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Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. FDA-2025-N-1733 for "Tool for the Prioritization of Food Chemicals for Post-Market Assessment"

To Whom It May Concern:

The undersigned members of the Food & Beverage Issue Alliance (FBIA) appreciate the opportunity to comment on FDA-2025-N-1733 for "Tool for the Prioritization of Food Chemicals for Post-Market Assessment." Our members are grateful for the additional 30-day extension to the comment period. As stakeholders in this process, we have a vested interest in promoting safe, science-based practices for food substances, including chemicals in food.

FBIA is a coalition of forty-eight allied U.S. based Food and Beverage Trade Associations, representing various parts of the supply chain, from farmers and agricultural processors to manufacturers of packaged goods, and retail establishments. FBIA, through collaboration with regulatory authorities, works to ensure that regulations and guidance are justified by verifiable, robust, peer reviewed, published science that is accessible through an open and transparent process.

Science-Based Approach

The undersigned FBIA associations encourage FDA's efforts in developing a science-driven, iterative approach to determine which food ingredients the agency would prioritize for post-market assessments through the agency's post-market chemical review program. In reviewing the outlined criteria for consideration, FBIA recommends placing greater weight on public health risk-related factors (e.g., risk, toxicity, exposure levels) over factors such as public interest or media attention. The goal of the prioritization tool should be to focus resources on chemicals that should be re-reviewed based on scientific evidence. A science-based approach focused on the most important public health factors will ultimately best serve FDA's mission to protect public health and uphold consumer confidence in the safety of the food supply and assure the monies provided to the agency by Congress are used prudently.

Additionally, the undersigned organizations encourage FDA to specify *total dietary exposure* to a particular food ingredient as a public health criteria for consideration, in addition to increases or changes in exposure. While identifying ingredients with increasing levels of exposure may be useful, relying too heavily on this single factor may overlook cases in which total exposure is already significant and warrants reassessment, even in the absence of an upward trend. Likewise, it would not be appropriate to prioritize food ingredients for which exposure remains very low and below levels of concern despite an observed increase in exposure. A comprehensive view of total

dietary exposure—based on high-quality occurrence data, use levels, and consumption estimates—is critical to understanding potential public health impacts.

Differentiating Contaminants

We recognize the importance of prioritizing contaminants for safety assessment. However, we believe that applying a framework for intentionally added substance may not be appropriate for contaminants (naturally occurring, formed during heat processing, etc.) Post-market reviews address chemicals that have already undergone a pre-market review process. However, contaminants are distinct in that they do not go through this pre-market evaluation. By definition, contaminants are substances that are unintentionally present in food. Combining contaminants with other substances that have received pre-market review could inadvertently suggest to the public that all these substances were pre-approved, potentially leading to consumer confusion. This approach could mislead the public and blur important distinctions in the regulatory process.

Moreover, contaminants present different technical and policy challenges. While ingredients are intentionally added to foods, contaminants are often unavoidable and unable to be completely eliminated. Managing contaminants typically requires complex mitigation strategies including research on preventing contamination, implementing agricultural or processing interventions, modifications in global sourcing, and/or development of better analytical tools. Factors such as natural occurrence, and feasibility of reduction are unique and critical to contaminant management and should be reflected in any prioritization framework.

In addition, contaminants, such as heavy metals, are already addressed through separate regulatory mechanisms, including targeted risk assessments, action levels, guidance levels, and FDA-led initiatives such as the *Closer to Zero* program.

Should FDA decide to include contaminants with ingredients that are intentionally added in its prioritization of post-market assessments, we recommend the agency parse the two into separate priority lists for public disclosure and communicate clearly the distinctions between these two categories.

Transparency and Stakeholder Engagement

The undersigned FBIA organizations also encourage FDA to enhance transparency and stakeholder engagement opportunities in the implementation of the prioritization tool. The public would benefit from a clear description of the scoring and weighting system, including how each decisional criterion is evaluated and how final prioritization rankings are determined. Publishing this information would build trust in the process and allow the regulated community to provide informed input on chemical-specific prioritization decisions. FBIA also recommends that FDA publicly communicate that the consideration of a substance for prioritization is not in itself an indication of harm to public health, and that the objective of prioritization is to determine which substances should undergo a full post-market risk assessment. The agency should ensure that the purpose for prioritization is not confusing to the public and that subsequent scores are not inadvertently fueling potential existing misinformation. In addition, we urge FDA to establish a mechanism for regular stakeholder engagement, including opportunities for public comment on prioritized chemical lists and on future iterations of the prioritization tool itself. As the agency

refines this framework over time, it will be important to build informal avenues for feedback from public stakeholders, including industry, academia, and other interested parties.

Transparent Decision-Making Criteria

The FDA should clearly communicate the criteria and rationale used in decision-making processes and provide public transparency on the status of reviews and decisions. This includes:

- Detailed explanations of how food ingredients are selected for assessment and data sources used for prioritization;
- Transparent criteria for determining whether an assessment will be Focused or Comprehensive;
- Publicly available summaries of the Fit for Purpose Decision Tree outcomes and prioritization scores;
- Establishing criteria for risk-thresholds and risk management actions, especially if involving other regulatory agencies in the review process; and
- A public portal that serves as a centralized resource for stakeholders, offering a database of chemicals under review, real-time status updates, access to data, summaries of FDA decisions, and historical review timelines.

Conclusion

The below FBIA signatories to these comments share FDA's commitment to providing consumers with safe and nutritious food, and support the Agency's efforts to launch an enhanced systematic process for the post-market assessment of chemicals in food to ensure that existing clearances for these ingredients are based on the most current science and risk assessments and remain safe for their intended and authorized uses.

The following FBIA signatories appreciate the Agency's consideration of our recommendations. We look forward to further opportunity to comment on the development of FDA's post-market assessment program.

Sincerely,

1. Alliance for Chemical Distribution
2. American Bakers Association
3. American Frozen Food Institute
4. American Spice Trade Association
5. The Association for Dressings & Sauces
6. Calorie Control Council
7. Council for Responsible Nutrition
8. FMI- The Food Industry Association
9. Independent Bakers Association
10. International Dairy Foods Association
11. International Food Additives Council
12. Juice Products Association
13. National Confectioners Association

14. National Fisheries Institute
15. National Seasoning Manufacturers Association
16. North American Millers' Association
17. Refrigerated Foods Association
18. SNAC International