ENZYME TECHNICAL ASSOCIATION™

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Aug 17, 2017

Via Email: GMOlabeling@ams.usda.gov

United States Department of Agriculture
1400 Independence Ave., SW, STOP 0249
Washington, DC 20250-0249

Re: United Stated Department of Agriculture Proposed Rule GMO Questions Under Consideration (posted June 28, 2017; https://www.ams.usda.gov/rules-regulations/gmo-questions)

Dear Sir and Madam:

The Enzyme Technical Association ("ETA" or "Association") is a trade association that represents manufacturers and marketers of enzyme products in North, Central, and South America. It has been in existence since 1970 and maintains an active role in assisting in the development of regulations and policies that affect the enzyme industry. ETA represents the majority of the enzyme product industry in the Americas.

The ETA is pleased to respond to the United States Department of Agriculture's Agricultural Marketing Service's (AMS) request for input regarding the establishment of a National Bioengineered Food Disclosure Standard (hereafter Disclosure Standard) in accordance with the 2016 amendments to the Agricultural Marketing Act of 1946 (AMA). *See* Public Law 114-216; 7 U.S.C. 1621 et seq. (AMA Amendments). ETA is committed to a safe, cost effective, and sustainable food supply, and enzymes are an important factor in that equation.

ETA has reviewed the 30 proposed questions, and provides input on a number of them below. ETA requests, however, that AMS take away the following two key points from the recommendations provided below.

1. The Disclosure Standard should apply to finished food products only.

While years of safety review have established the well documented safety of bioengineered foods, ETA recognizes that the Disclosure Standard is one of consumer transparency, which ETA fully supports. With that said, ETA understands the congressional intent of the AMA Amendments is to apply the Disclosure Standard to finished food products intended for consumption, *and not to food ingredients used in the*

food production process. While ingredients are food as defined under the Federal Food, Drug and Cosmetic Act (FFDCA), there are already regulations in place which allow for an exemption from labeling for some ingredients such as processing aids. A regulation governing disclosure of such ingredients is unnecessary, inconsistent with the intent of the AMA Amendments, and should be out of scope. Further, requiring disclosure (under the AMA Amendments) of processing aids or other ingredients would be in conflict with other regulations promulgated under the FFDCA.

2. Enzyme preparations should be excluded from the disclosure as a bioengineered food.

Second, ETA understands the AMA Amendments as *excluding ingredients such as enzyme preparations from the scope of any disclosure requirement* because an enzyme is a protein, and it is not considered to be genetic material. We provide more detail on both of these issues in our responses to specific AMS questions below.

Background on Enzymes and Enzyme Production

To assist the USDA in understanding ETA's recommendations, it is helpful to provide some basic information on the nature, structure, and function of enzymes. Enzymes are specialized proteins that act as catalysts. They are found in nature and are produced by all living cells and perform fundamental biochemical reactions required to support life. Just like any other protein, enzymes are made up of amino acids. The amino acids link together in a long chain, which is folded up into a complex structure. There are thousands of different enzymes found in nature. Indeed, enzymes are naturally present in nearly all foods consumed by humans including fresh fruits and vegetables, meat, and grains.

Industrial enzymes have a long history of safe use in many applications including the production of breads and baked goods, wine, cheese, beer, sugar syrups, oil, and pet foods, often as food processing aids. It is well documented that the use of enzymes continues to offer critical benefits such as reduced use of raw materials, water and energy, which results in less waste, improved economy for manufacturers, the provision of healthful food at affordable cost to consumers, and with reduced environmental impact.

Commercial microbial enzymes are produced using a contained fermentation process of specially selected nonpathogenic, nontoxigenic strains of microorganisms.[1] Many commercial enzymes are produced by microorganisms that are bioengineered although not every available enzyme comes from a bioengineered microorganism. The enzyme protein is separated from the spent production biomass which includes the production

[1] A very small number of industrial enzymes are derived from plant or animal sources.

microorganism and residual ingredients from the fermentation media. It is important to note that the use of bioengineering techniques is necessary for the actual production of certain enzymes because not all microorganisms can be cultivated under industrial conditions. This reduces the cost of enzyme production; thereby reducing the cost of food or other consumer products for all consumers. Many enzymes have no economically feasible alternative without the use of genetic engineering techniques.

Responses to AMS Questions Under Consideration

We provide input on 10 of the 30 AMS questions below, addressing those questions of particular significance to the enzyme community first. For ease of reference, we repeat the USDA question and context information followed by ETA's input and recommendation.

Question 11. Could AMS consider whether a type of food is considered a bioengineered food under the determination process? (Sec. 293)

Context: AMS is considering if it could exclude certain food types such as medical food and dietary supplements, among others from requiring disclosure as bioengineered.

