support for biotechnology research, but calling for a cautious approach to commercialization. He also said that foreign companies should not be allowed to “dominate the agricultural biotechnology product market.” Page 2, USDA Foreign Agricultural Service, China, Agricultural Biotechnology Annual, December 16, 2016, https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Beijing_China%20-%20Peoples%20Republic%20of_12-16-2016.pdf

²¹ Legislative History at 4.

²² Nigeria enacted the Biosafety Act in 2015 that requires mandatory labeling of all products of agricultural biotechnology. Work in progress regulations have a 4% threshold.

²³ These include the 28 EU Member States, Russia, Ecuador, Iceland, Norway, Switzerland, Turkey, Ukraine, Botswana, Bosnia and Herzegovina, Belarus, Kazakhstan, Armenia, Kyrgyzstan).

²⁴ These include China, Peru, Columbia, Bahrain, Kuwait, Oman, Qatar, United Arab Emirates, South Korea, Ethiopia, Cameroon, India, Mozambique, El Salvador, Bolivia, Tunisia, Mauritius, Burkina Faso, Senegal, Mali, and Bangladesh.

²⁵ “Morocco’s heavy reliance on the EU market as the principal destination for its agricultural exports has instilled a reluctance among policy makers and producers to accept biotechnology products.” Morocco, Agricultural Biotechnology Annual, 2016, USDA Foreign Agricultural Service, Global Agricultural Information Network (GAIN Report Number MO1610), https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Rabat_Morocco_11-7-2016.pdf.

evidence that a low threshold in one country has a direct and dramatic negative impact on the acceptance of biotechnology by other countries. The EU's 0.9% threshold that has existed for some time has shunned the use of biotechnology within the EU and also with its trading partners who supply the EU with raw agricultural products and finished food products.

NEFB urges AMS to adopt a 5% threshold (Approach 2) and demonstrate its leadership on biotechnology

Of the thresholds that have been established world-wide, a 5% threshold is the most supportive of bioengineering and recognizes that the Act establishes a marketing standard, not a food safety standard. It is the lowest cost, lowest liability approach that results in consumer savings. It also has the least impact on the domestic and international value chain and is less of a burden on our developing foreign suppliers. It is the most compatible with our North American trading partners, Mexico and Canada. Finally, it is the closest to technology neutral of the mandatory categories.

Importantly, a 5% threshold is consistent with other U.S. regulatory programs. The USDA Organic Program allows up to 5% of non-organically produced agricultural ingredients which are not commercially available in organic form.²⁶ "The use of genetic engineering, or genetically modified organisms (GMOs), is prohibited in organic products."²⁷ However, "[t]here aren't specific tolerance levels in the USDA organic regulations for GMOs. As such, National Organic Program policy states that trace amounts of GMOs don't automatically mean the farm is in violation of the USDA organic regulations. In these cases, the certifying agent will investigate how the inadvertent presence occurred and recommend how it can be better prevented in the future."²⁸ If an organic consumer product can retain the organic label with up to 5% non-organic content, the Disclosure Standard should be set at 5% as well. Indeed, federal courts have held that consumers hold products labeled organic to a higher standard than even products labeled natural. *See e.g., Pelayo v. Nestle USA Inc.*, 989 F. Supp. 2d 973, 979 (C.D. Cal. 2015). Having the same 5% threshold reduces consumer confusion and avoids any implication that biotechnology is less safe or less desirable and therefore must be treated more stringently than organic products. Congress clearly established the Act as a marketing tool, not a food safety standard. A 5% threshold is consistent with that intent. In addition, the grain trade has coalesced around a 5% low-level presence threshold, although there isn't an international standard.

Establishing a threshold below 5% (Approach 3), as many groups will urge, denigrates biotechnology

NEFB implores USDA to keep Congress's intent in mind that "[n]othing in the [disclosure] requirement can be used to denigrate biotechnology."²⁹ Approach 3 is not supportive of bioengineering or bioengineered foods, crops or biotechnology. For over 20 years the U.S. has battled foreign countries that reject U.S. exports because of their overly restrictive biotechnology standards, based principally on fear (the precautionary principle), not science.³⁰ This has resulted in higher food costs to foreign

²⁶ USDA Labeling Organic Products, <https://www.ams.usda.gov/sites/default/files/media/Labeling%20Organic%20Products.pdf>.

²⁷ <https://www.ams.usda.gov/publications/content/can-gmos-be-used-organic-products>

²⁸ <https://www.ams.usda.gov/publications/content/can-gmos-be-used-organic-products>

²⁹ Legislative History at 2.

