



National Milk Producers Federation

2107 Wilson Blvd., Suite 600, Arlington, VA 22201 | (703) 243-6111 | www.nmpf.org

August 25, 2017

Mr. Bruce Summers
Acting Administrator
Agriculture Marketing Service
U.S. Department of Agriculture
1400 Independence Avenue, S.W.
South Building Room 3069
Washington, DC 20250

Submitted via GMOLabeling@ams.usda.gov

Re: Questions Under Consideration for the National Bioengineered Food Disclosure Standard

Dear Mr. Summers:

The National Milk Producers Federation (NMPF), based in Arlington, VA, develops and carries out policies that advance the well-being of dairy producers and the cooperatives they own. The members of NMPF's cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of more than 32,000 dairy producers on Capitol Hill and with government agencies. Visit www.nmpf.org for more information.

NMPF submits these comments in response to the Department's request for stakeholder input on questions that are being raised during the promulgation of a proposed rule to implement the National Bioengineered Food Disclosure Standard. Our input is provided below for most of the questions raised. Before answering the questions though, we feel that it is important to raise a point that appears to be absent from the dialog, namely the conveyance of false and misleading information and the urgent need to educate consumers about bioengineering.

There are too many entities that are constantly conveying messages that bioengineering is dangerous and they have vilified its use despite incontrovertible scientific evidence that shows it is safe and there is no material difference between a bioengineered food and its non-bioengineered counterpart. For example:

Jeffery Smith at the Institute for Responsible Technology¹ has made some very revealing statements which include:

1) "Labeling GMOs was never the end goal for us. It was a tactic. Labels make it easier for shoppers to make healthier non-GMO choices. When enough people avoid GMOs, food companies rush to eliminate them. Labeling can speed up that tipping point—but only if consumers are motivated to use labels to avoid GMOs."

2) "Our ultimate goal, to eliminate GMOs, is happening more and more with each non-GMO announcement."

¹ <http://responsibletechnology.org/even-though-obama-just-signed-the-dark-act/>

Agri-Mark, Inc.
Associated Milk Producers Inc.
Bongards' Creameries
Cooperative Milk Producers Association
Cortland Bulk Milk Producers Cooperative
Dairy Farmers of America, Inc.
Ellsworth Cooperative Creamery
FarmFirst Dairy Cooperative
First District Assoc.
Foremost Farms USA
Land O'Lakes, Inc.
Lone Star Milk Producers
Maryland & Virginia Milk Producers Cooperative Association
Michigan Milk Producers Association
Mid-West Dairyman's Company
Mount Joy Farmers Cooperative Association
Northwest Dairy Assoc.
Oneida-Madison Milk Producers Cooperative Association
Prairie Farms Dairy, Inc.
Premier Milk Inc.
Scioto County Cooperative Milk Producers' Association
Select Milk Producers, Inc.
Southeast Milk, Inc.
St. Albans Cooperative Creamery, Inc.
Swiss Valley Farms
Tillamook County Creamery Association
United Dairyman of Arizona
Upstate Niagara Cooperative, Inc.
Zia Milk Producers, Inc.

3) “This major shift in the marketplace has come about due to compelling, behavior-change messaging. And that’s IRT’s specialty. It involves: Accurately conveying the health dangers of GMOs in compelling ways.”

Also, the Non-GMO Project makes its share of provocative statements².

1) “One of the elements that sets the Non-GMO Project Standard apart from other non-GMO claims is the requirement to test high-risk ingredients for GMO contamination. An ingredient can be classified as high risk if it is derived from, contains derivatives of, or is produced through a process involving organisms that are known to be genetically modified and commercially produced.”

2) “Animal products such as milk, meat, eggs, and honey are considered high-risk inputs due the prevalence of GMOs in animal feed. As such, animal products are evaluated by looking at the feed and testing high-risk inputs in the feed.”