ETA Comments: ETA appreciates the opportunity to address this issue, and recommends that AMS exclude enzyme preparations from the Disclosure Standard. As explained above, many enzyme preparations are used as processing aids and processing aids are already exempt from labeling under Food and Drug Administration (FDA) regulations. The unique role of the enzyme in food processing is as a catalyst. Due to the specific nature of enzymes, only small amounts are required to make desired modifications to the property of a food. Many enzymes do not become a component of the food ingredient or final food because processing of the food ingredient after the enzyme catalyst has performed the expected function often reduces or eliminates the enzyme from the product. For this reason alone, enzymes used as processing aids should be out of the scope of the Disclosure Standard.

Further, while many enzymes are produced by microorganisms that have been bioengineered, the production organism and biomass are removed following enzyme production, and thus, these production materials are themselves only used as processing aids. As a result, a food or food ingredient, such as an enzyme, that is produced using a bioengineered microorganism as a processing aid should be exempt from the Disclosure Standard as long as the microorganism is removed from the

fermentation product. This is consistent with the GM labeling requirements in the EU[2] where the resulting exempt enzyme preparation is referred to as "produced with" a genetically modified organism rather than "produced from" such a microorganism. To avoid unnecessary confusion and to facilitate international trade, the US should not adopt a mandatory labeling approach that is more stringent than that in the EU. Thus, enzyme preparations that are used in food, either as processing aids or finished food ingredients, should be out of scope of the Disclosure Standard.

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: whether a food contains a substance that has been modified using recombinant in vitro DNA techniques (Sec. 291(1)(A)), whether 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.

ETA Comments: The mere use of a bioengineered food ingredient, such as a **processing aid,** in the production of a food product should not result in a characterization of the finished food as a bioengineered food. Processing aids, by their very definition in 21 C.F.R. § 101.100, are used during the food production process and are not functional in the finished food. Therefore, because they are exempt from labeling on the finished food, disclosure under the AMA Amendments should not be required.

Further, for harmonization purposes, it is important to note that processing aids are out of scope for labeling in the EU's bioengineered food and feed disclosure regulation. *See* (REGULATION (EC) No 1829/2003, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:268:0001:0023:EN:PDF).

[2] Report from the Commission to the Council and the European Parliament on the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed. Brussels, 25.10.2006 COM(2006) 626 final report.

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Question 8. What is the amount of 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.

ETA Comments: As noted in response to questions 10 and 11, enzyme preparations should be out of scope of the Disclosure Standard. The use of processing aids, which may be from genetically engineered sources, in the food production process is insufficient by itself to result in a food being deemed "bioengineered" because the processing aid is either not in the finished food product, or it is not functional in the finished food and is present at insignificant levels.

Thresholds should not be applied that would result in bioengineered ingredients being viewed as contaminants or that would encourage food manufacturers to substitute ingredients to avoid disclosure.

It is important in today's world to use genetic modification techniques to enable production of safe and sustainable foods in a cost-effective manner. Some foods have no economically feasible alternative without the use of genetic modification, including enzymes. Requiring disclosure where only trace amounts of genetically modified material may be in the finished food product will raise costs in tracking and testing of products, which ultimately will be passed to consumers in higher food prices.

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.

ETA Comments: USDA should simply harmonize the regulatory language with that set forth in the law. ETA agrees that the definition of "animal" should be broad enough to encompass invertebrate such as crickets and bees, as suggested in the USDA call for input.

Question 4. Will AMS require disclosure for food that contains highly refined products, such as oils or sugars derived from bioengineered crops? (Sec. 291(1)(A))

Context: Many processed foods may contain ingredients derived from bioengineered crops, such as highly refined oils or sugars that contain undetectable levels of bioengineered genetic material such that they are indistinguishable from their non-engineered counterparts. AMS is considering whether to require disclosure for foods containing those derived ingredients that may be undetectable as bioengineered.

ETA Comments: Highly purified products should not be the target of the Disclosure Standard. As noted in ETA's responses to questions 8 and 10, the AMA Amendments require AMS to determine whether a food product *contains* genetic material modified through in vitro recombinant DNA techniques, and the amounts of bioengineered substance contained "in order for the food to be a bioengineered food." *See* AMA section 293(b)(2)(B). Thus, the focus of the legislation is on the content of the finished food product, not on the process to develop the finished food. As a result, because bioengineered material is insignificant and generally not detectable in highly purified products such as oil, sugars, etc., clearly this is at a quantity that is not the focus of the legislation such that disclosure should be unnecessary.

If the level of bioengineered substance in highly purified products becomes a target of disclosure, **traceability** becomes a significant burden for the regulator as well as the manufacturer, and the additional steps necessary to trace such insignificant levels results in additional cost which would be reflected to the final product price in the market.[3]

Question 1. What terms should AMS consider interchangeable with bioengineering? (Sec 291(1))
Context: The disclosure standard would be a mechanism to inform consumers about their food. AMS is considering the advantages and disadvantages of allowing the use

[3] REGULATION (EC) No 1830/2003. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:268:0024:0028:EN:PDF

of other terms to provide for disclosure.

Question 2. Which breeding techniques should AMS consider conventional breeding? (Sec. 291(1)(B))

Context: AMS is considering what would be defined as modifications that could otherwise be obtained through conventional breeding because these modifications would be exempt from mandatory disclosure.