³⁰ See also "In the EU, different types of civil society organizations have militated against agricultural biotechnology since it was first introduced in the 1990s. They are generally opposed to economic growth and globalization. They see more risks

consumers and less sustainable food production. In many instances, these restrictive thresholds are used as a non-tariff trade barrier to imports to protect their domestic producers.

Adopting a threshold of less than 5% would complicate our trade with our major and neighboring trading partners, Canada and Mexico, neither of which require any disclosure. As the legislative history directs, "...the Secretary, when determining the amounts of a bioengineered substance that may be present in food, or the threshold requirement, **shall minimize the impacts on all aspects of the domestic and international value chain.**"³¹ Any threshold of less than 5% maximizes impacts to all aspects of the domestic and international value chain.

Moreover, the Non-GMO Project, whose stated mission is to "to change the way our food is grown and made," has a 0.9% per ingredient threshold above which a product cannot bear its Non-GMO Project verified label.³² That is not Congress's intent. Congress made clear that the Disclosure Standard cannot "denigrate biotechnology," which is precisely the Non-GMO Project's undeniable objective in order to drive bioengineered foods out of the market. To adopt the same threshold used by the Non-GMO Project is unsupportable and unacceptable to the American farmer that embraces advancements in agriculture like biotechnology.

In sum, USDA will determine whether the United States will continue to treat the presence of bioengineered substance in food as a "non-disparaged low-level presence ingredient" or a "contaminant." It is our belief that the 5% threshold is the only threshold that (1) allows the United States to remain a world leader in the production of bioengineered crops, (2) minimizes impacts on the value chain, (3) minimizes the regulatory burden on farmers, and (4) is consistent with other U.S. marketing standards. Any lower threshold would treat bioengineered ingredients as a contaminant and not be technology neutral and would "denigrate biotechnology" in contradiction of Congress.³³

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*

than opportunities in technical progress and campaign for a broad application of the precautionary principle. Some of them defend an ideal science that would focus solely on understanding phenomena, and not on developing useful and profitable applications; others reject or strongly criticize science and progress, in line with philosophers such as Hans Jonas and Bruno Latour. They are skeptical of new technologies, in general, and for biotechnology specifically they feel it is dangerous, of little public benefit, and developed by companies that seek private profit at the expense of the common good. As part of their political strategy, their actions include lobbying public authorities, acts of sabotage (destruction of research trials and cultivated fields), and communication campaigns to heighten public fears." Page 37, USDA Foreign Agricultural Service, European Union 28, Agricultural Biotechnology Annual, December 6, 2016.

[https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual Paris EU-28 12-6-2016.pdf](https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual%20Paris%20EU-28%2012-6-2016.pdf).

³¹ *Id.*

³² Non-GMO Project, <https://www.nongmoproject.org/about/mission/>.

³³ Legislative History at 2.

disadvantages, based on cost, clarity, and other factors, of using a single disclosure category or multiple disclosure categories.

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 our 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.*

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.*

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.

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. NEFB agrees with the Congressional interpretation and urges 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. NEFB also urges 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 aids.
- 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.³⁴ For that reason, FDA regulations do not require the declaration of processing aids or incidental additives in the ingredient statement on food labels.³⁵ 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.³⁶ 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*

³⁴ 21 C.F.R. §

³⁵ *Id.*

³⁶ Regulation (EC) No 1829/2003 (clause (16)), <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:268:0001:0023:EN:PDF>.

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.

AMS should not allow manufacturers to continue using the disclosures established under the Vermont law that contradicts the Disclosure Standard enacted by Congress most importantly because the Vermont law disclosures conflict with the plain language and intent of the Act. The Vermont disclosures have highly restrictive thresholds and include food ingredients that are derived from but do not contain genetic material. While such disclosures may have been consistent with Vermont's unfounded health, safety, and nutritional concerns, Congress expressly rejected Vermont's approach and instead defined bioengineering with respect to a food as one that contains genetic material. Thus, adhering to Vermont's prescribed disclosure language ("Produced with Genetic Engineering," "Partially Produced with Genetic Engineering," or "May be Produced with Genetic Engineering") cannot be reconciled with the Act. Further, adhering to this language would be misleading because it would imply differences in certain food products when none exist. For the many reasons stated in response to question 4, any language that includes "produced from," "derived from" or "sourced from" is unacceptable when the ingredient provided to the consumer is no different than an ingredient derived from a conventional or organically grown crop.

