On September 25, 2024, the U.S. Food and Drug Administration (FDA) held a public meeting on the Development of an Enhanced Systematic Process for Post-Market Assessment of Chemicals in Food—namely, food additives, color additives, generally recognized as safe (GRAS) substances, substances used in contact with food, and chemicals present as unintentional contaminants. This meeting followed FDA's publication of a discussion paper on this topic.

Overview of the September 25 Meeting

At the outset of the meeting, Jim Jones, FDA's Deputy Commissioner for the Human Foods Program, set the stage by outlining the need for a formal post-market assessment review process. He highlighted increased consumer concerns and the emerging patchwork of state food additive and chemical bans. Importantly, Jones emphasized that despite limited resources, FDA plans to act in the short term to develop and implement a robust

approach to post-market surveillance.

Dr. Kristi Muldoon Jacobs, the Director of the Office of Food Additive Safety (OFAS), provided additional details on FDA's current thinking. Key highlights include:

- **FDA wishes to improve its transparency and stakeholder engagement for post-market review.** Dr. Jacobs cited the list of chemicals under FDA review on its website as a potential mechanism of informing and updating stakeholders. During the meeting, stakeholders asked FDA to consider additional opportunities for stakeholder engagement. For example, Sarah Gallo from the Consumer Brands Association urged FDA to consider seeking public input before implementation to avoid shocks or disruptions in the food supply chain.
- **FDA is a science-based agency.** FDA will continue to account for consumer concerns. At the same time, FDA made clear that reliable scientific information is paramount to the agency's decision making. Indeed, when asked during the Q&A session whether FDA will "exclude" industry-sponsored testing when reviewing information, Dr. Jacobs responded that "FDA does not want to turn down good data." She emphasized that data will be evaluated fairly and impartially.
- **Self-GRAS is authorized by the Federal Food, Drug, and Cosmetic Act.** Dr. Jacobs stated that FDA reviews GRAS conclusions as part of its GRAS Notice program and made clear that FDA does not always agree with a Notifier's GRAS conclusion, as evidenced from letters to notifiers available on its GRAS Inventory. However, she also noted that companies may self-affirm the GRAS status of a substance consistent with the Federal Food, Drug, and Cosmetic Act and FDA's GRAS regulations, and only Congress—not FDA—has the authority to amend the federal statute.

Proposed Post-Market Assessment Process

During the meeting, Dr. Jacobs outlined FDA's proposed process for post-market assessments. Specifically, FDA intends to evaluate substances (*e.g.*, food additives, color additives, GRAS substances, food-contact substances, and contaminants) using a "Fit for Purpose" process, which includes:

1. **Signal monitoring** using AI/machine learning where possible to monitor signals that indicate a substance may need to be re-evaluated.
2. **Triage** of the review by both AI/machine learning and FDA staff to identify relevant and quality information that warrants further consideration.
3. **FDA assessment through either a Focused or Comprehensive Assessment.** Following the triage process, FDA will determine the exact pathway using a number of factors, such as changes in exposure, susceptibility of vulnerable subpopulations (*e.g.*, infants), toxicity, new scientific information and potential impact, external stakeholder activity/attention, decisions made by other regulatory bodies (*e.g.*, JECFA, EFSA, etc.), and public interest. FDA anticipates that Focused Assessments (involving a more limited scope and without formal stakeholder engagement) will typically be completed within four months to one year, whereas Comprehensive Assessments (involving complex and resource-intensive substances and potentially multiple opportunities for formal stakeholder engagement) may take years to complete.
4. **Risk management review**, where FDA may propose taking regulatory actions (*e.g.*, recommending recalls, revoking authorization of food additives, etc.) or do nothing.
5. **Publication of final assessment and implementation of any risk management actions.** Depending on the regulatory action taken, there may be additional steps and opportunities for public comment before a final rule is issued.

An overview of the above process is displayed on page 6 of FDA's discussion paper. In addition to describing FDA's proposed process, the discussion paper poses questions on which the agency is seeking feedback, both during the meeting and through the comment period.

Next Steps

FDA is accepting comments on its proposed post-market assessment process until December 6, 2024. We encourage companies to contact us if they wish to submit comments or have questions on the proposed post-market review process.

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