



Responses of the American Beverage Association

To

Proposed Rule Questions Under Consideration by the Agricultural Marketing Service of
the United States Department of Agriculture

To Implement the National Bioengineered Food Disclosure Standard

Submitted to GMOLabeling@ams.usda.gov

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The American Beverage Association (“ABA” or “the Beverage Association”) is pleased to provide its responses to the Agricultural Marketing Service’s (“AMS”) “Proposed Rule Questions Under Consideration” as AMS considers drafting a proposed rule to implement the National Bioengineered Food Disclosure Standard.

The ABA is the national trade organization representing the broad spectrum of companies that manufacture and distribute non-alcoholic beverages in the United States. Our members are producers, marketers, and distributors of virtually every no-, low-, mid-, and full-calorie non-alcoholic refreshment beverage, including bottled waters, ready-to-drink coffees and teas, sports drinks, energy drinks, water beverages, 100 percent juices, fruit drinks, and soft drinks.

Relevant AMS Scoping Questions

1. What terms should AMS consider interchangeable with ‘bioengineering’? (Sec. 291(1))

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

ABA Position: The definition of “bioengineered food” should stand on its own rather than attempt to also define a technology or process and should not serve to limit or extend other aspects of the National Bioengineered Food Disclosure

Standard law or other Federal laws or regulations relating to bioengineered food. “Bioengineering” as defined under Section 291(1) should be a term all to its own and its definition is separate from possible text disclosure language under Section 293 such as “bioengineered,” “genetically engineered,” “GMO,” among others - terms that are not necessarily interchangeable with “bioengineering” as defined under section 291(1). Specifically, to the extent AMS permits the term “genetically engineered” or “genetic engineering” to be used in disclosure text, we ask that the Agency clarify that these terms are not interchangeable with “bioengineering” as defined under section 291. The ability to use these terms in disclosure text should have no impact on the meaning of “genetic engineering” as that term is used in section 295(b) of the law. Section 295 establishes broad federal preemption related to any requirement relating to the labeling of whether a food or seed is genetically engineered or was developed or produced using genetic engineering. Additionally, AMS should clarify that the term “genetically engineering” as used in section 295(b) is broader than the term “bioengineering” in section 291(1). This request is consistent with congressional intent and would help to clarify the broad scope of the preemption provision in 295.

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.

ABA Position: AMS should require disclosure of bioengineered ingredients in food when disclosure is consistent with the disclosure law. It is clear from the legislative history of the law that Congress intended for ingredients from bioengineered crops and genetically engineered animals to be disclosed. Accordingly, ABA believes the following disclosure principles are consistent with the law:

- The scope of ingredients that are to be considered for disclosure must align with Sec. 292 (c) (1). “This subtitle shall apply only to a food subject to the labeling requirements under the Federal Food, Drug, and Cosmetic Act (21

U.S.C. 301 et seq.)...” and be limited to those that would be found on the ingredient statement on the packaged food or beverage;

- Refined ingredients derived either from bioengineered crops or genetically engineered animals should be disclosed only when the *de minimis* threshold for disclosure on a ready-to-drink finished beverage basis is met. If the percent of cumulative ingredients derived from GM-crops does not exceed the threshold, no disclosure should be required. For calculation purposes, water and/or salt weight contributions to the finished beverage formulations (as ready-to-drink) should be included as part of the finished beverage.

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.

ABA Position: 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 disclosure requirements 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). Likewise, GE-derived substrates that become feed stock for plants or microbes should be treated similarly to those fed to animals wherein the resulting product would no longer qualify as ‘bioengineered’.

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.

ABA Position: Disclosure should be triggered only when the *de minimis* threshold for disclosure (on a ready-to-drink finished beverage basis) is met. The *de minimis* threshold for disclosure should apply to the finished ready-to-eat food or ready-to-drink beverage. If the percent of cumulative ingredients derived from GM-crops (or GE-animals) does not exceed the threshold, no disclosure should be required. For calculation purposes, water and salt contributions to the finished beverage formulation should be included as part of the finished beverage. Relative to the appropriate *de minimis* threshold for disclosure, insights and perspectives can be drawn from international GMO disclosure standards.

Essentially, a product should not be disclosed as bioengineered if ingredients contained therein can be traced to a non-bioengineered crop or animal(s) or if the sum of those ingredients derived from a GM-crop (or GE-animal) fall below the *de minimis* threshold. What constitutes a non-bioengineered crop or animal should be determined by existing national and/or international agricultural standards.

A food or beverage **must be** disclosed as bioengineered if the sum of ingredients contained therein - that are derived from GM-crops (and/or GE-animals) and that can be traced to a bioengineered crop or animal as the source material - exceed the *de minimis* threshold for disclosure on a ready-to-eat or ready-to-drink finished product basis.

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.

ABA Position: In general, there should only be a few disclosure categories (to avoid confusion). It is important to permit a disclosure that accommodates foods

that may not consistently contain ingredients strictly from bioengineered crops for example due to production, seasonal variations among others. In other words, AMS should provide an option for ‘may contain’ product disclosures when the origin of the disclosed ingredient(s) can periodically switch from a bioengineered crop and a non-bioengineered crop due to significant production and/or seasonal variations – e.g., beverages that contain sugar, which can be derived from cane (non-bioengineered) or beet (largely bioengineered). “May contain” is not perfect, but might be the most appropriate language available.

