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

RE: Docket FDA-2025-N-1733: Tool for the Prioritization of Food Chemicals for Post-Market Assessment

August 18, 2025

To Whom it May Concern:

The International Dairy Foods Association (IDFA), Washington, D.C., represents the nation's dairy manufacturing and marketing industry, which supports more than 3 million jobs that generate $198 billion in wages and $779 billion in overall economic impact. IDFA's diverse membership ranges from multinational organizations to single-plant companies, from dairy manufacturers and cooperatives to food retailers and suppliers, all on the cutting edge of innovation and sustainable business practices. Together, they represent most of the milk, cheese, ice cream, yogurt and cultured products, and dairy ingredients produced and marketed in the United States and sold throughout the world. Delicious, safe and nutritious, dairy foods offer unparalleled health and consumer benefits to people of all ages.

IDFA supports the U.S. Food and Drug Administration's efforts to implement a proactive, robust, transparent post market assessment program for ingredients intentionally added to food and unavoidable chemical contaminants. We appreciate the opportunities we continue to be provided to shape and inform the development and implementation of this program, including opportunities to submit comments.

I. General Comments

IDFA specifically appreciates the FDA providing us with an opportunity to comment on its T*ool for the Prioritization of Food Chemicals for Post-Market Assessment* and we support the agency's approach of having this tool undergo robust peer review. Our ability to provide meaningful comments, however, is made more challenging because the agency's proposed *Enhanced Systemic Process for the FDA's Post-Market Assessment of Chemicals in Food* shared in a discussion paper with associated questions and open for stakeholder comment (Docket No. FDA-2024-N-3609) has not yet been finalized.

The aforementioned discussion paper describes a multi-step process that includes signal detection, triage, prioritization, scoping, scientific assessment (safety, risk, and/or hazard), risk management review, and risk management action. We recommend that the FDA confirm its current thinking on where in the overall Post-Market Assessment Process the prioritization step and application of the prioritization tool would take place for both Comprehensive and Focused Assessments, and whether the current document reflects an evolution in the proposal.

Given the current Administration's focus on food and color additives and GRAS substances, IDFA supports the FDA's efforts over the last year to elevate and develop a meaningful post-market assessment program that is science-based, data-driven, reproducible, and transparent. We believe it is essential that the prioritization process be largely driven by science, especially new scientific information that could change the prior understanding of risk and thus the risk management of a particular substance. Using peer-reviewed evidence-based data and following the weight of the evidence will ensure that FDA's decisions represent gold standard science and risk assessment. IDFA urges the FDA to continue to emphasize that the purpose of its prioritization tool is to score select substances for consideration for rereview and that the tool itself does not serve as a risk assessment of the substances scored.

It is very important that the public *not* interpret a high prioritization score to mean that a substance is harmful to human health or that it has the potential to be more harmful than substances with lower prioritization scores, when it simply means there is a reason to prioritize it for post-market assessment. Additionally, if a post-market assessment is conducted, it could result in a finding that there is no public health risk or a finding that the substance requires risk management and associated communication.

Lastly, the FDA states that a chemical's total risk score will *inform* its prioritization efforts but not determine its prioritization. The agency states that its risk managers and agency and department leadership will ultimately determine the prioritization of a substance. While we understand that politics, legislative and risk assessment activities of other governmental bodies and nongovernmental organizations, including industry, consumer and environmental advocacy groups, and public opinion will be factors considered by the agency when prioritizing its post-market assessment work, we urge the FDA to rely heavily on science to prioritize food substances for these rereviews.

II. Comments to Specific Questions in the Request for Information on FDA's *Tool for the Prioritization of Food Chemicals for Post-Market Assessment*

QUESTIONS 2.a. and c. and 3.a. relating to the appropriateness of Public Health criteria definitions and scoring.

- *IDFA supports the Public Health criteria identified for risk ranking chemical substances, but additional clarity and emphasis are needed.*

  IDFA supports the Public Health criteria identified for use with this tool including toxicity of the chemical, whether there is evidence of changes in exposure, consideration of susceptible populations who may consume the food and impactful new scientific information. With that said, IDFA offers the following recommendations for FDA's consideration:

  a) *Exposure:* To further improve the tool's relevance, FDA should consider data on current exposure to the substance in addition to any evidence of changes in exposure. Unless there is a consideration of current exposure, the output of the Public Health criteria will be hazards based and not risk based. The FDA should also emphasize that exposure estimation must relate to oral and not dermal or other types of exposure. IDFA would also be supportive of establishing separate criteria that would specifically account for absolute exposure. Importantly, FDA should be cautious about using production data to evaluate exposure because the data may not be representative of actual consumer exposure without considering how much of a substance is present in the U.S. food supply.

  b) *Susceptible Populations:* The FDA only explicitly identifies infants as a susceptible population in its tool. We would propose that a susceptible subpopulation for children up to three years of age as per the Codex definition for young child also be considered.

QUESTION 4.b. FDA is considering equal weighting among the Total Public Health Criteria Score and the Total Other Decisional Criteria Score to determine the overall Post-market Assessment Prioritization Score. i. Should different weights be applied when determining the overall Post-market Assessment Prioritization Score?

- Equal weight should *not* be given to the total Public Health and total Other Decisional criteria scores when calculating the overall Post-Market Assessment score. Public Health Criteria should greatly outweigh non-science factors.

