

FDA Releases Infant Formula Risk Management Plan Fact Sheet

Article By:

Food and Drug Law at Keller and Heckman

- On November 22, 2023, FDA released a [one-page fact sheet](#) answering questions regarding the redundancy risk management plan requirement in the Food and Drug Omnibus Reform Act of 2022. The fact sheet is intended to provide information to manufacturers of critical foods, which FDA defines as any infant formula or medical food. The redundancy risk management plan requirement was established in response to the 2022 infant formula shortage caused by insanitary conditions at a formula plant that led to a voluntary recall and temporary production stoppage.
- The fact sheet describes the requirements for a redundancy risk management plan, which every critical food manufacturer is required to develop, maintain, and implement. According to FDA, a risk management plan may identify and evaluate risks to critical foods, as well as mechanisms to mitigate supply chain disruptions. A separate plan is needed for each manufacturing facility, but not for each product that is manufactured within the same facility.
- Additional safety information for consumers and manufacturers is available on FDA's infant formula landing page.

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