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VIA ELECTRONIC SUBMISSION

U.S. Department of Agriculture
Agricultural Marketing Service
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Re: USDA Seeks Input in Developing a Proposed Bioengineered Food Disclosure Rule

The Council for Responsible Nutrition (CRN)[1] respectfully submits the following comments to the 30 questions posted by U.S. Department of Agriculture (USDA) Agricultural Marketing Service (AMS) that are for consideration by stakeholders. Due to the short comment period, we first submit comments for questions 4, 8, 10 and 11 and request an opportunity to submit additional comments, including further elaboration on Question 11, at a later time.

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.

[1] The Council for Responsible Nutrition (CRN), founded in 1973 and based in Washington, D.C., is the leading trade association representing dietary supplement and functional food manufacturers, marketers and ingredient suppliers. CRN companies produce a large portion of the functional food ingredients and dietary supplements marketed in the United States and globally. Our member companies manufacture popular national brands as well as the store brands marketed by major supermarkets, drug stores and discount chains. These products also include those marketed through natural food stores and mainstream direct selling companies. CRN represents more than 150 companies that manufacture dietary ingredients, dietary supplements and/or functional foods, or supply services to those suppliers and manufacturers. Our member companies are expected to comply with a host of federal and state regulations governing dietary supplements and food in the areas of manufacturing, marketing, quality control and safety. Our supplier and manufacturer member companies also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Learn more about us at www.crnusa.org.

CRN Comment:
AMS should exempt from disclosure highly refined products, such as high refined oils or sugars that contain undetectable levels of bioengineered genetic material.

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.

CRN Comment:
The amounts of a bioengineered substance that may be present in food in order for the food to be considered a bioengineered food should be addressed in a manner similar to that described in the Vermont GMO labeling rule[2] concerning foods with minimal genetically engineered content. CRN recommends that a bioengineered disclosure should be required if the aggregate weight of the genetically engineered material in the food is more than 0.9 percent of the total weight of the food. Disclosure should not be required for foods with less than 0.9 percent bioengineered genetic material.

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 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 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.

CRN Comment:

[2] Consumer Protection Rule 121. Labeling Foods Produced with Genetic Engineering. Available at: https://consumermediallc.files.wordpress.com/2016/06/final-rule-cp-121.pdf.

Similar to other industry associations, CRN recommends that a food should not be considered a bioengineered food **solely** because it contains:

- An ingredient(s) derived by the chemical transformation of materials directly obtained from a bioengineered crop. Examples include vitamin C and sugar alcohols.

- An ingredient(s) authorized by National Organic Program for use in certified organic foods. Examples include vitamins B2 and B12, which are produced by genetically bioengineered microorganisms.

- Processing aids, incidental additives and secondary direct food additives that may be derived from a bioengineered source material. These substances have a functional role in ingredients but no function in the final product.

In addition, foods should not be considered bioengineered solely because they are produced via a fermentation process, including when the fermentation organism and the feedstock are (or are derived from) products of bioengineering. The National Bioengineered Food Disclosure Standard Law is clear that animal products should not be considered bioengineered solely because the animal consumed feed products from, containing, or consisting of a bioengineered substance (Sec. 293(b)(2)(A)). By the same principle, foods produced by a fermentation process using a bioengineered organism and foods produced using bioengineered ingredients in the substrate/feedstock should not be considered bioengineered. For example, CoQ10 that is produced by a bioengineered microorganism should not be considered a bioengineered food. In addition, microorganisms should not be considered bioengineered if they are grown in broth/media that may contain bioengineered ingredients, such as starches from bioengineered grains and byproducts derived from bioengineered animals.

We also recommend that AMS consider issuing a guidance document that outlines the factors that should be considered when assessing whether a product/ingredient is bioengineered and subject to disclosure. Providing specific examples or case studies in the guidance document would be beneficial.

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 it could exclude certain food types such as medical food and dietary supplements, among others from requiring disclosure as bioengineered.

CRN Comment:
As the leading trade association representing dietary supplements and functional foods, CRN believes that AMS should consider exemptions for certain classes of foods from mandatory disclosure. For example, medical foods, foods for special dietary uses, and dietary supplements are each regulated in many respects as "food," however, they have their own separate definitions in the federal Food, Drug & Cosmetic Act, and are subject to their own unique regulatory paradigms. Particularly where these items provide health benefits or are intended for specialty populations, their health-related attributes beyond their taste, aroma, and satiety attributes provide justification for their exclusion from the generalized mandatory disclosure. Any

exemptions from the mandatory program should be based on criteria that are clear and scientifically and legally justified. AMS should allow for additional stakeholder input before final determinations regarding exemptions of certain classes of foods from mandatory disclosure.

Respectfully submitted,

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Council for Responsible Nutrition