IDFA opposes the equal weighting of total Public Health and total Other Decisional criteria. A data-driven and reproducible method for prioritizing post-market assessments must be grounded in science and the weight of the evidence and not based on subjective and unmeasurable activities by third parties and political bodies that may lack any scientific basis. The Institutes of Medicines defined public health as "what we as a society do collectively to assure the conditions in which people can be healthy;" this should be the ultimate objective of this prioritization process and justifies giving the Public Health criteria emphasis. Subjective "activities," "attention," "watching," and "monitoring," by 3rd parties are generally not measurable and difficult to meaningfully quantify or objectively score. In fact, as proposed, the three Other Decisional criteria would individually outweigh the four Public Health criteria. Moreover, with overlapping activities across the criteria, there is a risk that certain activities might impact the score of multiple criteria or may overlap with earlier stage signal monitoring. We urge the FDA to place far more emphasis on or to exclusively consider the Public Health criteria when ranking chemicals for post market assessments. If not exclusively considered, we believe the weight of the total Public Health score should be substantively higher than the total Other Decisional criteria when calculating the total ranked score.

IDFA also believes it is important to enable differential weighting between individual Public Health criteria. For example, if there is sufficient weight of evidence that a chemical may have a previously unaccounted for high risk and it is possible that there is a substantive current exposure, the Public Health criteria should overall have a high score irrespective of criteria such as a change in exposure or vulnerable subpopulations.

Given the FDA's limited resources, we strongly encourage the agency to focus those resources on analyzing scientific information and data. As stated, IDFA believes non-scientific and subjective information should be given no weight at all, or far less weight than scientific information, and we urge FDA not to direct the same level of resources towards the review of the political and public opinion landscape as is used to review the science and evidence.

QUESTION 6 – Additional Comments

- Unintentionally added environmental contaminants and intentionally added ingredients are extremely different categories of food substances with very different regulatory frameworks. In fact, environmental contaminants do not undergo pre-market safety reviews and therefore cannot technically undergo a "post market" assessment. As a result, we believe there should be two independent prioritization categories (intentionally added substances and environmental contaminants) and that the agency should consider how to factor in the feasibility and practicality of mitigating risks associated with environmental contaminants when ranking them.

If the FDA's tool is used to risk rank unavoidable environmental contaminants and intentionally added food and color additives and GRAS substances, IDFA recommends that the agency factor into the risk ranking process the feasibility and practicality of available mitigation options for environmental contaminants in food. IDFA is concerned

that prioritizing an unavoidable environmental contaminant with unrealistic or unmitigable risks will diminish consumer confidence in the FDA and/or the food system more generally and has the potential to confuse consumers. For certain contaminants that may be ubiquitous in the environment and not easily removed, there may be no practical or feasible means to mitigate their presence in food.

Moreover, due to limitations in current assay methodologies, detecting, characterizing, and quantifying certain environmental contaminants in food, such as polycyclic aromatic hydrocarbons (PAHs), can be challenging and ultimately impact risk mitigation. Maintaining a contaminant's priority risk ranking, potentially indefinitely due to the lack of available analytical methodologies or risk mitigation options, will not further FDA's public health goals and may erode public confidence in the agency by appearing to be indecisive and non-action oriented.

In addition to risk mitigation strategies, risk management and communication strategies for environmental contaminants will differ from those of intentionally added food substances. For all of these reasons, we strongly urge the FDA to separate unintentionally added environmental contaminants and intentionally added ingredients into two separate prioritization categories with accurate names for each category; rename the post market assessment program to include both categories; and create two distinct prioritization lists. This will make it easier for the FDA to educate consumers on the differences between the two categories and to level set on expectations for risk mitigation, with the potential to avoid consumer confusion and build consumer confidence in the FDA's human foods program.

- <u>The Tool's Scoring Results Should be Made Public</u>

With increased attention paid by the public and state legislatures to substances used in the manufacture of food, it is important that the FDA be transparent and share the results of its risk ranking including the details as to why a substance is or is not being prioritized for assessment. IDFA specifically recommends that the FDA share the individual scores for each criterion and the total scores for Public Health and Other Decisional criteria with the final score for each substance. As stated, information shared should always be accompanied by an explanation of the purpose of the substance's ranking on the list and a disclaimer that foods containing the substance are safe to eat pending rereview and further risk assessment. Finally, the FDA should also notify the public about the cadence for the risk ranking exercise.

In conclusion, IDFA appreciates the agency's efforts to develop its *Tool for the Prioritization of Food Chemicals for Post-Market Assessment* to be incorporated as part of the *FDA's Enhanced Systemic Process for the FDA's Post-Market Assessment of Chemicals in Food*. We recommend the agency place substantively more weight on or only consider the scientific criteria and minimize consideration or not consider at all the non-scientific criteria associated with the tool when scoring substances for prioritization. We also recommend that environmental contaminants be ranked separately from intentionally added food ingredients and that the ability to mitigate the risk be

considered as part of the ranking exercise for environmental contaminants. Lastly, we support transparency and the publication of FDA's results of prioritization and ranking of substances for assessments that include sufficient detail to ascertain why a substance is ranked higher or lower.

Should you have any questions on these comments please reach out to us.

Respectfully submitted,

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