NEFB also urges AMS not to allow the use of "May be Produced with Genetic Engineering". First, the "may be" language is ambiguous and therefore creates a perception that the food manufacture is uncertain about a product's ingredients. Second, "produced with" implies that the food is "derived from" or "sourced from" a bioengineered crop, contrary to the intent of the Act. Third, the term "genetic engineering" is broader than and therefore inconsistent with the Act's definition of bioengineering. Similarly, "Partially Produced with Bioengineering" is incorrect because it implies that the food is "derived from" or "sourced from" a bioengineered crop.

The terminology that NEFB urges AMS to use is "*contains* bioengineered ingredients" or "*May contain* bioengineered ingredients." These statements are informative, truthful, and not misleading. They also adhere to the Act's definition of bioengineering and would not require manufacturers to change labels when they change sources between bioengineered and non-bioengineered ingredients.

NEFB urges AMS to adopt one standard text disclosure language to fulfill the Act's purpose to establish uniformity in disclosure. As AMS is well aware, there are many terms used to describe whether a food is or is not bioengineered, most of which are not accurate nor well understood by the general public. NEFB believes uniformity is best accomplished and consumer understanding advanced by limiting on package text to "contains bioengineered ingredients" or "may contain bioengineered ingredients."

Just as important as the text is the font size and location on the package. For consumers who want to know what is in their food, the information is located on the Nutrition Facts Panel, the ingredient list and the allergy warnings, all under FDA's authority. Any information about bioengineered ingredients or non-bioengineered ingredients should be located as close to the ingredient list as possible, but not in a font size larger or more prominent than the allergy warning which alerts consumers that the food contains an allergen that can be harmful or fatal to sensitive individuals. Non-GMO labeling efforts attempt to imply to consumers that a product is safer, healthier or more nutritious than other products derived from biotechnology, which is false and misleading. Therefore, all text information or symbol regarding bioengineered food should be located in close proximity to the ingredient list and allergy warning in a font size that does not exceed that information. The legislative history also provides guidance in this area, stating: "Congress intends USDA to establish any text or the symbol that could

appear on packaging to solely satisfy the disclosure requirement and not be used as a tool to denigrate biotechnology.”³⁷ Giving the on-package disclosure more prominence than allergy warnings would potentially denigrate biotechnology.

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.*

The symbol designed for compliance with the bioengineered disclosure standard must be non-disparaging of the technology.

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

Context: *See Questions 23-25.*

The mandatory text provided in the online disclosure statement should be the same as that required for the on-package disclosure text. 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.*

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 response to Question 14) definitions / terms of reference for a Digital Link and a Carrier.

³⁷ Legislative History at 3.

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 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 (i.e., bullets 2 and 3).

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.*

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 NEFB’s 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 area available to bear labeling.*

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 packages, small packages are defined as “having a total surface area available to bear labeling of less than 12 square inches. . . .”³⁸ 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

³⁸ 21 C.F.R. § 101.9(j)(13)(i)(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?*

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):

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 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.

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 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. § 121.2; 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.*

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.

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. NEFB appreciates 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 "unpackaged foods and foods 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, NEFB 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, NEFB 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 "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." 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, NEFB wants to emphasize 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,³⁹ 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), . . .

(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.

³⁹ 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.

(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.*

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.*

“Scan” will likely be a ubiquitous call-to-action for a long time so NEFB believes 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, we 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 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.

For question 24, USDA-AMS should refer to the response from the Coalition for Safe, Affordable Food, of which Farm Bureau is a member.

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.

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.

The starting point for ease and effectiveness should be the guidelines / principles described in question 14.

The electronic or digital link and its carrier must:

- Must be broadly read by consumer devices 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-dimensional 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.

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.

As USDA-AMS considers how best to implement Sec. 293(g)(2) of the Law, NEFB 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. For the purposes of crafting the recordkeeping provisions of this rule, it would be reasonable and realistic for USDA-AMS to operate on the premise that food products or ingredients subject to mandatory disclosure are to be considered bioengineered unless documentation supports that they are non-bioengineered.

Correspondingly, if no bioengineered source for that ingredient is commercially available, USDA-AMS should recognize that the ingredient would not require mandatory disclosure or records to verify that the food is not bioengineered. Focusing recordkeeping requirements on the very small percentage of non-bioengineered crops is a reasonable approach, especially when traditional and organic producers are already following identity-preserved requirements throughout the chain of custody of a non-bioengineered ingredient for which they are compensated for in higher market prices.

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 record-keepers 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, NEFB underscores that any recordkeeping requirements administered by USDA-AMS should be viewed through the lens and scope of market differentiation; and not 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 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, NEFB understands 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.*

There should not be any new burdens placed 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 NEFB's 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 to 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.*

To reiterate, there should not be any new burdens placed 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.

NEFB offers 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.*

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.*

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.