

HHS, FDA Announce Multiple Initiatives on Food Safety, Quality and Compliance

Fronts

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By: Anna K. Abram, Nathan A. Brown, Oluwaremilekun O. Mehner

In the past week, the U.S. Food and Drug Administration (FDA), in collaboration with the Department of Health and Human Services (HHS) announced three new initiatives related to food safety and food supply chain transparency. Outlined below, these new initiatives align with HHS Secretary Robert F. Kennedy Jr.'s recent announcements to focus on bolstering food safety, including <u>the recent directive</u> to the FDA to explore the revision of the longstanding Generally Recognized as Safe (GRAS) rule.

Operation Stork Speed

On March 18, 2025, HHS and FDA announced "<u>Operation Stork Speed</u>," aimed at enhancing the safety, nutritional quality and availability of infant formula. Through this initiative, FDA plans to increase testing for heavy metals and other contaminants in infant formula. The agency is also calling on industry to "develop new infant formulas and clarify opportunities to help inform consumers about formula ingredients." The agency states that it will use "both longstanding and newly granted" authorities to carry out its stated goals, including:

- Issuing a Request for Information (RFI) to start a comprehensive update and review of infant formula nutrients;
- Increasing testing for heavy metals and other contaminants in infant formula and other children foods;
- Extending the personal importation policy; and
- Working with both industry and consumer stakeholders to increase transparency and collaborating with the National Institutes of Health (NIH) and other scientific bodies



to address scientific research gaps related to health outcomes associated with formula feeding.

Chemical Contaminants Transparency Tool for Foods

On March 20, 2025, the agency unveiled the <u>Chemical Contaminants Transparency Tool</u> (CCT Tool), a searchable online database that consolidates information on contaminant levels in human foods. The database lists the contaminant name, commodity, contaminant level type, level value and reference. To date, FDA has published a variety of contaminant levels for poisonous or deleterious substances in food in various guidance documents and regulations for industry. With the CCT Tool, the agency aims to consolidate this information for ease of reference. Certain contaminant levels such as allowable levels listed in the quality standard for bottled water and marine biotoxin safety levels are not included in the tool.

Extension of Compliance Date for Food Traceability Rule

Also, on March 20, 2025, the agency announced its intention to extend the compliance date for its 2022 final rule on Requirements for Additional Traceability Records for Certain Foods (Food Traceability Final Rule) by 30 months. Implementing Section 204(d) of the Food Safety Modernization Act (FSMA), the <u>Food Traceability Rule</u> mandates enhanced recordkeeping requirements for certain high-risk foods to improve the agency's ability to respond to foodborne illness outbreaks and contamination events. Citing concerns among covered entities about meeting the initial compliance deadline of January 2026, FDA plans to extend the compliance date using notice and comment rulemaking at a later date. FDA intends to engage with stakeholders and assist industry with implementation.

Industry participants should expect to see further policy updates and closely monitor forthcoming guidance.

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