There are no health dangers associated with bioengineered foods and stigmatizing animal products from animals fed bioengineered feed is absurd and contrary to the language in the statute. These assertions are blatantly false and misleading. Unfortunately, the decade-plus negative characterization of the use of bioengineering has stigmatized products associated with it and consumers are being misled.

The Food and Drug Administration (FDA) in its guidance³ on labeling bioengineered foods states:

The FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any food that is misbranded. 21 U.S.C. § 331(a). Under section 403(a)(1) of the FD&C Act, a food is misbranded if its labeling is false or misleading in any particular. 21 U.S.C. § 343(a)(1). Section 201(n) of the FD&C Act (21 U.S.C. 321(n)) provides that labeling is misleading if, among other things, it fails to reveal facts that are material in light of representations made or suggested in the labeling, or material with respect to consequences that may result from the use of the food to which the labeling relates under the conditions of use prescribed in the labeling, or under such conditions of use as are customary or usual. 21 U.S.C. § 321(n). In a 1992 “Statement of Policy: Foods Derived from New Plant Varieties” (1992 Policy) (Ref. 5) FDA explained its interpretation of the FD&C Act with respect to foods derived from new plant varieties, including varieties developed using bioengineering. **In the 1992 Policy, FDA stated that it was not aware of any information showing that bioengineered foods differ from other foods in any meaningful or uniform way, or that, as a class, foods developed by the new techniques present any different or greater safety concern than foods developed by traditional plant breeding (Ref. 5) [emphasis added].** Further, FDA concluded that the

² <https://www.nongmoproject.org/gmo-facts/high-risk/>

³ Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants

method of development of a new plant variety (including the use of new techniques such as rDNA technology) is generally not material information within the meaning of section 201(n) of the FD&C Act, and would not usually be required to be disclosed in the labeling for the food. This determination was reviewed and upheld by the court in *Alliance for Bio-Integrity v. Shalala*, 116 F. Supp. 2d 166, 178–79 (D.D.C. 2000) (finding that FDA’s determination that genetic engineering, alone, is not a material fact that warrants food labeling was entitled to deference) (Ref. 10). Labeling provided by manufacturers on a wholly voluntary basis regarding whether a food was or was not bioengineered as described in this guidance is acceptable to FDA, provided that such labeling is truthful and not misleading. Some consumers are interested in the information provided in such labeling.

In that same guidance, FDA cautions the reader against making false and misleading statements with respect to bioengineering.

Further, **a statement may be false or misleading if, when considered in the context of the entire label or labeling it suggests or implies that a food product or ingredient is safer, more nutritious, or otherwise has different attributes than other comparable foods because the food was not genetically engineered [emphasis added]**. For example, the labeling of a bag of specific type of frozen vegetables that states that they were “not produced through modern biotechnology” could be misleading if, in addition to this statement, the labeling contains statements or vignettes that suggest or imply that, as a result of not being produced through modern biotechnology, such vegetables are safer, more nutritious, or have different attributes than other foods solely because the food was not produced using modern biotechnology.

NMPF opines that the pervasive anti-bioengineered rhetoric not only implies that bioengineered foods are not safe, it screams it. And, due to the constant rhetoric, any disclosure that a product is “not bioengineered” is an assertion that that product is safer. NMPF asks how can we overcome the fearmongering and educate consumers about the safety of bioengineered products and the benefits that they convey? Should we require a qualifying statement, like the one below, to be used whenever a disclosure is made regarding the presence or absence of a bioengineered ingredient?

“No material difference has been shown between ingredients created using bioengineering and ingredients created without bioengineering.”

We have a serious problem on our hands: consumers are constantly being misled and we must stand up for science, either with a qualifying statement, or by some other means. We absolutely cannot stand by and do nothing. Further, we believe that such a statement as above will go a long way in educating consumers and is consistent with the statute which requires that food disclosures shall not assert or imply that a bioengineered food is safer than, or not as safe as a non-bioengineered counterpart.

