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

Dear Food and Drug Administration,

Institute of Food Technologists (IFT) commends the FDA on their efforts to bring forward a post-market review prioritization tool that is science- based, data-driven, systematic, and reproducible. With many components across disciplines and stakeholders to consider in the prioritization, the IFT is grateful for the opportunity to provide comments, elevating the expertise of our community. IFT is a global organization of more than 11,000 members who are committed to connecting global food system communities to promote and advance the science of food and its application. We believe science is essential to improve food for everyone and ensure the global food system is equitable, sustainable, safe, and nutritious. We are pleased to share our commitment to science with our responses and feedback to the proposed "Tool for the Prioritization of Food Chemicals for Post-Market Assessment".

1. ***The purpose of the Post-market Assessment Prioritization Tool is to assist in making decisions about which chemicals, including both intentionally added substances and unintentional contaminants in food, are a priority to review. Is the modeling approach we proposed appropriate for this purpose? If not, please explain your reasoning and provide alternatives for FDA to consider. Please be specific and provide references, as appropriate.***
   FDA's effort to measure and weigh criteria in food safety, public health and other criteria, utilizing multi-criteria decisions analysis, is thoughtfully designed and reflective of input from multiple stakeholders but would benefit from transparency to build trust and confidence in the inputs and confirm if further stakeholder voices are needed. While it is clear the FDA seeks to ensure the prioritization, tool is grounded in science and informed by other decisional criteria, it is essential to ensure science is leading the consideration and food chemicals, specifically additives and contaminants, with scientific concerns are prioritized for further review to ensure protection of public health. This balance of science and other decisional criteria requires careful consideration, clearly delineating the purpose is to prioritize food chemicals for review, specifically additives and contaminants, and not a consideration of safety or assessment. It is essential FDA is transparent in both the development and utilization of the tool, from sharing the scorings and outcomes publicly to clarifying the strategic goals, objectives and sub-objectives. With this purpose in mind, IFT has several considerations to help further enhance the proposed tool.

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Modeling Approach: The Multi-Criteria Decision Analysis (MCDA) methodology could be enhanced to ensure reproducibility and consistency. Consider integrating best practices to MCDA methodology. One approach is outlined in the Practical Guide for Multi-Criteria Analysis, University College of London (Dean, January 2022).

Criteria Selection & Understandability: The current tool would benefit from clearer criteria for the objectives and sub-objectives (Mu, 2017) to ensure decision-makers and stakeholders alike have a shared understanding of assumptions, criterion, and dimensions of the problem (Mouter, 2020), (Dodgson, 2009), (Macharis, 2015).

Measurability and non-redundancy: The scoring approach and definitions are unclear, and some aspects appear to be redundant, which may lead to inconsistencies in scoring (Paulo Anciaes, 2020)**,** (Zeleny, 1982), (Keeney, 1992).

Equity: The current design may create equity concerns among stakeholders, as it may not adequately represent the concerns and priorities of all parties involved (Vanclay, 1999).

2. ***The draft Post-market Assessment Prioritization Tool currently includes four Public Health criteria and three Other Decisional Criteria.***
   a. ***Are the four Public Health criteria appropriate for the purpose of the tool? If not, please explain what changes might be considered and why.***

      The four general criteria are important to include, however, the specific descriptions and scoring for all four need further transparency to show how they are fit for purpose. It is unclear if the four criteria achieve the objectives and sub-objectives by the MCDA methodology, as these objectives and sub-objectives are not shared in detail. Additionally, there is also a lack of clarity on how the criteria are connected to the objectives, general goals, and fundamental values and principles of the MCDA value tree.

   b. ***Are the three Other Decisional criteria appropriate for the purpose of the tool? If not, please explain what changes might be considered and why.***

      As a prioritization tool and not a scientific assessment, including other decisional criteria could help support the FDA's broad objectives. However, when integrating additional subjective criteria in prioritization, it would be best to weight and consider them independent of the scientific considerations. Separating the considerations would help to ensure food chemicals, specifically additives and contaminants, with scientific concerns related to public health are prioritized.

