March 19, 2021

Mae Wu
Deputy Under Secretary
Marketing and Regulatory Programs
United States Department of Agriculture
1400 Independence Avenue, SW
Washington, DC 20250

Re: National Bioengineered Food Disclosure Standard (Docket No. AMS-TM-17-0050)

Dear Ms. Wu:

The undersigned organizations are members of the Food and Beverage Issue Alliance (FBIA), a coalition of food and beverage trade associations. We are writing to respectfully request that the USDA's Agricultural Marketing Service (AMS) maintain the compliance date for the National Bioengineered Food Disclosure Standard (NBFDS or Standard) of January 1, 2022, and exercise enforcement discretion for products that do not yet bear the disclosure on their label or in labeling materials (e.g., accessible via a digital or electronic link) for an additional year until January 1, 2023.

The undersigned organizations appreciate AMS' leadership in the development of the NBFDS and welcomes the opportunity to continue working with the agency under your leadership in 2021, the last year of industry's voluntary compliance period. Over the last several years, the undersigned FBIA member associations worked closely with AMS to focus on finding solutions to challenges arising from the development and implementation of the Standard. We remain committed to working with the USDA to achieve our shared goal of providing accurate and consistent information to consumers regarding bioengineered (BE) foods. However, delays in the availability of guidance on the Standard, difficulty getting the documentation needed to make compliance decisions, the existence of unresolved technical issues, and the unrelenting time and resource demands occasioned by the COVID-19 pandemic, all support the need for continued AMS support and enforcement discretion.

Given the implementation challenges that remain, the undersigned organizations have the following recommendations for AMS to support continued efforts by regulated entities, such as ingredient suppliers and manufacturers, to comply with the Standard.

1) The agency should retain the current compliance date of January 1, 2022, but exercise enforcement discretion for those products that do not yet bear the disclosure until January 1, 2023 to allow companies to come into compliance and collect appropriate records for all products under the scope of the NBFDS.
2) AMS should continue to host stakeholder roundtables and broaden outreach efforts, especially to ingredient suppliers and analytical laboratories. These roundtables would facilitate robust discussions of implementation challenges, quickly address technical stakeholder questions, and identify future agency actions, including future guidance, that would be most impactful to regulated entities across the supply chain.

We believe granting these requests is in the best interest of consumers. By providing sufficient time for regulated entities to fully assess their ingredients and products under the rule, and continuing outreach efforts to industry, companies will be able to avoid a situation where they simply "over-disclose" foods as "bioengineered" because they have not yet had time to determine the BE status of their products. Over-disclosure under the BE standard does not serve consumers because those consumers looking to know more about BE foods will not have accurate information.

To support this request, we have outlined several issues in greater detail below that would be alleviated with additional AMS stakeholder outreach/education and compliance time through enforcement discretion. In the Spring of 2020, a group of FBIA members sent a letter to Secretary Perdue requesting additional compliance time for NBFDS along with a survey outlining specific compliance issues common to our member companies.[1] Many of these concerns, especially as related to COVID-19, have only worsened over the last six months. Granting enforcement discretion and working with the supply chain on education efforts will allow manufacturers and suppliers in the food and beverage industry to address these challenges and efficiently implement the Standard.

Outstanding Questions and Technical Implementation Challenges related to AMS Guidance Documents Across the Supply Chain

Confusion Surrounding AMS Guidance Documents

In July 2020, AMS released final guidance documents on validating a refining process and selecting a test method to demonstrate the absence of detectable rDNA. These guidance documents were critical in determining whether BE disclosure is necessary for many ingredients. Most ingredient suppliers waited to conduct testing or validation until the final guidance was published in order to avoid having to conduct these efforts twice. Once the guidance was published, it took time for suppliers to review and digest the guidance.

