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THE TOP FDA CONCERNS IN 2023

The infant formula crisis of 2022 still dominated FDA activity in the food sector throughout 2023. The agency issued numerous letters and guidances, both to help manufacturers protect the supply of infant formula and to show that it was proactively working to prevent another serious incident. There were three more infant formula recalls in 2023, which shows there are still issues in the industry that need to be addressed.

However, the FDA's activity wasn't isolated to one product. The agency dealt with a range of other foodborne illness recalls including a large outbreak of salmonella in cantaloupe and a growing concern for applesauce tainted with lead.

The FDA is not only looking to help manufacturers and distributors make their processes better, but it is also focused on improving its own systems. The agency is working to implement a major restructuring with the aim of adding more efficiency and accountability throughout the organization.

Infant Formula Update

Since the 2022 recall of infant formula due to *Cronobacter sakazakii* (*C. sakazakii*) contamination, ensuring the safety and availability of infant formula has been a top priority. In 2023, the FDA took additional actions to address safety challenges in the wake of the 2022 recall and the resulting infant formula shortage. These actions included 47 routine inspections of infant formula manufacturing facilities in accordance with the Food and Drug Omnibus Reform Act of 2022, as well as issuing warning letters to three infant formula manufacturers.

In March 2023, the FDA published a letter to the industry noting areas of concern identified during inspections, calling on companies to ensure they are in compliance with all regulatory requirements, and requesting voluntary notification to the FDA of any positive testing for *Cronobacter* or *Salmonella* in infant formula. The agency said that it should be notified even if the contamination is discovered before the affected product is distributed.

Internally, the FDA has initiated hiring to support a "dedicated investigator cadre" to inspect infant formula manufacturing sites. It also added staffing resources for the proposed new Office of Critical Food and updated its infant formula compliance program for investigators, analysts, and compliance officers.

Despite efforts by the agency and the industry to combat infant formula contamination, there were three additional formula recalls due to potential *C. sakazakii* contamination in 2023. One company announced a recall of one of its brands of formula on March 17, 2023. The recall was limited to 13 lots of the product and was issued out of caution rather than any positive tests from distributed products.

The two other recalls were initiated by a second company that had two prior incidents of its finished products testing positive for *C. sakazakii* in 2022. Following inspection of the company's Michigan and Minnesota facilities in late 2022 and early 2023, the FDA issued a warning letter to the company in August 2023. This letter discussed concerns with the manufacturer's root cause analysis and its failure to conduct whole genome sequencing.

While the second company's root cause analysis pointed to an ingredient manufactured by a third party, the FDA indicated that whole genome sequencing would have provided more information about the strain of *C. sakazakii*. The agency said this information, in turn, could have better informed the root cause analysis and the necessary corrective actions.

In February 2023, following additional FDA review of sanitation records from the Michigan facility and discussions with the agency, the company announced a recall of two batches of one brand of infant formula due to a risk of contamination. The product was manufactured in the same continuous production campaign as one of the samples that tested positive for *C. sakazakii*. This recall impacted approximately 145,000 cans of formula. It was followed by another recall of six batches for a different brand of powdered infant formula in late December after the Israeli Ministry of Health identified a positive finding during product sampling upon import. Upon notification from the Israeli Ministry of Health, the FDA initiated a for-cause inspection of the facility.

Subsequent testing by both the FDA and company has been negative for Cronobacter, although the manufacturer has expanded the recall to 19 countries. Given prior Cronobacter issues at the company's manufacturing facilities, as well as the FDA's August 2023 warning letter, it remains to be seen what, if any, further enforcement the agency may pursue following these recalls.

When the 2023 recalls are considered, three of the four largest U.S. infant formula manufacturers have issued a recall in the past two years.

Other Foodborne Illness Under Scrutiny

Outside of the FDA's ongoing efforts to combat infant formula contamination, the agency also published nine public health advisories arising from investigation of foodborne illnesses in 2023. While *Salmonella* and *Listeria* were the primary reasons for these advisories and the corresponding recalls, potentially toxic morel mushrooms, elevated levels of lead in applesauce pouches, and Hepatitis A contamination in strawberries were also concerns.

An outbreak of *Salmonella* infection in cantaloupes first reported in November 2023 resulted in one of the year's most widespread series of recalls. Growers initiated several recalls in late 2023. Later, nine more companies that further processed or repackaged the contaminated products were added to the recall. The contaminated products were distributed nationwide and were associated with 407 cases of illness and six deaths.

CFSAN Reorganization

In addition to its steady pace of enforcement actions, the FDA began efforts to restructure oversight of food under a new unified Human Foods Program (HFP) in 2023. The proposed changes arose from a report by the independent Reagan-Udall Foundation conducted in the wake of the infant formula crisis. The evaluation identified a number of areas for improvement including siloed operations, a lack of a single individual as a leader, and the need for internal agency reviews, clearly defined roles and responsibilities, and feedback from stakeholders and contributors.

Since the initial publication of the report in December 2022, the FDA has taken steps toward restructuring the Center for Food Safety and Applied Nutrition (CFSAN), the Office of Food Policy and Response (OFPR), and functions of the Office of Regulatory Affairs (ORA) under the new HFP. In August 2023, James Jones was named Deputy Commissioner for Human Foods and in December, the agency released its proposal for reorganization.

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Among the proposed changes, the ORA will be renamed the Office of Inspections and Investigations. In addition, an Office of Critical Foods will be established within the Nutrition Center of Excellence and be tasked with ensuring the safety of infant formula. Also included in the plan is making the Office of Coordinated Outbreak Response and Evaluation (CORE) & Emergency Preparedness responsible for preparing the agency for food-related outbreaks, including recalls.

The reorganization also establishes an Office of Integrated Food Safety System Partnerships, which would coordinate with state and local regulatory agencies to strengthen food safety and response activities. The proposed reorganization is currently undergoing the required external review process. The FDA hopes that it will be able to implement the plan during 2024.

What's Ahead for 2024

Based on its activities in 2023, it is clear that even as the major internal changes move forward, the FDA will continue its enforcement actions, especially around critical foods such as infant formula. However, it will need to clearly communicate to stakeholders which offices have oversight over which processes and how any mandatory reporting processes may change. There may be a transition period while food companies and regulators get aligned.

For further insight on U.S. product safety spanning the Automotive, Medical device, Pharmaceutical, Food and drink, and Consumer product industries, download the full edition of the **Recall Index report:**

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