

What went wrong in 2022 baby formula crisis?

August 13 2024, by Laura Reiley



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A critical shortage of powdered infant formula revealed significant challenges in the supply, market competition and regulation of formula in the United States, according to a new report reviewed and co-authored

by Cornell researchers.

The [consensus study report](#), mandated by Congress and published July 25 by the National Academies of Sciences, Engineering and Medicine, found that resiliency planning across the baby formula sector is needed to reduce the likelihood of a supply-chain disruption and to adequately protect the formula supply from such disruptions, especially for the most vulnerable.

The committee concluded that the Food and Drug Administration could use its authority to require infant formula manufacturers to develop redundancy risk management plans to further safeguard against disruptions. It also suggested that messaging to parents and caregivers about formula should be streamlined, and identified the relatively high use of infant formula in the U.S. as potentially heightening the effects of a shortage, with breastfeeding as a possible buffer in future shortages.

"The committee's work is noteworthy because it used a vulnerability framework, previously used only for the study of drugs, to identify factors that needed to be addressed," said Kathleen Rasmussen, professor emerita in the College of Human Ecology, who was among the co-authors of the report along with reviewer Angela Odoms-Young, the Nancy Schlegel Meinig Associate Professor of Maternal and Child Nutrition in the College of Human Ecology and the College of Agriculture and Life Sciences.

The federal government began an investigation in 2022 after four American babies fell ill, two fatally, from a *Cronobacter sakazakii* [bacterial infection](#) after drinking powdered formula manufactured at an Abbott Nutrition plant in Michigan. The company voluntarily recalled 5 million units of powdered formula and closed the plant for five months to address problems identified by the FDA, sparking a nationwide shortage and skyrocketing prices.

More than half of infant formula is sold through the U.S. Department of Agriculture's food assistance program for mothers and babies, known as WIC. During the formula crisis, WIC recipients were disproportionately affected because their benefits allowed specific products from manufacturers that held the state-determined contracts.

Odoms-Young has worked in revising food packages for this and other government food assistance programs and in developing culturally responsive programs and policies that promote health equity, food justice and community resilience. Rasmussen was tapped for the committee due to her longstanding research on maternal and [child nutrition](#), including work on breastfeeding as well as the WIC program. Both Odoms-Young and Rasmussen are in the Division of Nutritional Sciences.

"We felt the consolidation of production, not necessarily manufacturers, was problematic," Rasmussen said. Before the 2022 crisis, Abbott had produced 40% of the nation's powdered formula, much of it at the Sturgis factory. And just three companies—Abbott, Mead Johnson and Nestlé Gerber—held the majority of the WIC contracts across the country.

Rasmussen said this consolidation of production can be problematic not only in the case of contaminants such as Cronobacter.

"We had to ask if this is just about Cronobacter, or is this a bigger problem with the entire supply chain," she said. "One of the things we learned was all kinds of other things can cause a shortage. With all of formula's ingredients, you have to think back to the sources."

Production has historically been consolidated in the Midwest, she said, for ease of shipment proximity to rail lines and via rivers. These places are now frequently subject to floods, tornados and other extreme

weather events.

"They have different hazards now than when these factories were built," she said. She also said that the committee found that many of the formula-manufacturing facilities were old and less modern.

"It's very expensive to create a factory from scratch," she said, so many are retrofitted from other uses. She also said to minimize potential pathogens, dry formula manufacturing lines should be separate from liquid ones. For the Abbott facility in Michigan, this was not the case.

But even beyond a focus on the country's manufacturers and supply chains, Rasmussen said the committee addressed how messaging about powdered formula needs to be clearer. Powdered formula is not a sterile product, unlike liquid formula, which undergoes a "kill stage" for pathogens that is not possible for powder.

Cronobacter infections are rare, and the vast majority of exposed children will never become ill. At particular risk are newborns and babies with compromised immune systems. Parents of infants need to be given consistent messages about the preparation and risks associated with powdered formula.

"What do the Centers for Disease Control and Prevention say? If you ask your doctors, what do they say? We felt the government had to have clear materials at every level, information that is consistently used by doctors and agencies," Rasmussen said. "It's pretty clear parents don't know about keeping formula scoops dry, about keeping the formula covered at all times."

The committee found that U.S. caregivers are inundated with marketing messaging about [infant formula](#), which affects purchasing and preparation decisions. That messaging, as with all nutrition guidance,

needs to be clear and consistent.

Drawing on the conclusions of the committee, the FDA aims to make regulatory adjustments and improvements to food safety protocols.

More information: Report: [Challenges in Supply, Market Competition, and Regulation of Infant Formula in the United States.](#)

Provided by Cornell University

Citation: What went wrong in 2022 baby formula crisis? (2024, August 13) retrieved 14 August 2024 from <https://phys.org/news/2024-08-wrong-baby-formula-crisis.html>

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