With that said, NMPF provides our responses to the questions raised by AMS.

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.

NMPF Response:

No terms other than “bioengineering” should be considered interchangeable with “bioengineering” for the purposes of section 291(1) of the National Bioengineered Food Disclosure Law (the “Law”). Use of a single term for purposes of the mandatory disclosure standard would be simplest for consumers.

Additional information: The bipartisan Senate Report⁴ on the Law 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 USDA-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 USDA-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.

USDA-AMS should recognize that language used to comply with the former Vermont labeling requirement is still being used by manufacturers today. Use of consistent mandatory disclosure language is beneficial for consumers and the industry. Therefore, USDA-AMS should establish a compliance date that provides sufficient time [NOTE: Conforms to response to Question 12] for those companies still using the required Vermont language to come into compliance with the national mandatory disclosure standard.

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.

NMPF Response: “Conventional breeding” should encompass breeding methods that use the organism’s gene pool and other methods that enable efficient movement of native genes from unadapted to elite organisms. As reflected in the bipartisan Senate Report on the Law, this approach is consistent with Congress’s direction that the USDA-AMS mandatory disclosure marketing program “be technology neutral and reflect technological changes over time.” The concept of “conventional breeding” does not apply to most microorganisms, but many other

⁴ S. Rep. No. 114-403 (2016)

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 program.

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

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

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.

NMPF Response: The relevant statutory text in the definition is “contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques and for which the modification could not otherwise ... be found in nature.” Recombinant DNA techniques can be used to create 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 a 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.

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.

NMPF Response: The statute is clear as to what is and what is not bioengineered. No disclosure within the USDA-AMS mandatory marketing program should be required if a food does not meet the applicable statutory definition set forth in Section 291. Further, per the bipartisan Senate Report, “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 rDNA techniques and this same modification could not be otherwise obtained through conventional plant breeding or found in nature. Subparagraph (A) limits application of the definition to a particular type of genetic material (a food containing genetic material modified through rDNA techniques).” If food does not, therefore, contain the type of genetically modified material just described, it would not qualify for mandatory disclosure under the USDA-AMS mandatory marketing program. The bipartisan Senate Report goes on to note that “the statutory definition of bioengineering is fully consistent with the approach adopted by most countries to date.”

Chymosin is another example of a refined ingredient. Chymosin is commonly derived from a genetically engineered bacterial culture. As the culture grows, chymosin is produced and is ultimately extracted resulting in a pure enzyme that is used in cheesemaking. The National Organic Program allows for the use of chymosin made in this manner in organic foods.

Specifically, the National Organic Program allows for the use of non-organic enzymes with the stipulation that they must be derived from edible nontoxic plants, nonpathogenic fungi or nonpathogenic bacteria. The bacteria used to make chymosin are non-pathogenic.

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

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

NMPF Response: When USDA promulgates this rule, USDA should clearly reference the definition of bioengineering and the qualifier that Congress provided in the National Bioengineered Food Disclosure Standard. While other federal agencies and may define bioengineering differently from that, USDA can make it clear as to what bioengineering means with respect to this regulation. Specifically, USDA should state in the rule:

Bioengineering has the meaning given it in section 291 of the National Bioengineered Food Disclosure Standard. The definition of the term bioengineering under section 291 shall not affect any other definition, program, rule or regulation of the Federal Government.

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, food 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. NMPF 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.
- NMPF 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.

USDA’s Organic regulations have their own definition of recombinant DNA techniques. NMPF interprets the parts of the current definition for the Organic standard’s excluded methods of genetically modified organisms that refer to “recombinant DNA technology” that result in products “that are not possible under natural conditions” and which “do not include the use of traditional breeding” to already be similar to the definition of “bioengineering” in the Law.

NMPF supports consistency between the two standards, where appropriate. However, any proposals affecting the definition of bioengineering for disclosure should go through the rulemaking process and request public comments.

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.

