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Public Meeting on FDA's Proposed Process for Post-Market Assessment of Chemicals in Food

The FDA recently reorganized Human Foods Program has made the reassessment of chemicals in the food supply one of its key priorities moving forward. The emphasis on chemicals follows recent state laws that ban certain food additives, in part because some states have perceived the FDA as slow to reassess chemicals once new science emerges. The Agency held a public meeting on September 25, 2024 to discuss its proposed Enhanced Systematic Process for the FDA's Post-Market Assessment of Chemicals in Food, which it outlined in a Discussion Paper published in August ("**Discussion Paper**").[1]

The FDA already engages in some post-market regulation of food additives, but it is reactive, limited, disjointed, and often does not allow for stakeholder engagement. Director of the Office of Food Additive Safety, Kristi Muldoon Jacobs, said there are currently only three circumstances when FDA examines a food additive already in the market—if a petition is submitted to FDA, in response to great public interest or inquiry, or it may be initiated by FDA experts who monitor literature or participate in public meetings.

In his opening remarks, Jim Jones, Deputy Commissioner for Human Foods, cited the increasing number of state laws on food additives as a source of pressure for the Agency rework its approach to food additive regulation. He noted that while the states are well within their rights to pass these laws, national uniformity would facilitate industry compliance and consumer confidence in food supply safety.

The stated goals are for the new process to be predictable yet flexible, transparent with opportunities for stakeholder participation, scientifically driven, and focused on public health.

Discussion Paper

The Discussion Paper proposed a process starting with a broad information review, with the help of Artificial Intelligence and Machine Learning software, to gather all possible sources of information that may indicate that a marketed food additive may need further assessment. In this initial detection stage, FDA proposes it will sweep all available sources, from scientific publications and regulatory actions in other countries to social media posts. FDA will then 'triage' the information to identify what merits further review and subsequently determine what type of review—Focused or Comprehensive Assessment—may be appropriate.

A Focused Assessment may be appropriate when a relatively low complexity issue is identified, and it would be limited in scope to the source of information identified, would not include formal public involvement, and the risk assessment and risk management review would be completed in about 4 -12 months.

A Comprehensive Assessment may be appropriate when the Focused Assessment does not produce a satisfactory conclusion or if the Agency determines at the 'triage' stage that the issue will be too complex or resource intensive to be resolved with a Focused Assessment. Before any substantive analysis, chemicals that are selected for Comprehensive Assessment would be prioritized using a scoring method that incorporates multiple risk factors like level of toxicity, scientific changes or increased exposure since the chemical was last assessed (if ever), and exposure of the chemical to vulnerable populations. The chemicals receiving the highest risk score will then be subject to a multi-step scientific

risk and safety assessment and risk management review. This process will allow for formal public involvement and is estimated it may take years to complete.

Public Discussion of Enhanced Systematic Process for the FDA's Post-Market Assessment of Chemicals in Food

The September 25, 2024 meeting included presentations from the Office of Food Additive Safety, consumer advocates from Environmental Working Group and Center for Science in the Public Interest, an industry representative from Consumer Brands Association, and Professor Norbert E. Kaminski, PhD offering an academic perspective. Members of the public submitted questions to a panel of three Agency representatives, and the final segment allowed stakeholders who registered to speak to deliver three-minute comments. This final segment brought comments from state and federal legislators, food industry advocates, consumer advocates, scientists, academics, and concerned citizens.

Stakeholders generally agreed that:

- The process must be publicly transparent (including public updates as each chemical progresses through the assessment steps);
- The FDA does need to review food additives, beyond the existing Generally Recognized as Safe ("**GRAS**") premarket notice system and any existing post-market review;
- The review process should be rooted in science; and
- The FDA needs to provide more clarity on how it will decide what chemicals will be reviewed and by which type of assessment.

There were also areas where the stakeholders disagreed, such as:

- Whether the initial information review should be limited to reliable sources of information;
- Whether the FDA should assemble a committee of expert advisors for either type of review or keep the assessment in-house;
- Whether the public should be involved in the prioritization step and if all chemicals should be prioritized by risk, not only those slotted by the Agency for Comprehensive Assessment;
- Whether pesticides or environmental contaminates should be reviewed with this framework; and
- Whether this framework or similar is sufficient to address risks presented by food additives that the Agency may not know are currently in the food supply, as many currently marketed additives have never received GRAS status.

Next Steps

In the Discussion Paper, the FDA specifically requested feedback on the following six questions:

1. When and how should the FDA engage the public on post-market assessments?
2. Is the frequency and mechanisms of the envisioned public engagement described in Section V of the discussion paper appropriate? If not, please provide alternative areas for engagement/communication, additional information that you believe should be shared publicly, and rationale for the change.
3. Should the FDA integrate an advisory committee review into our post-market assessment process? If yes, at what stage, and what should the committee's role be?

4. Are the Fit for Purpose Decision tree questions in Section III of the discussion paper appropriate? If not, what questions would you add or how would you modify the questions to be more appropriate to the task?
5. Is the Prioritization of Risks scheme the FDA outlines in this document appropriate for ranking food chemicals, (including contaminants, food ingredients, and those substances used in contact with food) for post-market assessments? If not, please explain why and how would you modify the Prioritization of Risks scheme? Please provide supporting rationale for the changes.
6. Is the FDA's two-pronged approach of Focused Assessments and Comprehensive Assessments appropriate to assess public health risks of chemicals in food? If not, please explain why and provide an alternative process, including rationale for such alternative(s).

The public comment period is open until December 6, 2024.[2] Dr. Muldoon Jacobs stated that the goal is to have the program implemented by the end of the 2025 calendar year.

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[1] FDA, Discussion Paper: Development of an Enhanced Systematic Process for the FDA's Post-Market Assessment of Chemicals in Food (August 2024) (available at: https://www.fda.gov/media/180942/download).
[2] Docket (FDA-2024-N-3609) (available at: https://www.regulations.gov/docket/FDA-2024-N-3609).