

U.S. Food and Drug Administration (FDA) Public Meeting: The Development of an Enhanced Systematic Process for the FDA's Post-Market Assessment of Chemicals in Food

September 25, 2024 12:30 – 4:30 pm ET Great Room, White Oak Campus and Virtual

Docket No. <u>FDA-2024-N-3609</u> Comments Period Ends: December 6, 2024

In the <u>Federal Register</u> of August 12, 2024, the U.S. Food and Drug Administration (FDA) announced a public meeting and request for comments to engage with stakeholders and invite input on various topics included in the FDA's *Discussion Paper: Development of an Enhanced Systematic Process for the FDA's Post-Market Assessment of Chemicals in Food.*

The FDA is working to establish an enhanced systematic process for the post-market assessment of chemicals in food, including <u>ingredients considered generally recognized as safe (GRAS)</u>, <u>food additives</u>, <u>color additives</u>, <u>food contact substances</u>, and <u>contaminants</u>. The systematic process is intended to guide our post-market assessment work in the new Human Foods Program and will include a transparent process for identifying and prioritizing food chemicals currently in the market for safety reviews. This project is part of a larger <u>enhanced approach for food chemical safety</u>.

We invite interested persons, including those participating in the public meeting, to provide information on topics related to the process outlined in the <u>discussion paper</u>.

In particular, we welcome feedback on the following 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).

We will consider all comments made at the public meeting or received through the docket to help inform our thinking and further the development of the enhanced systematic process for the FDA's post-market assessment of chemicals in food.

The public comments are due on **December 6, 2024**.

There are two ways to comment:

Comment electronically at:

- Development of an Enhanced Systematic Process for FDA's Post-Market Assessment of Chemicals in Food; Public Meeting; Request for Comments - Docket No. <u>FDA-2024-N-3609</u> (https://www.regulations.gov/).
- **Electronic comments must be submitted on or before December 6, 2024.** Please note that late, untimely comments submitted after December 6, 2024, will not be considered.

Written comments may be mailed to:

Dockets Management Staff (HFA-305) Food and Drug Administration 5630 Fishers Lane, Rm. 1061 Rockville, MD 20852

Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before December 6, 2024.

NOTE: The comment due date indicated on Regulations.gov is based on Eastern Time. In this instance the comment due date is listed as December 6, 2024, so comments are due on that date by 11:59 PM ET. Also, please note that comments are not retrievable once submitted. To make changes, submit another comment referring to your previous comment correcting any errors and/or re-stating your position or opinion.