NMPF Response: NMPF urges USDA-AMS to use the ingredient declaration on the product label to evaluate predominance of ingredients to determine how the Law will apply to multi-ingredient food products. As described in 21 C.F.R. § 101.4(a), 9 C.F.R. § 317.2(f)(1), 9 C.F.R. § 381.118(a) and A Guide to Federal Food Labeling Requirements for Meat, Poultry and Egg Products, 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.

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.

NMPF Response: Congress made it very clear “A regulation promulgated by the Secretary in carrying out this subtitle shall— ‘(A) prohibit a food derived from an animal to be considered a bioengineered food solely because the animal consumed feed produced from, containing, or consisting of a bioengineered substance.’” The Just Label It! Organization, in its comments stated that “Based on EWG’s assessment of 64 countries that currently require disclosure of GMO foods, no country requires disclosure for such food products solely because the products were derived from animals which were fed GE grain.” USDA should make it clear that there is a global consensus that feeding bioengineered grain to an animal has no effect whatsoever on meat and milk products derived from that animal and that those products cannot be considered bioengineered.

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).

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, “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.” NMPF supports the Congress’ conclusion.

With respect to bees and crickets, they are in the *Phylum Arthropoda* - the largest phylum which consists of insects. There are over 1 million species of insects existing today. The *Phylum Arthropoda* is in the *Kingdom Animalia*. So, bees and crickets are animals and we do not see anything in the Act to suggest that Congress intended to limit the application of this provision to only certain segments of the *Kingdom Animalia*. What a bee or a cricket consumed is irrelevant for the purposes of disclosure.

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

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

NMPF Response: When determining any threshold or amount of a bioengineered substance present in food that triggers mandatory disclosure, USDA-AMS should reinforce that the bioengineered food disclosure standard is a marketing standard, and not a health, food safety or nutrition standard. As such, USDA-AMS should consider exploring a 5% threshold level, which is consistent with low level presence standards in the National Organic Program, which is another food marketing program administered by USDA-AMS. In addition, the regulations should make clear that, whatever threshold or amount of a bioengineered substance triggers mandatory disclosure, voluntary disclosure below that level is permissible provided that the disclosure is truthful and not misleading.

Additional information: When determining the amounts of a bioengineered substance that may be present in food, or the threshold requirement, USDA-AMS should adhere to the Congress’ instruction in the bipartisan Senate Report to “minimize the impacts on all aspects of the domestic and international value chain.” USDA-AMS should also consider that while there are

multiple international thresholds pertaining to the presence of a bioengineered substance, no single international standard or consensus exists.

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

The science is clear, the presence of bioengineered material in a food is not a food safety issue, it is a marketing issue. Establishing a low threshold such as 0.9% is indicative of a level that a regulatory authority might set to deal with a deleterious substance or contaminant. We note that the National Organic Program allows for up to 5 % non-organic content in organic products. That is also a situation where the limitation is being imposed for non-food safety purposes (e.g. marketing purposes). We further note that the US would not be alone in establishing a five % threshold as several other countries has established that precise limitation. NMPF believes that because this is a marketing standard, not a food safety standard the appropriate de minimis level should be 5 %, below which mandatory labeling would not be required.

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

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

NMPF Response: The Law creates two categories of mandatory disclosure within the USDA-AMS marketing program: one for food that is “bioengineered” and one for 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 help 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.

Further the National Bioengineered Disclosure Standard is a standard whose basis is whether or not a food *contains* “genetic material that has been modified through in vivo recombinant deoxyribonucleic acid (DNA) techniques” not whether or not it was derived from bioengineered crops or animals. NMPF believes for simplicity and to avoid consumer confusion there should be only a category where a product *contains* and a category where a product *may contain*. NMPF further takes issue with what constitutes “derived from” or as some laws call for “produced with”. Depending on how those very ambiguous phrases are defined, a new category based upon such determination could be absurdly over-inclusive. Congress passed, and the President signed, a mandatory disclosure law based on whether a product *contains* a defined substance, USDA should issue its regulation in conformity with the Congressional direction it was given.

