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January 21, 2025
Kristi Muldoon Jacobs
Director, Office of Food Chemical Safety, Dietary Supplements & Innovation
FDA Human Foods Program
Silver Spring, Maryland 20993
RE: Development of an Enhanced Systematic Process for the FDA's Post-Market Assessment of Chemicals in Food (Docket No. FDA-2024-N-3609)

Founded in 1939, the Institute of Food Technologists (IFT), is a non-profit, scientific organization with over 11,000 individual members. Our members hold roles in academia, government and industry with broad expertise including food laws, regulations, toxicology, food safety and other food science fields. Our mission is to advance the science of food and its applications across the global food system to ensure sustainable, safe, and nutritious food for all. IFT appreciates the opportunity to provide input on the FDA's development of an enhanced systematic process for post-market assessment of chemicals in food.

As noted in our previous oral comments, we believe it is essential that both pre- and post-market assessments ensure end-to-end transparency for approval of ingredients and foods. We commend the FDA's efforts toward transparency as evidenced by the release of the discussion paper, Development of an Enhanced Systematic Process for the FDA's Post-Market Assessment of Chemicals in Food and the September public meeting that engaged the public and key stakeholders. The proposal put forward includes considerable research, reviews, and discussion, and we appreciate the opportunity to provide feedback on the proposed process.

In the updated process the FDA must continue to be grounded in science, transparent in their assessment and analysis, and clear in their communication to the public. Specifically, the FDA needs to bring forward transparency in its review of information, signal monitoring, and horizon scanning efforts that identify and inform the FDA on potential ingredients that need review. The current monitoring process outlined is vague and does not indicate what level of evidence, consumer concern, scientific publications, and/or other activities would necessitate triage and consideration for assessment.

While the FDA should engage the public throughout the post-market assessment process with clear communications, there should also be a defined pathway for the public to submit concerns or comments for consideration in the signal monitoring phase. Following signal monitoring, the FDA should inform the public on the process, assessments, outcomes, and changes. A range of media and channels, including social media and other non-traditional media, should be used to connect with consumers. Providing the public with clarity on the prioritization, capacity, resource allocation, and timeliness of the process, will help manage the expectations of the public and foster increased trust.

In addition to engaging the public throughout the process, developing an advisory committee to help support prioritization, review frequency, and provide consultation on controversial topics would be beneficial. Any advisory committee should be appropriate to the needs, transparent in its makeup, selection, and duration, and help support the FDA's effort in a timely manner.

In considering the proposed fit-for-purpose decision tree, the overall questions are scientifically sound. To clearly highlight how the scientific questions would be applied, we recommend including examples of what would result in a focused vs. comprehensive assessment. We also recommend providing guidance on the strength and type of evidence needed for a focused vs. comprehensive assessment. The prioritization of risk schemes, while appropriate, would benefit from additional detail, particularly on toxicity.

Overall, the FDA's proposed two-pronged approach is appropriate and efficient for assessing the public health risk of chemicals in foods but needs additional detail to reduce ambiguity, principally in the signal monitoring, prioritization, decision tree determinations, and timelines for each step of the process.

IFT commends the FDA on its efforts to bring forward a post-market assessment of chemical food safety that is scientifically grounded and constituent informed. Building capacity for timely pre- and post-market assessment is critical to ensure public health, promote consumer trust in our food system. As FDA continues to develop the post-market assessment process, IFT will engage our membership and provide feedback to the FDA. IFT and our members are committed to helping ensure we have an adequate, safe, and nutritious food supply for everyone.

Please contact Bryan Hitchcock, Chief Science Officer & Executive Director Global Food Traceability Center (bhitchcock@ift.org, 312-604-0225) if IFT may provide further assistance.

Sincerely,

Bryan Hitchcock, IFT Chief Science Officer & Global Food Traceability Center Executive Director