The Glutamate Association

August 23, 2017

Submitted Electronically to GMOLabeling@ams.usda.gov

Re: AMS Questions on Bioengineered Food Disclosure Law

To Whom it May Concern,

The Glutamate Association (TGA) appreciates the opportunity to respond to the U.S. Department of Agriculture (USDA) Agricultural Marketing Service's (AMS's) questions for public comment as the agency works to develop regulations implementing the National Bioengineered Food Disclosure Standard. TGA is an association of manufacturers, national marketers, and processed food users of glutamic acid and its salts, principally the flavor enhancer and sodium salt of glutamic acid.

In the following comments, we provide responses to questions 2, 3, 4, 7, 8, 10, and 11 regarding the scope of the standard and question 12 regarding the disclosure text that should be required. We repeat each of the questions and then provide our perspective.

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

TGA Response:
AMS should clarify that mutagenesis is outside of the scope of the definition of "bioengineering."

The statute defines "bioengineering" as referring to a food that contains genetic material that has been "modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques," where the modification could not otherwise be obtained through conventional breeding or found in nature. Mutagenesis is not an "in vitro recombinant DNA technique," so foods produced using mutagenesis are outside of the scope of the definition of "bioengineering." Nevertheless, for the sake of completeness, we ask that AMS expressly clarify that mutagenesis does not meet the definition of bioengineering because it could otherwise be obtained through conventional breeding or found in nature.

The breeding technique using mutagenesis is called "mutation breeding." According to the Food and Agriculture Organization of the United Nations (FAO), mutation breeding of plants has been used since the 1930s, so it should be considered a conventional breeding method with a long history of use.[1] More than 3,200 officially released mutant varieties from 214 different plant species are registered in the "FAO/IAEA Mutant Variety Database."[2]

[1] Joint FAO/IAEA Programme: Nuclear Techniques in Food and Agriculture: Mutation Breeding, http://www-naweb.iaea.org/nafa/pbg/mutation-breeding.html.

[2] Joint FAO/IAEA Programme: Nuclear Techniques in Food and Agriculture: Plant Breeding and Genetics, http://www-naweb.iaea.org/nafa/pbg/.

Mutagenesis can occur as a result of exposure to mutagens, such as chemicals or radiation, but it also commonly occurs in nature and at least some of the mutagenesis chemicals are derived from nature. It is widely believed that mutation and selection is the primary processes of evolution. Mutation breeding simply facilitates this natural process by using chemicals or radiation. Therefore, it results in a modification that could otherwise be obtained through conventional breeding or found in nature.

USDA's National Organic Program (NOP) has also recognized that ingredients developed with the use of mutagenesis, such as docosahexaenoic acid (DHA) algal oil, may be used as an ingredient in organic foods. Under the NOP, bioengineering is considered an "excluded method" that cannot be used. The National Organic Standards Board (NOSB) specifically considered whether the form of mutagenesis that may be used to develop this ingredient should be considered an "excluded method" and recommended that DHA algal oil be listed for use in organic foods, reflecting its conclusion that no excluded methods are used to make the ingredient.[3] The National Bioengineered Food Standard requires USDA to consider establishing consistency between the bioengineered food disclosure standard and the Organic Foods Production Act.[4] It would be inconsistent to classify mutagenesis as a form of bioengineering under the disclosure standard when it is not considered an excluded method under the USDA organic standards. Such a position also would run contrary to AMS's stated policy of establishing consistency between this standard and the NOP.[5]

Lastly, we note that mutagenesis is outside the scope of GMO labeling regulation in the European Union (EU).[6]

For these reasons, we ask AMS to make clear that mutagenesis is excluded from the definition of bioengineering.

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

TGA Response:
Microorganisms modified by so-called **"self-cloning"** and **"natural occurrence"** techniques, in which the host and donor microorganisms belong to the same or phylogenetically closely related species/genus, should be considered modifications "found in nature" and therefore excluded from the definition of bioengineering.

The definition of these terms varies slightly by country. The EU defines self-cloning as follows.

