Sustainable Food Policy Alliance
1299 Pennsylvania Ave NW, Floor 12
Washington, DC 20004
info@foodpolicyalliance.org
(202) 337-0808

August 18, 2025

Dr. Martin A Makary
Commissioner
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. FDA-2025-N-1733-0001: "Tool for the Prioritization of Food Chemicals for Post-Market Assessment"

Commissioner Makary,

Sustainable Food Policy Alliance (SFPA) member companies Danone North America, Mars, Incorporated, Nestlé USA and Unilever United States appreciate the opportunity to review and comment on the Food and Drug Administration's request for comments entitled "Tool for the Prioritization of Food Chemicals for Post-Market Assessment." In addition to the comments below, we have also attached our Jan. 21, 2025, comments "Re: Development of an Enhanced Systematic Process for the Food and Drug Administration's Post-Market Assessment of Chemicals in Food; Public Meeting; Request for Comments (FDA-2024-N-3609)," which provide additional details of our position and our FY2025 funding request for FDA.

We support FDA's efforts to establish an enhanced post-market assessment of chemicals in foods. A dedicated workstream on post-market assessment will help enhance confidence in the safety of our food system and continue to guide industry in providing safe foods for American consumers. That is why our member companies have supported an increase in FDA resources for reassessment work, and why we hope that the Agency will be able to move quickly to establish these new processes.

As such, we appreciate this work by FDA to gather feedback on the prioritization criteria and methodology and the agency's commitment to transparency and scientific rigor that comes with subjecting the updated prioritization tool to comprehensive external review. A transparent prioritization process with criteria that meet the needs of public health and

stakeholders is of critical importance. Providing an opportunity for public comment, followed by an independent, third-party peer review, will help ensure that the tool is robust, credible, and reflective of a broad range of expertise and perspectives. We encourage the FDA to continue engaging diverse external reviewers and to make the outcomes of these reviews publicly available to further enhance accountability and transparency.

SFPA is supportive of a Multi-Criteria Decision Analysis (MCDA) Method. We believe that employing such methodology will help develop a systematic and reproducible process for prioritization.

We appreciate FDA's request for feedback on the scope, criteria, definitions, weighting utilized in the proposed methodology. We have several suggestions for FDA's consideration:

Prioritization of Contaminants vs. Intentionally Added Substances
FDA asked for feedback on the proposed approach to combine both contaminants and intentionally added substances—which include food additives, color additives, GRAS substances, and food contact substances—in the prioritization methodology. We believe that it may be more appropriate to separate the ranking and associated criteria for contaminants vs. intentionally added ingredients. FDA's actions in the contaminant space, such as their Closer to Zero program, address both safety and feasibility of further lowering contaminants in food commodities. As a result, toxicity and changes in feasibility are important criteria for prioritization. For intentionally added substances, safety assessments have already been performed, so scientific developments since the last safety assessment should be more prominent in prioritizing substances for review. Given these differences we encourage FDA to run parallel prioritization processes for contaminants and intentionally added substances.

Criteria & Definitions
We are supportive of the inclusion of both public health and other decisional criteria, recognizing the need to ensure FDA resources are being used efficiently to protect public health and maintain and improve public confidence in FDA's oversight of the food supply. While we are generally supportive of the criteria included in the methodology, we would like to recommend some refinement and clarification in certain circumstances detailed below:

- **Toxicity:** We agree with the different aspects of toxicity that are described in this rubric and propose that when considering each of these aspects, a Weight of Evidence approach be utilized. There are well-established, scientifically valid

approaches to evaluating and documenting a Weight of Evidence approach to considering available data. Implementing a Weight of the Evidence approach into the prioritization would allow for further refinement of the prioritization, by placing a greater emphasis on the substances in which the dataset, as a totality, indicates that further assessment would be warranted. In addition, FDA specifically asked for feedback on use of NAM(s) in developing scores for this criterion. It is critical to apply a Weight of Evidence approach that would allow a higher weighting to robust (e.g. validated at international level or sufficiently mature) studies whether those are NAMs or traditional safety studies.

- **Change in Exposure:** We support inclusion of this criterion as it can help to identify increases in exposure that have taken place due to changes in consumption (particularly over maximum exposure estimates used in previous assessments) or changes in categories of use since risk assessments were last used. We believe that changes in production volumes do not provide an accurate picture of changes in consumption, particularly if it is not possible to determine what volume of the increased consumption actually entering the U.S. food supply. Time efficient methods could be used to incorporate exposure assessment into the risk prioritization, such as extraction of data from other markets or through the use of high-throughput exposure data. We then suggest the addition of a preliminary risk assessment score to the overall prioritization framework, that is the integration of the available in vivo toxicology studies (prior to their extensive review as foreseen under the re-evaluation) with preliminary estimates of exposure. Such a way of initial prioritization is not unique, with examples available elsewhere to take inspiration from, e.g. the US EPAs Database-Calibrated Assessment Product.

- **Susceptible subpopulation:** It would be helpful for FDA to further clarify how they will define food "intended" for a susceptible subpopulation. The definition should take into consideration what and how such data could be used to identify such foods, given the challenge of informing whether a generic food category in summary databases (e.g. NHANES) is targeted toward a susceptible population.

