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VIA ELECTRONIC SUBMISSION

Agricultural Marketing Service
Docket Clerk
1400 Independence Ave. SW
Room 4543-South
Washington, DC 20250

Re: Proposed Rule: National Bioengineered Food Disclosure Standard. 83 FR 19860 (May 4, 2018). Docket No. AMS-TM-17-0050.

The Council for Responsible Nutrition (CRN)[1] appreciates the opportunity to provide comments on the proposed rule issued by the Agricultural Marketing Service (AMS) titled, "National Bioengineered Food Disclosure Standard." CRN is the leading trade association for the dietary supplement and functional food industry, representing manufacturers and marketers of dietary ingredients and of national brand name and private label dietary supplements and functional foods.

CRN supports the goal of the National Bioengineered Food Disclosure Standard (NBFDS) to provide reliable information about the presence of bioengineered (BE) material in food products, including dietary supplements. Similar to nutrition information on food labels, BE disclosures will help consumers to make informed choices about the products they purchase. CRN appreciates the approach being pursued by AMS that emphasizes informed decision making but

[1] The Council for Responsible Nutrition (CRN), founded in 1973, is a Washington, D.C.-based trade association representing 150+ dietary supplement and functional food manufacturers, ingredient suppliers, and companies providing services to those manufacturers and suppliers. In addition to complying with a host of federal and state regulations governing dietary supplements and food in the areas of manufacturing, marketing, quality control and safety, our manufacturer and supplier members also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Visit www.crnusa.org.

does not make judgments about the health effects or safety of BE foods and food ingredients. Consumers are best served by an objective, non-inflammatory disclosure framework that respects the intent of the NBFDS without unduly alarming consumers about the presence of BE material in food products.

CRN encourages AMS to develop a practical standard that allows food manufacturers to implement labeling changes efficiently. A national system for BE disclosure is sensible because it obviates the need for state-level BE disclosure laws, which existed in Vermont and had been initiated in several states prior to the passage of the NBFDS law. State-level BE disclosure laws would be unworkable, as food manufacturers that offer products for sale nationally would have to comply with separate sets of requirements for any single product in commerce. A reasonable, national standard for BE disclosure allows food manufacturers to provide information related to BE foods in a consistent manner. CRN's comments on specific aspects of the proposed rule are below.

I. AMS should develop a single official list of commercially available BE foods.

CRN supports the use of a BE food list based on commercially available BE plants to help firms determine which foods and food ingredients are potentially BE foods subject to the NBFDS. Agricultural biotechnology is a dynamic component of the food supply, which is global and complex. The ten BE plants commercially available in the U.S. that AMS proposes are a good starting point for food manufacturers, who would then need to determine which food ingredients are derived from those BE plants in order to make BE disclosure decisions.

However, instead of two lists—one identifying highly adopted BE plants and the other identifying BE plants that are not highly adopted—AMS should create only one list identifying the ten BE plants that are currently available commercially. The recordkeeping for food manufacturers would be simplified with just one consolidated list of BE foods. In addition, with just one list, the text disclosure would consistently be "Bioengineered food" or "Contains a bioengineered food ingredient." A definitive statement offers transparency and clarity. The statements "May be bioengineered" or "May contain a bioengineered food ingredient," which AMS proposes as text disclosure for a food that is or contains an ingredient from a non-highly adopted BE plant, could cause consumer confusion about the presence of BE material in food products. The ambiguity of the qualifying language "may be" or "may contain" should be

avoided to provide clear information to consumers. Lastly, because the food environment will continue to evolve over time, the BE food list should be updated periodically to include new commercially available BE foods or to exclude those that are no longer commercially available. Whichever process AMS implements for updating the BE food list should provide opportunity for public input.

II. AMS should incorporate factors into the definition of "bioengineered food" that would permit exclusion of certain food products from the disclosure requirement.

CRN agrees that AMS should recognize certain factors or conditions that would appropriately limit the scope of the definition of "bioengineered food," thus excluding certain products from the requirements of the NBFDS. We offer the following comments on the two factors that AMS discusses in its proposed rule.

Factor A: A food that is not subject to FDCA labeling requirements should not be within the definition of "bioengineered food."

CRN agrees with AMS's proposal that a bioengineered incidental additive is not within the definition of "bioengineered food" and should not be subject to BE disclosure. The Federal Food, Drug, and Cosmetic Act (FDCA) and implementing regulation at 21 CFR 101.100(a)(3) exempt incidental additives from inclusion on the ingredient statement on a food label because they are present in food at an insignificant level and do not have any technical or functional effect in the food. AMS proposes that food components exempt under 21 CFR 101.100(a)(3) would also be exempt from the NBFDS. AMS's proposal is consistent with the statute, which in part limits the NBFDS to foods that are subject to labeling requirements under the FDCA.

In addition to incidental additives, other types of food components may be exempt from labeling pursuant to 21 CFR 101.100(a)(3). CRN recommends AMS to clarify that processing aids and substances migrating to food from equipment or packaging which are exempt from labeling requirements pursuant to 21 CFR 101.100(a)(3) would not be subject to BE disclosure under the NBFDS, unless the food components would require disclosure pursuant to other labeling requirements under the FDCA. The food and dietary supplement industry is accustomed to complying with labeling requirements under the FDCA, and thus an identical standard for compliance with the NBFDS would provide consistency and clarity. It will be highly disruptive

and resource intensive to introduce a BE disclosure requirement for food components that are not already subject to FDCA labeling requirements, that would require a separate, additional evaluation of their regulatory status, and that do not appear on the food label for other established purposes.