> ***Self-cloning*** consisting in the removal of nucleic acid sequences from a cell of an organism which may or may not be followed by reinsertion of all or part of that nucleic acid (or a synthetic equivalent) with or without prior enzymic or mechanical steps, into cells of the same species or into cells of

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[3] 7 C.F.R. § 205.606(f); Formal Recommendation by the NOSB to the NOP, Docosahexaenoic (DHA) algal oil petition, Dec. 2, 2011, https://www.ams.usda.gov/sites/default/files/media/DHA%20Algal%20Oil%20Formal%20Rec.pdf

[4] National Bioengineered Food Disclosure Standard §293(f), 7 U.S.C. § 1639b(f) (2016).

[5] Memorandum from Elanor Starmer, Administrator, AMS to AMS Deputy Administrators re: Consistency between Bioengineered Disclosure and the National Organic Program, Sept, 19, 2016, https://www.ams.usda.gov/sites/default/files/media/PolicyMemoGMODisclosureNOPConsistency.pdf.

[6] Regulation (EC) No 1830/2003, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:268:0024:0028:EN:PDF; Directive 2001/18/EC, http://eur-lex.europa.eu/resource.html?uri=cellar:303dd4fa-07a8-4d20-86a8-0baaf0518d22.0004.02/DOC_1&format=PDF.

> phylogenetically closely related species which can exchange genetic material by natural physiological processes where the resulting micro-organism is unlikely to cause disease to humans, animals or plants. Self-cloning may include the use of recombinant vectors with an extended history of safe use in the particular micro-organisms.[7]

Japan defines "self-cloning" and "natural occurrence" as follows.

> ***"Self-cloning"*** refers to cases where the DNA ultimately introduced into a host—a living cell into which DNA is inserted by recombinant DNA techniques—is DNA only from microorganisms belonging to the same species as the host (taxonomically).
>
> ***"Natural occurrence"*** refers to cases where the recombinant—a host containing recombinant DNA—is equivalent in genetic composition to naturally occurring microorganisms.[8]

Self-cloning and natural occurrence are not considered bioengineering in Japan. The Food Safety Committee (FSC) in Japan does not require the safety review of food and food additives from microorganisms modified by self-cloning or natural occurrence. Based on the FSC's decision, the Ministry of Health, Labor and Welfare (MHLW) does not categorize foods produced via self-cloning and natural occurrence as genetically modified foods and food additives under Article 3, Paragraph 5 of the Assessment Procedure.

In the U.S., the terms "self-cloning" and "natural occurrence" are not defined by statute or regulation, but the National Institutes of Health (NIH) has issued guidelines defining the following processes, which refer to self-cloning and natural occurrence, respectively:

> Section III-F-3. Those that consist solely of the exact recombinant or synthetic nucleic acid sequence from a single source that exists contemporaneously in nature.
>
> Section III-F-6. Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. --- See Appendices A-I through A-VI, Exemptions under Section III-F-6--Sublists of Natural Exchangers, for a list of natural exchangers that are exempt from the NIH Guidelines.[9]

The combination of the host and the donor microorganisms shown in "Appendix A Exemptions under Section III-F-6—Sublists of Natural Exchangers" in the NIH guidelines should be regarded as modifications "found in nature." The Appendix refers to "natural exchangers" that consist entirely of DNA segments from different species that exchange DNA by known physiological processes. Even more so, the combination of DNA from the same species should be viewed as a modification found in nature.

The U.S. Environmental Protection Agency (EPA) also distinguishes between "intergeneric" and "non-intergeneric" microorganisms. An intergeneric microorganism is defined in EPA regulations as "a microorganism

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7 Directive 2009/41/EC, http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32009L0041.