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3. ***The draft scoring definitions for all criteria were developed to consider the expected variability in the types and extent of data available for the wide variety of food chemicals that may be considered for review.***
    a. ***Given this context, are the scoring definitions for the Public Health criteria appropriate for the purpose of the tool?***
        i. ***Are the definitions appropriately defined? If not, please describe changes that might be considered and why.***

        Further transparency on the fundamental principles, strategic goals, specific objectives and sub-objectives would help us better assess the appropriateness. For considerations in specific areas consider the following:

        3.1.1 Toxicity

        Consider adding "in silico" toxicity assessments and some built on AI tools (Myatta, 2018 July). Additionally, consider updating to have chronic toxicity as a separate type with bioaccumulation as a sub-set of that type (J.E. Hulla, 14 April 2014).

        3.1.2 Change in Exposure

        Change in exposure criteria, specifically who is being exposed to the food chemical, specifically additives and contaminants, is a critical question to consider in the criterion. A change in exposure for young adults is different from exposure for infants and young children in a high growth stage or pregnant women (Kordas, 2022). A rubric that considers demographic, age, nutritional deficiency, and genetics could better help frame a score (Silver, 2013,). Additional components to consider would be the amount consumed, preparation and conditions of use. The development of a more detailed rubric building off these components would improve the exposure criterion.

        3.1.3 Susceptible Population

        A three-way, Yes, Unknown, or No, scoring is limited. There are many sub-populations that have different susceptibilities. Evolving the current approach to a rubric, identifying the various sub-populations, defining susceptibility criteria for each, and linking to the exposure criteria, would better support prioritization of risk of vulnerable populations.

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3.1.4 New Scientific Information and Potential Impact

New scientific information and its potential impact is crucial consideration in the scoring process. Categorizing the types of new scientific data being evaluated and weighing them accordingly to ensure new findings that potentially flag a public health concern are appropriately prioritized for further assessment is essential to the usefulness of this tool.

ii. The toxicity criterion described in section 3.1.1 considers data for seven different toxicity data types and the score assigned reflects the highest toxicity data type score from the toxicity rubric, which is described in Appendix A Table A1. Is this the most appropriate strategy for assigning a toxicity criterion score? If not, please explain your reasoning and provide alternatives for FDA to consider. Please be specific and provide references, as appropriate.

Consider broadening the scale of the rubric for scoring along the lines of section 3.1.2 or 3.1.3 where the score of 3 was added. Having consistent scoring throughout the sub-sections of the tool is more likely to lead to consistency when summing scoring results in an MCDA type methodology. Furthermore, consider using a consistent 5-point scale or if ongoing, detailed, and refined, assessment of priorities is desired, a 7-point scale could be optimal for enabling statistical separation.

In addition to consistency in the scale used, a key consideration for the prioritization ranking tool is how many FDA subject matter expert's (SME's) will be completing the scoring tool for each section, as variation in both the number and the personnel involved may significantly impact scoring and make comparisons of prioritization outputs over time questionable (Joshi, Pai et. Al, 2015).

b. Are the scoring definitions for the Other Decisional criteria appropriate for the purpose of the tool?

i. Are the definitions appropriately defined? If not, please describe the changes that might be considered and why.

Scoring for Other Decisional criteria should be considered independently but if integrated, it should not be equally weighed. As noted in the scientific considerations in question 1, when integrating additional subjective criteria prioritization, it would be best to weigh and consider it independent of the scientific considerations. Separating the considerations would help to ensure food chemicals, specifically additives and contaminants, with scientific concerns related to public health are prioritized.

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ii. ***FDA is exploring quantitative and qualitative methods to help inform the scoring of the "building public confidence" criterion (Section 3.2.3) such as conducting public sentiment analysis (e.g., utilizing natural language processing). How might such tools or the information they provide be incorporated into this criterion? What additional strategies and metrics could FDA consider?***

Building public confidence in the FDA and our food system at large is critical and would be an outcome of a science-based, data-driven, systematic, and reproducible process for prioritization and resulting post-market assessment of food chemicals, specifically additives and contaminants. Instead of integrating qualitative measures in the prioritization tool, a separate process considering the sentiment, and other concerns, could be evaluated after the scientific components are completed. Since the criterion is seeking to achieve a separate goal for FDA, we believe it should be connected to objectives related to the goal of building public confidence, which is broader than post-market assessment prioritization of food chemicals, specifically additives and contaminants.

