Council for Responsible Nutrition
1828 L Street, NW, Suite 810 • Washington, DC 20036-5114
(202) 204-7700 • fax (202) 204-7701 • www.crnusa.org

February 07, 2020

VIA ELECTRONIC SUBMISSION

U.S. Department of Agriculture
Agricultural Marketing Service
1400 Independence Avenue, S.W.
Washington, D.C. 20520

Re: National Bioengineered Food Disclosure Standard: Validation of Refining Processes 84 Fed. Reg. 68816-68817 (December 17, 2019). Docket ID: AMS_FRDOC_0001-1997.

The Council for Responsible Nutrition (CRN)[1], the leading trade association that represents dietary supplement and functional food manufacturers and ingredient suppliers, respectfully submits the following comments on the draft instructions for ensuring acceptable validation of refining processes issued by the Agricultural Marketing Service (AMS) of the U.S. Department of Agriculture. CRN thanks AMS for providing provide guidance on the detectability provision of the National Bioengineered Food Disclosure Standard (Standard).

The draft instructions use food safety related terminology that is incompatible with the Standard's intent to provide a uniform standard for disclosure of information to consumers about the bioengineered (BE) status of foods. AMS emphasized in the preamble of the final rule that "nothing in the disclosure requirements set out in this final rule conveys information about the health, safety, or environmental attributes of BE food as compared to non-BE counterparts."[2] Further, the Statute states:

> *"(3) SAFETY.—For the purpose of regulations promulgated and food disclosures made pursuant to paragraph (2), a bioengineered food that has successfully completed the pre-market Federal regulatory review process shall not be treated as safer than, or not*

[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.

[2] National Bioengineered Food Disclosure Standard, 83 Federal Register 245 (21 December 2018), pp. 65835.

> *as safe as, a non-bioengineered counterpart of the food solely because the food is bioengineered or produced or developed with the use of bioengineering."*[3]

To be consistent with the purpose and spirit of the Standard, AMS should altogether avoid allusions to food safety in guidance.

Although AMS referred to food safety guidelines in developing its draft instructions, AMS should not adopt terms commonly associated with food safety but instead use terms that can be broadly applied to refining processes. CRN recommends that AMS simply use the term "key process step" or a similar term instead of the terms "critical control point" and "control measure" throughout the document. Separate terminology helps to prevent any possible misconception that modified genetic material is a food safety "hazard" and that it should be controlled for in the same manner that growth of pathogen microorganisms is controlled, for example, in a food safety system.

Further, AMS should modify Section 6b to remove "e.g. food safety testing" from the last sentence, which currently reads:

> *Examples of ongoing verification tools: observation of monitoring activities, review of records, and, in some cases, ongoing analytical tests (e.g. food safety testing).*

In addition, alternative approaches may be appropriate for regulated entities to employ to support the goal of the Standard. AMS should consider the acceptability of a general approach to validating a refining process that emphasizes analytical testing of the food/ingredient subjected to a refining process over time. Consistent results verifying that modified genetic material is not detectable in the food/ingredient at the end of the refining process can provide sufficient assurance that the refining process is effective at rendering modified genetic material undetectable. The steps outlined below are general and should provide flexibility for regulated entities to determine the appropriate approach for their specific and unique refining process. For example, refining processes for ingredients derived from microorganisms through fermentation such as certain vitamins, enzymes, and other ingredients, have special considerations that are different from refining processes for crop-derived ingredients.

The general steps to this approach include:

1. Determine an appropriate point during the refining process and appropriate substance(s) to conduct detectability testing of modified genetic material or confirm presence of modified genetic material of starting materials through records (e.g., supplier records confirming material is genetically modified).

2. Establish that a specified requirement of the end product is that modified genetic material is not detectable.

3. Determine, as applicable, detectability of modified genetic material at a point during the refining process by analytical testing of appropriate test substance(s). Test methods

[3] Public Law 114-216: National Bioengineered Food Disclosure Standard. (103 Stat. 834; 07/29/2016; enacted S. 764).

should be appropriate for intended use, i.e., fit for purpose.

4. Perform analytical testing of the finished food/ingredient to determine detectability of modified genetic material. Test methods should be appropriate for intended use, i.e., fit for purpose.
    - Define parameters and decision criteria (i.e., limit(s) that will be used to determine that the process was effective).

5. Validate: Assemble relevant information to determine if the process was effective
    - Determine frequency of analytical testing and perform repeat testing.
    - Determine if the process will produce an end product that consistently meets specified requirements.
    - Maintain record(s).

6. Re-validate (as applicable): If significant changes are made to the process or process deviations occur, the process should be re-validated to determine if the process, as modified, operates as intended to meet specified requirements.

CRN urges AMS to release instructions for validation of refining processes that reinforce the intention of the BE disclosure law and Standard and provide flexibility to enable regulated entities to support the goal of the Standard without undue burden.

Thank you for considering our comments.

Sincerely,

Haiuyen Nguyen
Sr. Director, Scientific & Regulatory Affairs