- **New Scientific Information:** We encourage FDA to clarify the time window for what is considered "new" within this criterion. For intentionally added substances, we believe it would be appropriate for this window to include new science developed since the last safety assessment was completed. In addition, we encourage FDA to build a Weight of Evidence approach into this criterion. The description of this criterion could be changed to the following:

Description: Is new scientific information available (e.g., new toxicity or adverse health effect data or studies; improvement in detection methods or limits; new data or studies on absorption, distribution, metabolism and elimination (ADME)) that when considered along with the totality of existing evidence would impact or change the conclusions of the previous assessment? If yes, what is the potential impact?

- **Addition of a feasibility criterion:** As previously stated, we believe that contaminants should be prioritized separately from intentionally added substances. For contaminants, FDA policy has recognized that it is unfeasible to eliminate contaminants in the food supply and has accounted for feasibility in developing action levels. As part of this policy, FDA has also recognized that levels should be revisited as feasibility of mitigating contaminants changes. Therefore, we recommend that a feasibility criterion be included in prioritization for contaminants. For instance, this criterion could cover whether new technological advancements have become available that could help with contaminant mitigation.
    - **External stakeholder activity/attention:** We recommend that FDA put a clear timeframe associated with this criterion. We would encourage FDA to consider the timeframe to be the window between prioritization cycles. For instance, if prioritization is conducted once every two years, the "lookback window" for this criterion should be the previous two years. We recommend revisiting the scoring methodology for the external stakeholder activity criteria. The current approach, assigning one point for "low or no attention", may disproportionately influence the overall score. To ensure a more balanced assessment, we suggest eliminating the one-point assignment for minimal activity and redefining the current three-point score as the new baseline. Additionally, we recommend narrowing the scope of the highest score (9) by removing "national news/social media coverage" from its criteria. This type of influence may be more appropriately aligned with a mid-tier score (5), to better reflect its relative impact.
- **Other government decisions:** We would recommend that the scoring description of this criterion be changed from "restrictive action by" to "action by." In addition, we recommend that this criterion's scope be limited to actions that were a result of scientific assessments. Other actions that are not driven by scientific assessment are more closely related to public sentiment and fit more closely with other criteria FDA has proposed in the "Other Decision Criteria" category.

- We recommend revisiting the scoring methodology for the "other government decisions" criterion. Assigning one point for a recent permissive action may disproportionately affect the overall score, particularly when the substance has already been reviewed and authorized for use. To ensure a more balanced assessment, we suggest removing the one-point assignment for permissive action and redefining the current three-point score, "no action by other governmental agencies", as the new baseline.

- **Building Public Confidence**: The description asks if a post-market assessment is not conducted, what potential impact may it have on public confidence in the safety of the U.S. Food supply? SFPA believes that ensuring consumer confidence in the U.S. food supply is a paramount outcome of communicating to the public in clear, easy to understand language. It is the results of post-market assessments as well as the rationale for not conducting a post-market assessment, rather than a criteria for prioritization.

Weighting of criteria

FDA asked for feedback on the weighting of the various criteria. Overall, we recommend that FDA place greater weight on "Public Health Criteria" than "Other Decisional Criteria" as that will help the agency focus scarce resources where they may have the greatest impact on protecting the health of Americans. For intentionally added substances, we believe that new information tied to safety and public health should be given the greatest weight. New information (defined as information produced since FDA's last review of a substance) on the safety of an ingredient or changes in consumption above the levels evaluated in FDA's previous reviews are the most critical factors in identifying potential safety concerns that could require additional scrutiny. This will assist the agency in addressing potential public health impacts that have not previously been evaluated.

Among the "Other Decisional Criteria" we are supportive of placing greater weighting on "Other Government Decisions" as such actions are more likely to create greater consumer interest/concern and have high implications for food producers. In addition, government actions, which were the result of scientific assessments, are also a higher indicator of the potential need for FDA to reassess safety.

As the weights of various criteria are adjusted, clear communication on the weighting and hierarchy of these criteria is essential to ensure that the process remains transparent, predictable, and focused on addressing the most critical risks to public health. By explicitly outlining how different factors, such as public health impact, regulatory actions in other jurisdictions, and consumer interest, will be prioritized, the FDA will foster greater

stakeholder understanding and confidence in the process. In addition, as the prioritization methodology is implemented, we encourage FDA to set clear timeline expectations for how frequently prioritization will occur, publish the full list of prioritized substances, and publish the full scoring used for prioritization. This level of transparency on the various aspects of prioritization work will also support more meaningful engagement from the public and industry, ultimately strengthening the effectiveness and credibility of the FDA's post-market assessment efforts.

As food companies serving millions of consumers, we believe that robust federal oversight of food ingredients is essential for maintaining public confidence in the safety of our food system and for providing the industry with the predictability needed to produce safe and affordable foods for Americans. We appreciate the FDA's efforts to develop a systematic approach for prioritizing chemicals for post-market assessment, utilizing existing information about each food chemical.

Sincerely,

Peter Rowan
Vice President
U.S. Public Affairs
Mars, Incorporated

Hanna Abou-El-Seoud
Director
Corporate and Government Affairs
Nestlé USA Inc.

Stefani Millie Grant
Associate Director
External Affairs and Sustainability
Unilever US Inc.

Thomas Patrick Maloney
Director
Government and Industry Affairs
Danone North America