By making the prioritization tool transparent to all stakeholders and the public, confidence in FDA priorities in this area will build naturally.

4. ***The prioritization methodology includes weighting factors.***
   a. ***FDA is considering equal weighting among public health criteria and (separately) among the Other Decisional criteria for the Post-market Assessment Prioritization Tool.***
      i. ***Should different weights be applied to the Public Health Criteria when determining the Total Public Health Criteria Score? If so, please specify the weighting scheme that might be considered and why.***

Different weights should be applied to the Public Health Criteria, as these criteria have substantial implications. For example, exposure changes are likely to be frequent, whereas impacts on toxicity or research defining public health impact changes for susceptible populations are likely less frequent and more impactful to the overall goal of protection of U.S. population public health related to food chemicals, specifically additives and contaminants.

      ii. ***Should different weights be applied to the Other Decisional Criteria when determining the Total Other Decisional Criteria Score? If so, please specify the weighting scheme that might be considered and why.***

If the Other Decisional Criteria is included in the Prioritization tool it should not be equally weighted as the scientific criteria. It is essential that the tool is

grounded in science and those concerns based on new findings, evidence and science are prioritized for post-market assessment.

5. ***The draft toxicity rubric uses traditional toxicity data (in vivo, as well as limited in vitro such as for genotoxicity), human health outcomes (e.g., adverse event reports) and epidemiological data for determination of the toxicity criterion score within the Public Health criteria. Considering that the prioritization process is not a comprehensive review, please address the following questions.***
    a. ***How might FDA incorporate information from new approach methodologies (NAMS) into the toxicity rubric?***
        i. ***Are there specific NAMS (e.g., systems biology, engineered tissues, artificial intelligence, in vitro, micro physiological systems, or other alternative data modeling tools) that would be most appropriate for use in the toxicity rubric? If so, please explain which NAM(s) would be most appropriate and why.***

        Many of the new NAMs have a scientific role in toxicity evaluation and therefore should have some degree of inclusion in the rubric. However, their newness means that there are likely unforeseen issues that still exist vs. the traditional data approaches. Therefore, consider a separate data component in the rubric that is weighted less than a contribution from the other data type components. Regarding their own differences and limitations to each other, it is advisable to set sub-rubric for them to determine the NAM type component score for the total toxicity score.

    b. ***Threshold of Toxicological Concern (TTC) approaches can be used to assess the toxicity of chemicals (food additives and contaminants) that lack sufficient safety data and have low dietary exposures. Although the Cramer classification scheme has historically been used in TTC approaches, FDA has recently developed the Expanded Decision Tree (EDT) that assigns chemicals to one of six EDT classes. How might such tools or information they provide be incorporated into the toxicity rubric?***

    Use of such tools could be included as a modifier to the scoring, consider consistently using at least a five-level (Likert) scoring mechanism for all the Public Health Criteria (i.e., 9, 7, 5, 3, 1). If using a 5 level Likert scoring mechanism, it would be possible to use the TTC or EDT approach to modify the score by one level (up or down depending upon the view on data sufficiency). The TTC approach lacking as much safety data as other components could lead to a reduction in the prioritization score.

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6. ***Do you have any additional comments? Please share them in your review.***
   IFT supports the development of a prioritization tool for food chemicals, specifically additives and contaminants, to guide resource deployment by FDA in this critical need area. However, we believe that a tool should be used beyond Post-Market evaluations, but for all Food Additive and Contaminants. Developing an inclusive prioritization tool that could be used for prioritizing all aspects of Food Additive and Food Contaminant evaluation could provide guidance and heightened transparency to the tool development process and ultimately support the FDA's goals of protecting public health and improving trust and confidence in the FDA and our food supply.

Transparency and inclusion of stakeholders is crucial to building confidence. From the development and utilization of the tool and clarifying the strategic goals, objectives and sub-objectives to sharing the scorings and outcomes publicly, transparency and stakeholder engagement throughout is essential.

We are grateful for the opportunity to review and comment to enhance the development. IFT is open to collaborating and supporting the FDA in the development of this tool and is available for further discussions and support. Please contact Bryan Hitchcock at bhitchcock@ift.org or at 312-604-0225 regarding questions.

Sincerely,

Bryan Hitchcock
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