8 GAIN Report Number: JA4005 "Japan Takes Step Forward to Improve its GE Product Review Process".

9 NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, Apr. 2016, https://osp.od.nih.gov/wp-content/uploads/2013/06/NIH_Guidelines.pdf.

that is formed by the deliberate combination of genetic material originally isolated from organisms of different taxonomic genera."[10] Only intergeneric microorganisms are required to be reported to EPA under section 5 of the Toxic Substances Control Act (TSCA). In contrast, non-intergeneric microorganisms, such as those produced via self-cloning and natural occurrence, need not be reported.

In conclusion, the plain language of the statute exempts from the definition of bioengineering those uses of rDNA technology "for which the modification could not otherwise be obtained through conventional breeding or found in nature."[11] For the reasons explained above, the modifications that are obtained through the use of self-cloning and natural occurrence can indeed occur through conventional breeding or be found in nature. Self-cloning and natural occurrence are techniques that are performed on organisms of the same species or into cells of phylogenetically closely related species which can exchange genetic material by natural physiological processes. Although recombinant DNA technology may be used in the process, the genetic modifications could result through conventional breeding techniques, such as the use of mutagenesis, and also occur in nature simply through the exchanges of genetic material that frequently take place between microorganisms. The products of self-cloning and natural occurrence, therefore, are exempt from bioengineering under the plain language of the statute.

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))

TGA Response:
The plain language of the statute defines bioengineering, with respect to a food, as a food that "contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques for which the modification could not otherwise be obtained through conventional breeding or found in nature."[12] To fall within the definition of "bioengineering," a food must contain bioengineered genetic material. AMS should adopt a plain language interpretation of this definition.

Highly purified or refined products, such as oils and sugars, do not "contain" any detectable amount of recombinant DNA. As a result, such foods fall outside of the definition of "bioengineering" and should not be considered bioengineered foods under the standard.

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))

TGA Response:
AMS should make clear that a **fermentation product** does not require disclosure as a bioengineered food solely because its nutrient sources are derived from bioengineered crops ("**bioengineered substrates**"). Like bioengineered feed consumed by an animal, bioengineered substrates are consumed by the microorganism during the fermentation process and therefore should not result in the need for a disclosure. In particular, the

10 40 C.F.R. § 725.3.
11 National Bioengineered Food Disclosure Standard §291(1), 7 U.S.C. § 1639(1) (2016).
12 *Id.*

microorganism uses the substrate as a food source to grow, consuming it as part of the fermentation process. To take monosodium glutamate (MSG) as an example, any residual levels of the bioengineered substrate following fermentation would be removed by the purification and isolation process used to make MSG. The bioengineered substrate would therefore be present at insignificant levels and have no technical or functional effect in the finished food.

Question 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))

TGA Response:
AMS should set a threshold of 5 percent as the amount of a bioengineered substance that results in the need for a disclosure. Such a standard would be consistent with the standards for labeling of bioengineered foods in Japan, Thailand, South Africa, Vietnam, and other countries. A 5 percent standard is consistent with the level of non-organic ingredients that may be present in a food labeled as "organic."[13] It also would appropriately recognize that the presence of less than 5 percent of bioengineered content (or any level) is not a health or safety issue, as FDA has repeatedly affirmed there is no material difference between foods from bioengineered crops and foods from conventional crops.

Additionally, a 5 percent threshold would account for the commingling of agricultural commodities that can result in low levels of bioengineered content in non-bioengineered commodities. The U.S. Grain Standards allow commodity grains, legumes, and seeds to contain a small percentage of another commodity grain as a result of commingling during production.[14] For instance, wheat may contain no more than 10 percent of other grains like soybeans.[15] By establishing a 5 percent threshold, AMS would likely be accounting for most of the inadvertent commingling with bioengineered crops that occurs in the food supply. (For IOM soybean – an industrial designation for soybeans from the U.S. states of Indiana, Ohio, and Michigan – the maximum ratio of bioengineered soy contamination in "non-GMO soybean" is reported to be 5 percent.) In contrast, if the threshold is set at a lower level, foods could be required to bear a bioengineered food disclosure based only on the inadvertent presence of bioengineered plants due to commingling.