Question 3. **Which modifications should AMS consider to be found in nature? (Sec. 291(1)(A)**

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.

ETA Comments: ETA grouped these three questions together because all address the scope of the AMA Amendments definition of "bioengineering" and what may be identified as a "bioengineered food" under a Disclosure Standard. Specifically, the statutory language limited application of the term "Bioengineering" to "a food that contains genetic material modified through in vitro recombinant [DNA] techniques," also referred to as the in vitro rDNA technique. *See* AMA Section 291 distinct (1)(A). The in vitro rDNA technique involves joining together DNA from two or more sources and introducing them into a host. *See FDA draft guidance for industry, Regulation of Intentionally altered Genomic DNA in Animals at p.4. (January 2017)*. Based on the specific definition in the AMA Amendments other genetic modification techniques, are therefore out of scope and not subject to the Disclosure Standard under the AMA Amendments.

With the statutory mandate in mind, it may be difficult to identify terminology that does not go beyond the in vitro rDNA technique. For example, we find that in some US documents, phrases such as "genetic modification" and "genetically modified organism" (or "GMO") includes mutagenesis, which does not involve the in vitro rDNA technique. Clearly, these terms cannot be adopted as interchangeable with "bioengineering." In addition, "genetic engineering" cannot serve as an interchangeable term in light of the preemption language in the AMA Amendments, which specifically preempts states from imposing any labeling requirements on "genetically engineered" food or seed in interstate commerce. *See* AMA Section 295(b). A Senate Report related to this law clearly demonstrates congressional understanding that the term "genetic engineering" extends beyond the in vitro rDNA technique, and specifies that limiting the definition of "bioengineering" to the in vitro rDNA technique is consistent with the approach taken by most countries.[4]

[4] *See* S. Rep. No. 114-403, at 3 (2016). This reports on an earlier Senate version of the legislation that mirrors the definition of "bioengineering" and the preemption language in the AMA Amendments.

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As a result, ETA recommends against adopting interchangeable terminology. If USDA seeks to apply additional interchangeable terms, it must assure that they are carefully defined to limit the scope to the in vitro rDNA technique.

AMS also asked for identification of conventional breeding techniques as well as techniques that could also occur in nature, which are specifically excluded from the AMA Amendments definition of "bioengineering." *See* AMA Section 291(1)(B). The safety of the technique and the resulting product is what should be of concern. Disclosure should not suggest that products of conventional breeding or bioengineering differ in safety.

Conventional breeding is a colloquial term and is based on the acceptability by the public of techniques that may have a long history of use. There are breeding techniques that may now seem commonplace, even while their initial introduction seemed innovative and may not have been widely accepted. By developing a list of techniques that are considered conventional breeding, we limit the opportunity for future techniques to be commonly accepted. Further to this point, this limitation may cause unnecessary concern in the mind of the consumer when the result of a new technique may be just as safe as the previously accepted technique. Disclosure should not hinder innovation or discourage manufacturers from using certain ingredients.

Further, by developing a conventional breeding techniques list, people may be encouraged to demand information about production methods and the specific techniques used. AMS should ensure that implementation of the Disclosure Standard does not impose requirements on food manufacturers or ingredient providers to reveal confidential business information or other competitively sensitive information relating to their production practices.

As it concerns AMS' request for information on modifications that can be found in nature, there is a wide range of genetic variability that can be found in nature. By defining which modifications can occur in nature, one may exclude certain variations that have not yet been discovered. Indeed, rDNA techniques can be used to create genetic modifications that do occur in nature. Just because an in vitro rDNA technique is used does not mean that the change cannot occur in nature.

Thus, in summary, ETA recommends against adoption of interchangeable terminology for the statutory term "bioengineering." However, if USDA seeks to include interchangeable terminology, it must carefully define these additional terms to include only the in vitro rDNA technique. Further, we do not recommend the development of a list of terms that are commonly associated with conventional breeding or that describe modifications that could occur in nature.

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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.

ETA Comments: In the absence of understanding what AMS will define as a bioengineered food, it is difficult to recommend the record requirements in this case. With that said, however, ETA points out that food producers already are required to maintain a number of records under existing Food Safety and Inspection Service (FSIS) and FDA rules related to the receipt, production, holding, and transportation of foods. To avoid an unnecessary burden on the industry, ETA recommends that AMS consider how these existing recordkeeping requirements can be used to establish compliance with the AMA Amendments.

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

Context: AMS is considering how the disclosure requirements should be applied to imported products.

ETA Comments: ETA believes that imported food products should be subject to the same requirements as domestic products under the Disclosure Standard.

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ETA thanks AMS for the opportunity to provide recommendations as it moves forward in developing a disclosure standard for bioengineered foods. If AMS has any questions or requires additional detail on the recommendations provided above, please contact Ann Begley, Secretary and General Counsel to ETA, for further information at ann.begley@morganlewis.com or 202-739-5613.

Very Truly Yours,

Vince Sewalt
Chair
Enzyme Technical Association

cc: Andrea F. Huberty