U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

Summary of Public Meeting on the Development of an Enhanced Systematic Process for FDA's Post-Market Assessment of Chemicals in Food

September 25, 2024

On September 25, 2024, the U.S. Food and Drug Administration (FDA) invited the public to attend a meeting titled "Public Meeting on the Development of an Enhanced Systematic Process for FDA's Post-Market Assessment of Chemicals in Food." The purpose of the public meeting was for the FDA to share the agency's enhanced systematic process for post-market assessment of chemicals in food and hear stakeholder perspectives on this proposal. Enhancing the FDA's approach to food chemical safety is among the agency's top priorities in the new Human Foods Program.

The feedback received from this public meeting, along with comments submitted to the accompanying docket, will help inform the FDA's thinking and further the development of the post-market assessment process. The docket remains open for comments until December 6, 2024. Electronic comments should be submitted through www.regulations.gov to docket number docket FDA-2024-N-3609. Written/paper submissions should be sent to Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All written comments should identify the docket number FDA-2024-N-3609.

Summary of comments from the public meeting:

The key themes and ideas raised during public comments by industry and consumer advocacy experts, government officials, research organizations, and other participants during the public meeting supported the FDA and our work to enhance the approach to food chemical safety, including the development of a systematic approach to the post-market assessment of chemicals in food. The themes and ideas listed below do not necessarily represent FDA viewpoints and are not exhaustive. A recording and transcript for the meeting will posted to the public meeting page in the coming weeks.

Overall Process

- Importance of an effective, consistent, transparent, systematic, and science-based post-market food chemical reassessment program that considers all relevant information about the potential risks of chemicals.
- Discussion of the steps in the process, such as prioritization and assessment, and the order of the steps in the process.
- Discussion of the scope of chemicals to include in the process, such as those intentionally added, indirect additives and/or environmental contaminants.
- Discussion of needed resources to support the improved organizational structure and the FDA's reenergized drive to enhance the agency's approach to food chemical safety in pre-market and post-market assessments.
- Importance of the FDA continuing to engage stakeholders in the development of this process and as the agency implements the process.
- Importance of FDA conducting timely assessments and taking timely actions to protect public health.

- Discussion of the FDA building capacity and expanding the FDA's authority for both pre- and post-market programs, including enhancing a program to monitor ingredients considered generally recognized as safe (GRAS).

Data Sharing and Engagement

- Discussion of the importance of exposure data to the process and developing new mechanisms that lead to industry sharing current safety and exposure data about chemicals on the market with the FDA.
- Importance of the FDA exploring opportunities to leverage the risk assessments and other scientific work done by federal partners and those in academia and research.
- Broad interest by stakeholders in continued engagement with the FDA to make steady progress toward its goal of enhancing food chemical safety.
- Discussion of when, how often, and mechanisms to engage stakeholders, including the public on post-market assessments.

External Reviews

- Discussion of the FDA integrating an advisory committee(s) review into the agency's post-market assessment process.
- Discussion of the use of peer review to help inform the agency's risk assessments.

Assessments

- Discussion of focused and comprehensive assessments and an interest in further clarifying the criteria used to determine the type of assessment that would be conducted.
- Discussion of the questions proposed for the Fit for Purpose Decision Criteria.
- Discussion about the type and amount of scientific data FDA should consider in the agency's assessments, including consideration of hazard, exposure, and cumulative effects.
- Discussion of the need for updated exposure assessments and using the best tools for exposure assessments.
- Discussion of the type of technical and scientific expertise the FDA should consider in staffing the post-market reassessment office.
- Exploring engaging the public on both focused assessments and comprehensive assessments.
- Importance of transparency on the assessments taking place, the cadence at which they will take place, and the timelines for the various types of assessments.
- Increased transparency about the tools used to conduct assessments.

Prioritization of Risks

- Discussion of risk prioritization and the multi-criterion decision analysis tool.
- Increased public engagement on which chemicals are prioritized for reassessment.

Additional Resources:

- Commenting Instructions: Public Meeting on the Development of an Enhanced Systematic Process for the FDA's Post-Market Assessment of Chemicals in Food (September 25, 2024)
- Discussion Paper: Development of an Enhanced Systematic Process for the FDA's Post-Market Assessment of Chemicals in Food

- FDA to Hold Public Meeting on the Development of an Enhanced Systematic Process for FDA's Post-Market Assessment of Chemicals in Food
- Public Meeting on the Development of an Enhanced Systematic Process for FDA's Post-Market Assessment of Chemicals in Food - 09/25/2024