By setting the threshold at a level that provides sufficient flexibility to account for commingling, AMS would ensure the bioengineered food disclosure standard is not disruptive to international trade, given other countries' labeling requirements for bioengineered foods. In contrast, if the inadvertent presence of bioengineered soy in wheat were to trigger a bioengineered food disclosure in the U.S., wheat that is shipped from the U.S. to other countries would be labeled as "bioengineered" and could in theory trigger the need for a disclosure on finished products in other countries that is not currently required. To ensure minimal disruption to trade, AMS should provide a flexible standard that accounts for the realities of agricultural commingling at low levels. A 5 percent threshold would accomplish this goal.

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13 7 C.F.R. § 205.301(a).

14 *See* FDA Q&A: Gluten-Free Food Labeling Final Rule, Question 15 (Nov. 2013), available at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm362880.htm.

15 7 C.F.R. § 810.2201.

Question 10. What other factors or conditions should AMS consider under which a food is considered a bioengineered food? (Sec. 293(b)(2)(C))

TGA Response:
The use of **bioengineered processing aids, including bioengineered microorganisms used in fermentation,** should not result in the need to label a food as bioengineered. 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.[16] For that reason, FDA regulations do not require the declaration of processing aids in the ingredient statement on food labels.[17] Therefore, their use in processing is not material to whether the finished food is bioengineered. Indeed, the EU recognizes that processing aids are outside of the scope of the GMO disclosure regulation.[18]

Processing aids should be treated the same as bioengineered feed consumed by an animal and should not result in the need for a disclosure. Like bioengineered feed, which is consumed by the animal and is not present in the finished food, processing aids by their very definition are present at insignificant levels and have no technical or functional effect in the finished food.[19] The statute gives AMS authority to set an amount of bioengineered content that does not result in the need for a disclosure, recognizing that minor amounts of bioengineered content should be excluded from the disclosure requirement. Because processing aids are present at an insignificant level in finished foods for the purpose of ingredient labeling, they should similarly be considered to be present at an insignificant level under the bioengineered food disclosure standard.

For example, a company may use a very small quantity of soy oil as a release agent on the conveyors used to convey a baked good. When the soy oil is used exclusively for preventing the baked goods from sticking to the surface of the conveyor and only nominal quantities of the oil would transfer onto the food (such as 150 ppm), it would meet the FDA definition of processing aid and would be exempt from ingredient labeling because it is present at insignificant levels and has no technical or functional effect on the food.

Another example involves the use of bioengineered microorganisms in making fermentation products. The microorganism will consume the substrate in the nutrient media, multiply, and produce a food ingredient. The microorganism is then separated from the nutrient media and the food ingredient is isolated and purified. Fermentation technology is used to make many food ingredients, such as alcohol through the yeast fermentation of carbohydrates or the treatment of alcohol with microorganisms to produce vinegar. Fermentation technology also is used to make many commonly consumed organic acids such citric acid, ascorbic acid, and malic acid. Ingredients such as MSG, enzymes, amino acids, and numerous other ingredients are made via fermentation. Since the microorganism is separated from the fermentation product, it qualifies as a processing aid and is exempt from ingredient labeling. We encourage AMS to recognize products developed from fermentation fall outside the definition of bioengineered food regardless of whether the microorganism has been produced with bioengineering. Such a position is consistent with the now-preempted state laws such as the one passed in Vermont that would have exempted processing aids and enzymes from the disclosure requirement.

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16 21 C.F.R. § 101.100(a)(3)(ii).
17 *Id.*
18 Regulation (EC) No 1829/2003 (clause (16)), http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:268:0001:0023:EN:PDF.
19 21 C.F.R. § 101.100(a)(3)(ii).

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))

TGA Response:

TGA recommends the language "Contains Bioengineered Material," since the law defines "bioengineering" as referring to a food "that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques."

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We appreciate the opportunity to submit our viewpoints on the many important issues the agency is considering as it implements the National Bioengineered Food Disclosure Standard. Thank you for your consideration of these comments.

Sincerely,

Tatsuya Sato
Chair
The Glutamate Association