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.

NMPF Response: Any determinations made under Section 293(b)(2)(C) must take into account the statutory definition in Section 291. See Question 11 for more information related to Section 293(b)(2)(C). As discussed above, the National Organic Program allows for the use of certain non-organic substances in organic foods and organic foods are automatically permitted by statute to make an absence claim with respect to bioengineering. Anything that can be used in an organic food and still allow that food to be considered organic and able to make an absence claim should not face a different outcome under the mandatory disclosure standard.

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.

NMPF Response: Yes, but 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 or the exemption of certain classes of food or ingredients from mandatory disclosure. USDA-AMS should be transparent in this process and consider providing information on its website to help the public and developers of bioengineered food or ingredients understand if their products are bioengineered and thereby subject to mandatory disclosure. Any exemption from the mandatory program should be based on criteria that are clear and scientifically and legally justified.

Additional information: According to the bipartisan Senate Report, “Congress intends the Secretary to provide exemptions and other determinations under which a food is not considered bioengineered.” The Report noted examples of exemptions provided by various states to their labeling mandates, including for food products that (i) made using enzymes, additives, or processing aids; or (ii) that have medicinal and supplementary applications. NMPF agrees with the Congressional interpretation and urges USDA-AMS to provide exemptions for products that (i) may include enzymes, additives, and processing aids and (ii) have medicinal and supplementary applications, to the extent those products would otherwise be subject to mandatory disclosure. NMPF 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.
- A processing aid, incidental additive, or secondary direct 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 products. By their very definition, processing aids are present at insignificant levels in the finished food and have no technical or functional effect in that food. For that reason, FDA regulations do not require the declaration of processing aids or incidental additives in the ingredient statement on food labels. Therefore, their use in processing is not material to whether the finished food is bioengineered. Indeed, the European Union recognizes that processing aids are outside the scope of its GMO disclosure regulation⁵. 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.

⁵ Regulation (EC) No. 1829/2003 (clause 16)

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

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

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

NMPF Response:

Where a manufacturer chooses to use the on-package text to disclose a bioengineered food, AMS should require one of the following two options to be used:

1. “Contains Bioengineered Ingredient(s)”;
2. “May Contain Bioengineered Ingredient(s)”;

where the name of the specific ingredient may be substituted for the term “ingredient” (e.g., corn, soy, etc.)

The term “may” should be permitted to reflect instances where companies use both bioengineered and non-bioengineered ingredients in the same product throughout the year at varying times.

AMS should also consider harmonizing the compliance date with other relevant labeling changes (e.g. nutrition facts panel) required by new regulations.

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.

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

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.](#)

NMPF Response: 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.

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.

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

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

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

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

- A compliant carrier:
- Must be able to contain a URL.
- The carrier must be open-sourced technology. The USDA must ensure rules do not confine companies to single-point (for profit) providers or create intellectual property issues. As mentioned in response to Q-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 Q-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.

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.

NMPF Response: Disclosure information required under this Act should be sufficient disclosure for items sold through vending. USDA-AMS recognizes that certain foods should be treated differently, and that USDA and other agencies consistently provide modified requirements for these foods. In particular, FDA has recognized that labeling certain foods is impractical and, as such, provided for a number of exemptions for traditional nutrition facts panel (NFP) labeling under 21 C.F.R. § 101.9 (“Nutrition labeling of food”). Although the mandatory disclosure standard is directed to marketing and not safety, health or nutrition, it is our position that USDA-AMS should 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”

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.

- In 21 CFR 101.9(j)(13)(i)(B), FDA defines small packages as those with less than 12 square inches in total surface area available to bear labeling.