Since the publication of the final guidance documents, a number of consistently reported challenges for suppliers and manufacturers demonstrate the need for additional flexibility with respect to the compliance timeline, as well as agency support. Some ingredient suppliers including smaller suppliers, for example, do not appear to have a clear understanding of the guidance and what information should be provided to their customers to make the appropriate BE disclosure determination. Further, some ingredient suppliers are experiencing significant testing backlogs, which impacts the ability to share information with manufacturers on the BE status of ingredients. For example:

- Ingredient supply chains are extremely complex, meaning that there may be several inputs that go into the manufacture of ingredients before finished ingredients can be sent to food manufacturers. As such, if ingredient suppliers do not have all the necessary information to make BE determinations for their ingredients, this impacts the ability to share BE determinations for ingredients supplied to food manufacturers.
- Some input and ingredient manufacturers struggle to understand the guidance documents and provide adequate documentation for their ingredients causing a cascade effect, as noted above. Further, some suppliers have indicated an inability to provide all validation information until Spring 2021, which does not provide adequate time for BE label changes by January 1, 2022.
- For manufacturers, challenges range from educating suppliers, waiting on suppliers to

[1] We note that ingredient suppliers and manufacturers have, through their trade associations and FBIA, requested additional time to comply with the rule on a number of occasions since the proposed rule implementing the NBFDS was initially published. The initial requests for additional time were based in part on the fact that food companies were required to update their labels to come into compliance with the revised Food and Drug Administration (FDA) Nutrition Facts Label rule which had a compliance date of January 1, 2020 (with an additional year for compliance for smaller manufacturers). The need to assess products and conduct two significant sets of label changes in response to regulatory requirements in a short time period, as well as the significant time and resources needed to update labels, made it clear from the outset of the rulemaking process that more time would be needed for compliance with the NBFDS.

issue BE statements, suppliers still working to validate their refining processes, and some suppliers providing inconsistent, incomplete, or non-responsive documentation. In some cases, FBIA members currently have adequate and accurate documentation for only 20% of their ingredients.

- For ingredient suppliers, as noted above, challenges arise when complete information is not available on BE status of inputs into ingredient manufacture. For example, if an antioxidant is added to a refined oil, but BE information is not available on that antioxidant, then an ingredient supplier may not be able to share appropriate records with a food manufacturer. In some cases, input suppliers have noted they do not plan to validate the process for manufacture of their inputs until the NBFDS goes into effect. This delay in conducting process validation could reflect a number of factors, including resource constraints, misunderstanding of how the compliance date applies and the significant information food manufacturers must have in order to make compliance decisions by that date, supply chain disruptions related to the pandemic that divert resources from NBFDS compliance, uncertainty over the status of the law in light of the pending Center for Food Safety lawsuit, and other factors. Additionally, food manufacturers may not be consistent in their requests or questions to suppliers related to BE determination of ingredients, meaning additional time is spent to respond to initial and follow-up questions, creating additional delays in providing BE determinations to manufacturers.

With the concerns and uncertainty outlined above, a few common themes have emerged among our members. First, in order to review ingredients and reach compliance decisions for so many individual products, internal systems will need modification. Some companies, for instance, do not have a quick and easy way to access information about all ingredients in their products. Second, rapid label changeover will necessitate disposing, and in many cases, landfilling, a significant amount of existing packaging and labeling that does not yet bear the disclosure. For example:

- One company reviewed over 5,000 of their SKUs and with each BE designation, a significant internal record-keeping and communication change is required. Due to the late publication of the guidance documents and outstanding questions, some suppliers needed to update their original answers, which necessitated that already completed artwork be revised again.

The undersigned organizations, therefore, have concerns regarding the significant amount of existing packaging and labeling that will need to be disposed of to have new packaging in place and ready to ship in commerce by the compliance date. This is very costly, and depending on the amount of packaging that needs to be disposed of, can easily run in the range of millions of dollars per company. Further, disposing of packaging and labeling that is otherwise compliant with current regulations, and is truthful and not misleading, has a significant environmental impact. Providing the requested enforcement discretion will allow manufacturers and suppliers to clear up technical questions, finish assembling and assessing the significant documentation needed for compliance, and flow through packaging to minimize waste.

Unresolved Technical Issues

The undersigned organizations continue to struggle with technical issues from the Standard that have not yet been addressed in AMS guidance. Many have been put forward to AMS staff for consideration. One such example, is around digital disclosure. For example:

- The Standard permits electronic or digital disclosure for both mandatory and voluntary disclosures (7 CFR 66.106). Helpfully, AMS has recognized that a combined “scan here” and “call” statement may be used, i.e., “Scan here for more food information or call xxx-xxx-xxxx” (or scan for info for small packages). Under the statutory language, this statement must

