The AACCI Molecular Biomarkers for Grain Technical Committee submits the following comments to the Questions posed by USDA AMS at https://www.ams.usda.gov/rules-regulations/gmo-questions for input in drafting a proposed rule.

AACCI COMMENTS TO USDA-AMS

AACCI members are active participants in most if not all food supply chain systems. It is critically important to our members that food at all levels in a supply chain is safe, available and sustainable. To guarantee these requirements all food regulations must be transparent, science-based and consider the product not the process used to create it. In addition Bioengineered Food Disclosure Standards must be operable without causing significant disruption of the food chain, or increase in cost to the consumer.

AACCI has published a guideline "AACCI Guideline for Disclosure of Bioengineered Products (AACCI Method 11-50.01)". An explanatory article is available at http://aaccipublications.aaccnet.org/doi/pdf/10.1094/CFW-62-3-0115 and a summary document at: http://methods.aaccnet.org/summaries/11-50-01.aspx The guideline itself is available as an open source document at http://methods.aaccnet.org/open/11-50.01.pdf.

The following responses are primarily drawn from these documents.

With regard to the questions specifically.

Specific Question and Context	
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.	Genetic knockouts and other results of genome editing that produce small changes are analogous to products created using conventional mutagenesis and thus these modifications would be exempt from 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	The comments under question 2 address the position on modifications induced by mutagenesis. Mutagenesis and genome re-

otherwise be found in nature because these modifications would be exempt from mandatory disclosure.	arrangements occur in nature (citation transposons etc.). Thus mutations and re-arrangements that mimic modifications that could otherwise be found in nature are common and would be exempt from mandatory disclosure.
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 drive to test to zero is becoming a major issue in supply chains. Thresholds for identity preservation, which are not necessarily based on safety and risk, vary depending on the property being defined. While certain interests have been promoting low thresholds for identity preservation, especially for GE derived products, these thresholds provide no useful dietary or safety information for the consumer. Their labels are based on testing, whereas those in industry prefer standards to be based on verified processes and use testing to verify processes, rather than using testing as the primary tool. The need to label depends on whether the trace ingredient is present in a significant amount and has a function in the finished food. If a substance is an incidental additive and has no function or technical effect in the finished product, then it need not be declared on the label and disclosure should not be required. If it is not possible to enforce or test whether the GE ingredient is present (e.g., fats, waxes, oils, sugars, and vitamins that do not contain DNA or protein), then we believe that such products should not be subject to labeling. AACCI has published AACC International Method 11-50.01 AACCI Guideline for Disclosure

	of Bioengineered Products in February 2017. AACCI considers that this should be the guideline as far as thresholds and other practices. In particular, labeling products "Non-GE" when there is no commercial GE equivalent might be considered misbranding and misleading to the consumer. For example, Canada requires a disclaimer when such labeling is employed in order to "ensure labelling is understandable, truthful and not misleading". This is particularly applicable to single ingredient products such as salt and water or to foods for which no GE versions have been offered for sale. Labeling such products as non-GE (or whatever term is decided upon) should be considered misleading and misbranding.
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	Labeling products "Non-GE" when there is no commercial GE equivalent might be considered misbranding and misleading to the consumer. For example, Canada requires a disclaimer when such labeling is employed in order to "ensure labelling is understandable, truthful and not misleading". This is particularly applicable to single ingredient products such as salt and water

bioengineering does not affect any other definition, program, rule, or regulation.	or to foods for which no GE versions have been offered for sale. Labeling such products as non-GE (or whatever term is decided upon) should be considered misleading and misbranding.
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.	AACCI has published AACC International Method 11-50.01 AACCI Guideline for Disclosure of Bioengineered Products in February 2017. AACCI considers that this should be the guideline as far as thresholds and other practices. See additional comments under Question 5.
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	AACCI has published AACC International Method 11-50.01 AACCI Guideline for Disclosure of Bioengineered Products in February 2017. AACCI considers that this should be the guideline as far as thresholds and other practices.

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.	
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 publically 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	AACCI has published AACC International Method 11-50.01 AACCI Guideline for Disclosure of Bioengineered Products in February 2017. AACCI considers that this should be the guideline as far as thresholds and other practices.

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.	
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.	The term to be used is difficult to define, as all crop plants are genetically enhanced or improved or bioengineered via breeding.

Guideline for Disclosure of Bioengineered Products[1]

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Producers wishing to use this standard must make reasonable efforts to prevent the commingling of genetically engineered (GE) with non-GE materials. The term "GE" is used for convenience; other terms such as "bioengineered" and "genetically modified" may be applicable. "Genetically modified organism" and "genetically engineered organism" are not used because they imply that a living organism is present, which is not the case in most foods, as emphasized in the Canadian regulations (1).

Labeling products "Non-GE" when there is no commercial GE equivalent might be considered misbranding and misleading to the consumer (2). Canada requires a disclaimer when such labeling is employed in order to "ensure labelling is understandable, truthful and not misleading" (1). This is particularly applicable to single ingredient products such as salt and water or to foods for which no GE versions have been offered for sale. Thus, we propose the following guideline for labeling food products:

- Products shall not be labeled "zero," "not present," or "free from" GE materials because the realities of crop and food and feed production preclude zero tolerance (2).
- Products sold, labeled, or represented as non-GE must have at least 95% non-GE content of materials that are also available as GE. They may be represented as "made with" non-GE content if they have at least 70% non-GE content of materials that are also available as GE. The broad non-GE label may not be used on these products.
- The ingredients list of products containing less than 70% non-GE content may identify specific ingredients as non-GE, if such materials are also commercially available as GE.
- In a multi-ingredient product labeled non-GE, all ingredients must be non-GE unless the ingredient(s) is not commercially available in non-GE form. Products that consist primarily of materials not commercially available as GE should not be labeled non-GE.
- The adventitious presence of trace amounts of other ingredients (for example, corn in soy) shall not preclude use of the standard.

[1]This proposal is consistent with U.S. organic standards and Canadian and Japanese food labeling standards for genetically engineered materials and with varietal seed purity standards. It is not relevant to the low level presence of genetically engineered products that are yet to be approved in the country of production or import.

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Guideline for Disclosure of Bioengineered Products (continued)

- If it is not possible to enforce or test whether the GE ingredient is present (e.g., fats, waxes, oils, sugars, and vitamins that do not contain DNA or protein), then the standard shall be optional. However, we believe that such products should not be subject to labeling.
- Applicants may apply other thresholds in contracts.

References

1. Government of Canada. 2016. National standard of Canada: Voluntary labelling and advertising of foods that are and are not products of genetic engineering. https://www.tpsgc-pwgsc.gc.ca/ongc-cgsb/programme-program/normes-standards/internet/032-0315/index-eng.html
2. U.S. Food and Drug Administration. 2016. Guidance for industry: Voluntary labeling indicating whether foods have or have not been derived from genetically engineered plants. https://www.fda.gov/RegulatoryInformation/Guidances/ucm059098.htm