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

NMPF Response: Although the mandatory disclosure standard is directed to marketing and not safety, health or nutrition, USDA should for consistency, define small and very small food packages using some of the principles that FDA applies when determining the appropriate format for nutrition labeling information or to determine that available labeling space is too small to accommodate nutrition facts information. Although FDA does not have a definition for very small package, small packages are defined as “having a total surface area available to bear labeling of less than 12 square inches. . . .” 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 or definition proposed above, the following accommodations should be made. USDA should provide flexibility about the form of disclosure for small packages. Small packages should have options on the size of the disclosure, as the space available will determine the size of the text or symbol that can be placed on the label. Additionally, manufacturers of food in small packages should be allowed to list a phone number with language such as “For nutrition information or other food facts, call 1-800-XXX-XXXX” or “For nutrition information or bioengineered food facts, call 1-800-XXX-XXXX” so that consumers have access to the disclosure information. Alternatively, small packages should be provided additional flexibility and be allowed to only provide a web address maintained by the manufacturer that provides information consistent with the electronic disclosure requirement about the bioengineered content of the food. Although we have not provided a recommendation for the definition of “very small packages” we would assume this size of package would have proportionally less available labeling space than the proposed 12 square inches or less for a “small package.” Therefore, due to the extremely limited labeling space on very small packages, USDA should not require disclosure in any form on very small packages.

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?

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

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

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").

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.

NMPF Response: Although the mandatory disclosure standard is directed to marketing and not safety, health or nutrition, for consistency's sake the term "small food manufacturer" should be defined in the same way it is defined under the FDA's Food Safety Modernization Act (FSMA) final rules 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.

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.

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

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

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

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

Context: AMS is considering how to treat establishments that sell food ready for human consumption, such as institutional food service, delicatessens, or catering businesses. In its regulations for Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments (21 CFR 101.11), FDA defines restaurant or similar retail food establishment and restaurant-type food. For FSIS, the FMIA provides for the mandatory inspection of commercial meat and meat products. The FMIA and implementing regulations do, however, provide exemptions from the continuous inspection provisions for retail operations and restaurants (9 CFR 303.1(d)(2)). NOP also defines retail food establishment in its regulations (7 CFR 205.2). AMS is using this information as it considers definitions for restaurants and similar retail establishments, with the understanding that these definitions will be used to determine what types of retail establishments are excluded from the requirements of the Law.

NMPF Response: Grocery stores offer a large variety of products, from large national brands of manufactured foods to unique local and seasonal offerings. While many of these products are traditional grocery items, others are offered for sale in diverse ways and in varying packaging formats. These might include made-to-order sandwiches packed by a store clerk in food-grade paper, a salad assembled by the customer and eaten on site in a reusable bowl, pasta salad sold by weight and packed into a plastic container, unpackaged bulk apples sourced from a farm down the road, and many more. We appreciate Congress’ recognition that unpackaged foods and items prepared in the grocery stores are exempt from the mandatory disclosure requirement and further appreciate the opportunity to comment on how USDA-AMS should define various terms in order to properly preserve this exemption.

As noted above, the Law excludes foods served in restaurants and similar retail food establishments from the mandatory disclosure requirement. USDA-AMS notes that food

retailers and restaurants are treated differently from traditional human food manufacturing facilities under USDA, FDA and the National Organic Program (NOP). For example, restaurants and retail food establishments are not required to register with the Food and Drug Administration under the Bioterrorism Act because they are selling foods directly to consumers. Addressing the food itself, the Senate Report specifically states that “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 NFP rule. Therefore, the NMPF 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, for consistency, we support, 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.

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 principal 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, we want 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, 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.

(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.

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.

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

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.

NMPF Response: “Scan” will likely be a ubiquitous call-to-action for a long time so we believe that verb is acceptable. If another technology presents itself that meets the principles set forth in answers to questions 14 and 15, and it is readily apparent that the term “scan” is no longer an appropriate verb to describe how a consumer may know to access information from that technology, then USDA-AMS should have flexibility to provide companies with the option to use different terminology. However, given the ubiquitous nature of “scan here for more information” and consumer awareness of that phrase 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 and 14 and 15 coupled with a compelling case that “scan here for more information” is no longer the best method to inform the consumer how to access information.