"accompany" the digital or electronic link. Inexplicably, the regulatory language in the Standard (7 CFR 66.106(a)) constrains the placement of the electronic disclosure by requiring it to be "directly above or below" the "scan here" statement. The Standard also requires the disclosure to be "directly adjacent" to the statement identifying the name and location of the handler, distributor, packer, manufacturer, or importer. For many products, compliance with these requirements is not possible due to space constraints and other mandatory information on the label. We appreciate AMS' leadership in utilizing modern digital solutions for compliance as an effective means of providing transparency and information to consumers, as provided for by Congress. Digital disclosure is even more relevant in today's COVID-19 world. Therefore, it would be helpful for AMS to address such problems through technical changes to the Standard to address these compliance issues. In particular, our members have asked AMS to recognize that the combined call-to-action statement may also appear "to the right or left" of the digital or electronic link, rather than requiring it to appear directly above or below that statement.

- Other examples of technical concerns that need to be resolved between ingredient suppliers and manufacturers include those around enzymes and fermentation products.
- Some ingredient suppliers and manufacturers appear to be struggling with uncertainty and unfamiliarity with the rule and recordkeeping required. Additional education and outreach to these parties would help food manufacturers to get the information needed to make compliance decisions.

The concerns outlined above show the critical need of additional education from AMS to ensure better understanding of the Standard across the supply chain. Many FBIA members use the AMS "BE Frequently Asked Questions" web resource to seek clarification on specific questions and submitted questions via emails to AMS. However, these questions do not receive timely consideration or response, and in some cases, the responses appear to be inconsistent with the final rule or raise additional questions. Given the concerns stated above, the undersigned members recommend AMS consider opportunities for further discussions among the food sector, ingredient suppliers, and analytical laboratories to better understand current challenges and regulatory expectations.

COVID-19 Response

The food industry is part of our nation's critical infrastructure as recognized by Department of Homeland Security's Cybersecurity and Infrastructure Security Agency's (DHS-CISA) Guidance for Tier 1 Type of Essential Critical Infrastructure Workers. The food industry value chain is working tirelessly to keep shelves fully stocked but faces unprecedented challenges daily that are pushing resources to the limits. The Centers for Disease Control and Prevention (CDC) designated the food and agriculture sector as a priority for COVID-19 vaccination. This will add another layer of complexity as our members work through vaccination logistics while maintaining production.

Many members of the undersigned associations remain limited in their ability to implement the NBFDS as their resources and the supply chain are being stretched to meet the demands of responding to the evolving and dynamic COVID-19 pandemic crisis. Finished food manufacturers are strained to provide staff resources to address the NBFDS compliance activities, such as determining which products require a disclosure and seeking supporting documentation from their suppliers. Resources within key functions are strained - Regulatory, Legal, Design, Package Engineering, Procurement and Supply Chain are all impacted. Due to the supply chain disruptions caused by the pandemic, many of the individuals tasked with NBFDS implementation have been diverted to managing ingredient supply to ensure production can be maintained. Suppliers, as well, have limited capacity to perform testing or respond to questions from their customers

regarding the BE status of ingredients, as they also are dedicating their work to respond to covid-19 related demands for their operations.

Responding to the COVID-19 pandemic is our top priority, and in conjunction with the other challenges identified above, we respectively request additional time to comply with the NBFDS through enforcement discretion.

The undersigned FBIA members appreciate the opportunity to provide these comments and recommendations to the new leadership at USDA and looks forward to continuing to collaborate with AMS to achieve success in gaining industry compliance with the Standard. Additional compliance time, supported by additional outreach and guidance from the agency, is critical to ensure manufacturers are able to bring their products into compliance with the NBFDS.

We welcome the opportunity to discuss the industry compliance experience with the Standard in a future meeting with AMS staff.

If you have any questions, please contact Jessica Hixson 703.836.4500 ext. 205, jhixson@snacintl.org.

Respectfully submitted,

American Bakers Association
American Beverage Association
American Frozen Food Institute
American Spice Trade Association
Calorie Control Council
Consumer Brands Association
Corn Refiners Association
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
Juice Products Association
National Confectioners Association
National Fisheries Institute
National Grocers Association
National Seasoning Manufacturers Association
North American Millers Association
Peanut and Tree Nut Processors Association
Refrigerated Foods Association
SNAC International
The Association for Dressings & Sauces
The Vinegar Institute
United Egg Producers

CC: Katharine Ferguson, Chief of Staff in the Office of the Secretary
Bruce Summers, Acting Deputy Under Secretary for Marketing and Regulatory Programs
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