March 4, 2020

Submitted electronically via www.regulations.gov

U.S. Department of Agriculture
Agricultural Marketing Service
1400 Independence Avenue SW
Washington, DC 20250

RE: Draft Instructions on Testing Methods: National Bioengineered Food Disclosure Standard
Doc. No. AMS-FRDOC-0001-2003

Dear Sirs and Madams:

The undersigned organizations of the Food and Beverage Issue Alliance (FBIA) appreciate the opportunity to provide input, on behalf of our members, to the U.S. Department of Agriculture's ("USDA") Agricultural Marketing Service ("AMS") on the draft guidance on testing methods for refined ingredients in relation to the National Bioengineered Food Disclosure Standard ("Final Rule").

We appreciate the work of AMS to develop this important guidance document that we view as essential for implementing testing of refined ingredients. We are generally supportive of the guidance but would like to raise the following points as AMS looks to finalize this document.

Qualitative vs Quantitative PCR Analysis

In the fourth paragraph in Section 2 on DNA-based test methods, AMS indicates that PCR includes both qualitative and quantitative measurements and correctly points out that the former verifies the presence or absence of modified DNA and the latter reveals how much modified DNA is detectable when present in a product. AMS also indicates that, "While quantitative PCR is preferred, either alternative is acceptable."

For the purpose of this Standard, we believe testing via quantitative PCR is not necessarily preferred as testing under the Standard is conducted to determine whether a food contains detectable modified genetic material. Thus, qualitative PCR analysis, with results reported relative to the limit of detection, provides acceptable results at a lower cost per sample when compared to quantitative PCR testing. Only

when testing is conducted to determine the percent of modified rDNA in a sample is quantitative PCR analysis necessary, such as when testing to determine percent rDNA for purposes of determining whether the rDNA material exceeds the allowance for inadvertent or technically unavoidable bioengineered presence.

PCR-Inhibiting Compounds

In the last paragraph in Section 2, the draft guidance states, "While PCR is widely used, it may be limited by PCR-inhibiting compounds and is dependent on isolation of high-quality DNA from a sample. In some instances, it may not be fit for purpose to test for detectable modified genetic material in a highly processed food product that consists almost exclusively of lipids or sugars that can inhibit the PCR reaction." We are concerned that this language is misleading and creates an unnecessary level of doubt concerning the appropriateness of PCR analysis for refined ingredients that are comprised exclusively or nearly exclusively of lipids and sugars.

Qualified laboratories have the capability to address inhibition issues with such food products using appropriately validated PCR methods, which, as noted in the draft guidance, is the "most widely used and commercially accepted test method for determining whether modified genetic material is detectable." PCR methods that are appropriately validated using ISO standards, including ISO 21571 and ISO 24276, assure the method is fit for purpose by including inhibition controls. Therefore, we request that the last sentence in the final paragraph of Section 2 be removed and replaced with the following sentence, *"Laboratories should conduct an inhibition test to confirm the absence of inhibition to reliably confirm the absence of detectable modified genetic material in highly processed sample matrices."*

Sample Size

We believe that AMS needs to issue additional guidance regarding sample sizes. We believe it is inappropriate and inconsistent with good laboratory practices (GLPs) for individuals or laboratories to use extraordinary sample sizes when testing to simply try and identify some detectable level of modified genetic material in refined ingredients. Extraordinarily large samples sizes would present many obstacles, including those associated with added cost, and impracticality related to handling of large samples in a laboratory setting, including increased potential for contamination. Sample sizes should be consistent with GLPs, and thus, we believe the AMS should consider adding guidance on maximum sample sizes or at minimum, indicate that sample size be fit for purpose in accordance with ISO 21571.

Consolidation of the Draft Guidance Documents

Finally, as this draft guidance on laboratory testing is so interrelated to the previous draft guidance on validation testing, we recommend that as AMS finalizes these documents, they consider combining the two drafts into a single document. This will provide a one-stop reference to assist manufacturers undertaking validation and testing in compliance with the Final Rule. Any additional guidance on sample size should also be incorporated into this singular document.

****

We appreciate the opportunity to provide comments and look forward to discussing this guidance further with AMS. Please contact Jessica Hixson (7038364500 ext. 205) or JHixson@snacintl.org with questions or concerns.

Sincerely,

American Bakers Association
American Frozen Food Institute
Calorie Control Council
Consumer Brands Association
Corn Refiners Association
Council for Responsible Nutrition
Enzyme Technical Association
FMI- The Food Industry Association
Independent Bakers Association
Institute of Shortening and Edible Oils
International Dairy Foods Association
International Food Additives Council
National Confectioners Association
National Grocers Association
Peanut and Tree Nut Processors Association
SNAC International