The on-package call-to-action should read “Scan here for more food information.” In addition, USDA-AMS should also permit “Scan here for more information.” Eliminating the word

“food” opens up digital disclosure capability far beyond this specific Law. Digital disclosure goes far beyond “food” and can provide information on ingredients, allergens, product source, social compliance, sustainability and more. There is also a likelihood that digital disclosure will be a compliant disclosure tool for State nonfood regulations (e.g. personal care, cosmetics, cleaning product ingredient and safety information). Using “scan here for more information” helps make consumer education easier.

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

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.

NMPF Response: NMPF defers to the Coalition for Safe Affordable Food on this issue.

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.

NMPF Response: NMPF defers to the Coalition for Safe Affordable Food on this issue.

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.

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

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

Second, the Law states that those subject to the mandatory disclosure requirement must maintain records that the Secretary of Agriculture “determines to be customary or reasonable in the food industry,” to demonstrate compliance. Keeping in mind that every single regulatory requirement adds time and cost for producers, the supply chain, food manufacturers, retailers and ultimately consumers, NMPF believes 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. NMPF further recommends that the rule expressly authorize recordkeepers to maintain their 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, NMPF 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, food 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 (NASEM) engaged in a comprehensive analysis of two decades of data on biotechnology and found that GE crops are safe to eat and have the same nutrition and composition as non-GE crops.

Still, we understand that the agency will be under enormous pressure to craft a rule that seeks to cast away science in order to create doubt over the health and safety of this technology. One way to avoid this outcome is to craft recordkeeping requirements that do not equate marketing claims (AMS’ mission) with health, food safety 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 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.

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.

NMPF Response: Again, USDA-AMS should adopt a premise that, for recordkeeping and enforcement purposes, food products or ingredients should be considered bioengineered unless documentation demonstrates otherwise. Correspondingly, if no bioengineered source for a particular ingredient is commercially available, USDA should recognize that the ingredient would not require mandatory disclosure or records to verify that the food is not bioengineered. There should not be any new burdens placed on those who must comply with this mandatory requirement and the recordkeeping provisions should not be as stringent as those dealing with food safety, health or nutrition.

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

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

If based upon its review of the disclosure, USDA-AMS reasonably believes a company is not in compliance with the disclosure standard, the agency can request to review a company's records

kept to establish compliance. If USDA-AMS determines a company is not in compliance with the disclosure standard, it should issue a written notification of noncompliance to the food manufacturer.

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

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.

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.

NMPF Response: To reiterate, believes it would be reasonable and realistic for USDA-AMS to operate on the premise that, for recordkeeping and enforcement purposes, food products or ingredients are to be considered bioengineered unless documentation supports that they are non-bioengineered. Correspondingly, if no bioengineered source for a particular ingredient is commercially available, USDA should recognize that the ingredient would not require disclosure or records to verify that the food is not bioengineered. 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 and nutrition claims or imposing new burdens or additional work on those impacted by the rule.

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

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

We offer the following recommendation 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.

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.

NMPF Response: USDA-AMS should maintain appropriate internal records of each examination, audit, or similar activity conducted by the agency, as well as the total number of audits performed and the details of the audits performed. If an entity is found to be out of compliance following exhaustion of the administrative process discussed in response to Question 28, it should be afforded the opportunity and time to work with USDA-AMS to address the issue to achieve compliance. If an entity is still found to be out of compliance after a reasonable amount of time to address the issue, USDA-AMS should use its web site to make public a simple declaration of an entity being out of compliance for a period of six months, or until such time as the reason for the finding of noncompliance is corrected.

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

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

We thank you for this opportunity to provide our views.

Sincerely,



Clay Detlefsen

Senior Vice President, Environmental and Regulatory Affairs & Staff Counsel