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.

ABA Position: Relative to ingredients derived from GM-microbes, an established precedence exists within the EU. Importantly, the EU Reg 1829/2003 (recital16) distinguishes between products produced “from GMO” and “with GMO”, the former subject to labeling and the latter not, provided the GMO is no longer present in the final product. Further clarification is provided by the Standing Committee: “Food and feed (including food and feed ingredients such as additives, flavourings and vitamins) produced by fermentation using a genetically modified micro-organism (GMM) which is kept under contained conditions and is not present in the final product are not included in the scope of Regulation (EC) No 1829/2003” and therefore not subject to the stated labelling requirements. (Standing Committee on the food chain and animal health, section on genetically modified food and feed and environment risk of 24 September 2004. p.2, para. 4) Moreover, the 2006 European Commission report on the ‘implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council on

genetically modified food and feed’ confirms that “when a GM micro-organism is used as a processing aid, the food and the feed resulting from such production process are not to be considered as falling under the scope of the Regulation”. (para. 10.2 in ‘Clarification of the status of food or feed produced by fermentation using genetically modified micro-organisms not present in the final product’)

Relevant AMS Organic Consistency Question

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

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.

ABA Position: It may be useful to address the application of future technologies at this time. AMS should make clear that the definition of bioengineered food for purposes of the disclosure law has no relevance to the term or similar terms used elsewhere in Federal law or regulation.

Relevant AMS Disclosure Questions

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.

ABA Position: AMS should permit both symbols and straightforward text that is accurate and not misleading. Because text statements can themselves drive unnecessary concerns about the presence of GMO ingredients, and the disclosure of such is a consumer preference and not a safety concern, AMS should permit symbols or text indicating products that would meet the applicable disclosure requirements and directing the consumer to more information.

Text examples include: “contains ingredients from a bioengineered crop,” “may contain ingredients from a bioengineered crop,” “produced with genetic engineering.” In addition, companies whose labels bear language pursuant to the Vermont law should be permitted to use that language (and be deemed to be in compliance with the Federal law) until they are otherwise required to make substantial label changes (revising a label to comply with the new nutrition facts regulation, for example). AMS should limit the variation of permitted texts (perhaps, one for foods that contain a bioengineered ingredient and another for those that ‘may contain’). Greater variability will invite confusion and may engender challenges to the disclosure made by individual companies.

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.

ABA Position: AMS should adopt a symbol akin to the USDA organic symbol that is non-disparaging to bioengineered food. AMS should provide for text to be part of the symbol to add in consumer understanding. AMS should provide general guidance for the placement of the symbol, but not be overly prescriptive as to location or prominence. Placement of the symbol does not have to be on front-of-pack but could be placed on back-of-pack as well. Flexibility in placement is imperative to accommodate the various package sizes across foods and beverages.

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.

ABA Position: Packaged foods are subject to a single set of label requirements, regardless of the channel through which the foods are sold. AMS should not impose requirements for foods sold in vending machines or online beyond whatever disclosure the package itself is required to bear.

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.

ABA Position: Section 293(d)(1)(A) clearly contemplates the possibility that “scan” may become an obsolete verb to describe what one would do with a smartphone to access information embedded in a barcode on the package. It is not clear that “scan’s” days are numbered, as the barcode technology is progressing with ever more information being accessible via a scan. It certainly makes sense to support the issuance of guidance to identify “equivalent language

as technology changes.” It might, therefore, be useful to recommend that AMS permit the use of any verb (“scan ” “tap,” “hold phone and press”, “see” or “go to” for example) that accurately conveys the action the consumer needs to take to get to the information. Since GMO information is not safety related, but the desire for such information is driven by personal consumer interests, we do not believe all such information needs to be directly on the label. Reasonably common steps or actions (visiting a website or calling a 800 number) to obtain such information should be allowed. Such avenues already exist on many packaged foods, and are also used for certain state-required bottled water quality report labeling (for a bottled water quality report, call or visit www...)

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.

ABA Position: AMS need not specify the text size for the food information that is accessed electronically/digitally. [AMS could consider a standardized format or report that could be made available online.]

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.

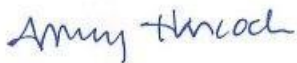
ABA Position: Relative to verification of non-GMO products, AMS should be flexible and seek not to serve as a repository of information or develop unnecessary record/registration systems that would be better managed by industry due to inherent intricacies within the supply chain.

Additionally:

- AMS should omit the requirement for recordkeeping where there is a 'bioengineering' disclosure, (e.g., beet sugar, corn, etc.)
- Allow for a centralized recordkeeping within each company as opposed to within each plant/manufacturing site in view of the infrastructure complexity overall. Centralized records similar to those maintained under the Food Safety Modernization Act ("FSMA") should be acceptable.
- Permit documentation from vendors (i.e., certificates or similar) as long as the supply chain remains consistent. Records would be required for up to two years beyond a product's removal from commerce.

We thank you for your consideration.

Respectfully submitted,

A handwritten signature in blue ink that reads "Amy Hancock".

Amy E. Hancock
Senior Vice President and General Counsel
American Beverage Association