



August 25, 2017

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

Submitted via [GMOLabeling@ams.usda.gov](mailto:GMOLabeling@ams.usda.gov)

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

Dear Mr. Summers:

The National Grain and Feed Association (NGFA) respectfully submits the following statement in response to questions posed by the U.S. Department of Agriculture's Agricultural Marketing Service (AMS) to inform your work on a proposed rule implementing the National Bioengineered Food Disclosure Standard.

Established in 1896, the NGFA is a U.S.-based nonprofit trade association that consists of approximately 1,050 grain, feed, grain processing, export and other grain-related firms that operate more than 7,000 facilities and handle more than 70 percent of the U.S. grain and oilseed crop. Also affiliated with NGFA are 26 state and regional grain, feed and agribusiness associations. Given the diversity of NGFA's membership, which includes biotechnology owners and providers, the views expressed in this statement may not necessarily reflect the views of every NGFA associate or affiliate member.

As a member of the Coalition for Safe and Affordable Food's (CFSAF) Steering Committee, the NGFA helped develop the Coalition's responses, and supports the Coalition's statement in its entirety. The NGFA, through its Biotechnology Committee, is taking this opportunity to provide several additional responses and insights important to grain, feed and processing industry stakeholders that expand upon those submitted by the Coalition.

This important law (P.L. 114-216) mandates the establishment of a uniform national disclosure standard for bioengineered food and prevents the state-by-state or other governmental subdivision patchwork of food labeling requirements that would have driven up food costs for consumers. As a Coalition member, the NGFA was involved extensively in the process that led to enactment of the law. As AMS develops the proposed rule for the bioengineered food disclosure standard, agricultural value chain stakeholders, including NGFA and its members, believe it is crucial for the agency to follow congressional intent, as provided in the Senate

Report. Finally, it is of paramount importance to reinforce that this is a marketing standard, and not a safety, health or nutrition standard, and should be crafted as such.

We stand ready to act as a resource as AMS continues the rulemaking process.

Sincerely,

A handwritten signature in black ink, appearing to read "Randall C. Gordon". The signature is written in a cursive style with a large initial 'R'.

Randall C. Gordon  
President

## 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 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 Report<sup>1</sup> 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 labeling 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” as statutorily defined 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.*

## 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.

*The NGFA concurs with the Coalition for Safe and Affordable Food’s response to this 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 NGFA concurs with the Coalition for Safe and Affordable Food’s response to this question.*

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<sup>1</sup> S. Rep. No. 114-403 (2016).

**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.

*The NGFA concurs with the Coalition for Safe and Affordable Food's response to this question, particularly as it pertains to the correction to use the term "refined ingredients" as opposed to "highly refined products."*

**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.

*The NGFA concurs with the Coalition for Safe and Affordable Food's response to this 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.

*The NGFA concurs with the Coalition for Safe and Affordable Food's response to this 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.

*The NGFA concurs with the Coalition for Safe and Affordable Food's response to this question, but takes this opportunity to firmly underscore that per the statutory provision in Section 293(b)(2)(A), a food derived from an animal (such as meat, milk and eggs) is not considered bioengineered solely because the animal consumed feed produced from, containing, or consisting of a bioengineered substance.*

*In addition, the bipartisan Senate Report provides clear direction to the agency, stating "it is the intent of Congress that the mandatory disclosure provisions **not apply** [emphasis added] to animal feed, pet food, or ingredients used in animal feed or pet food. Furthermore, 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."*

*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. Both the statute and Congress' stated intent are unequivocal, and remove any doubt as to how this questions is to be addressed. The NGFA believes 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.*

## **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.

*The NGFA believes USDA should adopt a 5 percent cumulative threshold level for raw agricultural commodities intended for further processing. This is consistent with the low-level presence standard in the National Organic Program, which is another food marketing program administered by USDA-AMS.*

*There is no international standard for bioengineered thresholds, nor is there any scientific basis for the threshold percentages because biotechnology does not raise safety, health or nutrition concerns.*

*Grain, feed and processing industry stakeholders have coalesced around a 5 percent low-level presence threshold. Of the thresholds that have been established world-wide, a 5 percent threshold is the most supportive of bioengineering, recognizes what is achievable using best practices given living plant organisms in nature, and recognizes that the Act establishes a marketing standard, not a food safety standard.*

**Additional information:** *When determining the amounts of a bioengineered substance that may be present in food when setting 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 also should 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 also must 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 under what is a marketing standard. Further, USDA-AMS should consider a threshold that supports continued use of bioengineered ingredients or substances, recognizing their contribution to a safe, abundant, affordable, and sustainable food supply. USDA-AMS also should consider consumers' interest in information about their food and the impact of mandatory bioengineered food disclosure on costs to the consumer, food processor and food manufacturer when determining what, if any, threshold or amount of bioengineered substances in a food triggers disclosure.*

## **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.

*The NGFA concurs with the Coalition for Safe and Affordable Food's response to this 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.

*The NGFA concurs with the Coalition for Safe and Affordable Food's response to this 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.

*The NGFA concurs with the Coalition for Safe and Affordable Food's response to this question.*

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

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

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

*The NGFA concurs with the Coalition for Safe and Affordable Food's response to this 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 NGFA concurs with the Coalition for Safe and Affordable Food's response to this 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 NGFA concurs with the Coalition for Safe and Affordable Food's response to this 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 NGFA concurs with the Coalition for Safe and Affordable Food's response to this 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.

*The NGFA concurs with the Coalition for Safe and Affordable Food's response to this 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 CFR 101.9(j)(13)(i)(B), FDA defines small packages as those with less than 12 square inches in total surface area available to bear labeling.
- b. FDA also has allowances for packages that have less than 40 square inches of total surface area available to bear labeling.

*The NGFA concurs with the Coalition for Safe and Affordable Food's response to this 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?

*The NGFA concurs with the Coalition for Safe and Affordable Food's response to this 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.

*The NGFA concurs with the Coalition for Safe and Affordable Food's response to this 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 NGFA concurs with the Coalition for Safe and Affordable Food's response to this 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 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.

*The NGFA concurs with the Coalition for Safe and Affordable Food's response to this 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.

*The NGFA concurs with the Coalition for Safe and Affordable Food's response to this 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.

*The NGFA concurs with the Coalition for Safe and Affordable Food's response to this 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.

*The NGFA concurs with the Coalition for Safe and Affordable Food's response to this 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 NGFA concurs with the Coalition for Safe and Affordable Food's response to this 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.

*The NGFA concurs with the Coalition for Safe and Affordable Food's response to this 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.

*The NGFA concurs with the Coalition for Safe and Affordable Food's response to this 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.

*The NGFA concurs with the Coalition for Safe and Affordable Food's response to this 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.

*The NGFA concurs with the Coalition for Safe and Affordable Food's response to this 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.

*The NGFA concurs with the Coalition for Safe and Affordable Food's response to this question.*