Factor B: A food in which recombinant DNA cannot be detected should not be within the definition of "bioengineered food."

AMS should exclude from the definition of "bioengineered food" a food in which modified genetic material cannot be detected. Certain foods are subject to a refinement or purification process that effectively removes bioengineered genetic material. These foods should not be subject to the NBFDS if recombinant DNA is not detectable and the removal of BE material is substantiated by documentation or test result. Excluding a food in which modified genetic material cannot be detected from BE disclosure is consistent with approaches taken by countries such as Australia/New Zealand[2] and Japan.[3] AMS also proposes that regulated entities would need to maintain records showing that the food subjected to a specific process to remove modified genetic material has been tested for that purpose by a laboratory accredited under ISO/ICE 17025:2017 standards, using methodology validated according to Codex Alimentarius guidelines. To further provide clarity on what AMS considers as "undetectable," the final rule should define "undetectable" based on a scientifically valid limit of detection. As detection methods evolve, AMS should update the regulation to reflect scientific developments with regard to recombinant DNA detection.

III. AMS should adopt reasonable and practical regulatory exemptions to facilitate compliance with the NBFDS.

AMS proposes several regulatory exemptions to implement sections of the NBFDS law that address exemptions to the BE disclosure requirement. CRN offers recommendations on two specific regulatory exemptions.

[2] GM Food Labelling, FSANZ (Sept. 2016), http://www.foodstandards.govt.nz/consumer/gmfood/labelling/Pages/default.aspx

[3] Library of Congress (Jun. 2015). Restrictions on Genetically Modified Organisms: Japan, https://www.loc.gov/law/help/restrictions-on-gmos/japan.php

A. Foods derived from organisms (rather than only "animals") that consumed BE feed should be exempt from disclosure under the NBFDS.

In the proposed rule, AMS proposes the following regulatory exemption that is also specified in the statute:

> *A food derived from an animal shall not be considered a bioengineered food solely because the animal consumed feed produced from, containing, or consisting of a bioengineered substance.*

CRN agrees with the principle underlying this exemption and therefore urges AMS to adopt a regulatory exemption that recognizes foods derived from organisms (beyond those generally categorized as "animals") that might consume feed or growth media produced from, containing, or consisting of a bioengineered substance. The regulatory exemption should include all organisms from which food is derived, including yeast and bacteria. For example, yeasts are used to produce dietary ingredients like vitamins. Yeasts may be fed a growth medium produced from, containing, or consisting of a bioengineered substance. The vitamin produced by the yeast is purified, contains no DNA, and is chemically indistinguishable from vitamins made using other methods. Similar to a food derived from an animal that consumed feed produced from, containing, or consisting of a bioengineered substance, a food derived from a yeast should not be considered a bioengineered food solely because the yeast was fed growth medium produced from, containing, or consisting of a bioengineered substance. CRN urges AMS to amend the proposed regulatory exemption as follows:

> *A food derived from an ~~animal~~ organism shall not be considered a bioengineered food solely because the ~~animal~~ organism consumed feed produced from, containing, or consisting of a bioengineered substance.*

B. A food in which an ingredient contains a BE substance that is unintentional or technically unavoidable and accounts for no more than 5% by weight of the specific ingredient should be exempt from disclosure under the NBFDS.

AMS proposes that a food with an amount of BE substances below an established level should be exempt from disclosure under the NBFDS. Many BE plants and non-BE plants co-exist

beginning at the farm, and throughout transport and food production. Although some food manufacturers have procedures in place to segregate BE and non-BE foods as they travel through the supply chain, some manufacturers have not adopted such practices. Thus, in order for the NBFDS to minimize cost and provide practicality, it must establish a reasonable threshold that takes into account the realities of the supply chain. AMS should establish a threshold to allow for the presence of unintentional BE substances in non-BE foods and ingredients. BE disclosure should not be required when a manufacturer uses non-BE ingredients but finds that a small amount of BE substances is unintentionally mixed with the non-BE ingredients. CRN suggests that AMS adopt Alternative 1-A, which would allow exemption from BE disclosure for a food in which an ingredient contains a BE substance that is unintentional or technically unavoidable and accounts for no more than 5% by weight of the specific ingredient. This threshold fairly recognizes that cross-contact with BE foods and ingredients cannot be completely avoided and enables food manufacturers to efficiently update their operations to provide appropriate BE disclosures.

Conclusion

The NBFDS law was established by Congress to provide additional transparency and accountability of food labeling to consumers. CRN respects that Congressional intent and honors the purpose of this law. However, issues of feasibility and practicality of compliance should also be recognized as the final rule is established. A single official list of commercially available BE foods would help simplify BE disclosure decisions for food manufacturers and would facilitate clear labeling. Food components exempt from labeling requirements under the FDCA, such as incidental additives and processing aids, should be excluded from the NBFDS, and so should food products in which recombinant DNA cannot be detected. Foods derived from organisms, including animals, yeasts, and bacteria, should not be considered bioengineered foods solely because the organisms were fed BE foods. Food ingredients that may contain small amounts of unintentional or technically unavoidable BE materials should not trigger a label disclosure, and to exempt them does no disservice to the law. Rather, these carefully developed exemptions will foster increased compliance and provide predictability to the enforcement of the NBFDS. CRN urges AMS to consider CRN's recommendations as it moves expeditiously toward finalizing the NBFDS.

Respectfully submitted,

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