



## US infant formula crisis increases scrutiny of the FDA

Both Republican and Democrat legislators have called for changes following a shortage of breastmilk substitute. Susan Jaffe reports from Washington, DC.

The leading US producer of infant formula resumed partial operations on June 4 following a 4-month shutdown, but it may take several more weeks before supplies return to normal, along with the shortage-induced panic and desperation of American parents. When the US Food and Drug Administration (FDA) can regain trust in its ability to police the nation's food manufacturers is another matter.

The agency's failure to respond quickly to health hazards at the Abbott Nutrition facility in Sturgis, MI, that released potentially contaminated formula across the country has provoked rare bipartisan outrage in Congress and equally rare apologies from the manufacturer. The shutdown and resulting shortage have also prompted calls for major changes in the FDA's food safety division, along with questions about why one supplier dominates the market.

The FDA is responsible for the safety of a wide range of products that represent about 20% of all annual US consumer spending. They include artificial hips, dietary supplements, gene therapy products, surgical lasers, prescription drugs for both humans and animals, nanotechnology products, cosmetics, blood and biological products, tobacco and electronic cigarettes, and most of the domestic and imported food that Americans eat (except for meat and poultry). The 1100 employees of the FDA's Center for Food Safety and Applied Nutrition oversee more than 220 000 facilities that pack, process, and store foods, dietary supplements, and cosmetics. The centre currently has 180 vacancies, an FDA spokeswoman said.

With such broad and diverse responsibilities, critics claim that the FDA cannot give food issues sufficient oversight. It treats food

safety like "a second-class citizen", said Representative Rosa DeLauro, a Connecticut Democrat who chairs the powerful House Committee on Appropriations. "I believe that the FDA has failed to prioritize the safety of all foods that are sold on our market", said DeLauro, who has served 31 years in Congress and is a long-time advocate for federal health and science agencies. She is working with her House colleagues and US Senate leaders on legislation to address the structural, staffing, and policy problems that the formula crisis has exposed.

### Boosting supply

Abbott provides 40% of the nation's infant formula, which is a supplement to or, in some cases, a substitute for breastmilk for millions of babies. In addition to regular formula, the company makes a specialty formula designed for newborn babies who cannot tolerate breastmilk because of allergies or genetic disorders.

"Breastmilk is the gold standard for infants", said Ginger Carney, Director of Clinical Nutrition and Lactation Services at St Jude Children's Research Hospital in Memphis, TN. "It provides 100% of all the nutrition for young babies but sometimes it is not available", she said, or the infant cannot digest it. Specialty formula might be their only food. Older children and adults who get nutrition through feeding tubes also depend on other types of formula, she said. Among infants born in 2018 in the USA, 75% received formula exclusively or in combination with breastmilk during the first 6 months of life, according to the US Centers for Disease Prevention and Control.

The shortage has been particularly acute for low-income families who receive infant formula through the government's Special Supplemental

Nutrition Program for Women, Infants and Children (WIC). In 2020, the programme served almost half of the infants born in the USA. WIC is the largest purchaser of formula, which it buys from just three companies, including Abbott. WIC participants can only receive formula from one of these manufacturers designated by their state. Nearly half of recipients are limited to Abbott. In May, 2022, Congress passed a law lifting these restrictions when there is a shortage or other emergency so that recipients can get any formula available.

The FDA allowed operations to restart after Abbott signed a consent agreement settling a lawsuit by the FDA against the company. Under the agreement, the company will—among other things—permit unannounced FDA inspections and hire an independent expert to ensure that formula is free of contaminants.

Abbott expects to make specialty formula first, and to start shipping it around June 20, the company said in a statement. Production of regular formula will begin "as soon as we can".

Meanwhile, the FDA has waived some requirements usually imposed on foreign-made formula to expedite imports. So far, it has approved shipments from the UK, Australia, Germany, and Mexico.

### "We let you down"

In May, FDA Commissioner Robert Califf was pummeled with questions when he appeared before three congressional committees convened in less than a week to investigate the shortage. During his testimony before the US House of Representatives' Committee on Energy and Commerce Subcommittee on Oversight and Investigation, Califf recounted the events leading up to Abbott closing

For the Abbott-FDA consent agreement see <https://www.justice.gov/opa/press-release/file/1506076/download>

the Sturgis plant in February, 2022, the same month he became Commissioner.

Generating the most criticism and disbelief from committee members was the FDA's slow response to a whistleblower complaint in October, 2021, from a former employee at the Sturgis facility, alleging a host of unsanitary conditions at the plant. 2 months passed before the FDA interviewed the whistle-blower in December. The complaint reached top FDA officials 4 months later, in February, 2022, due to what Califf described as COVID-19-related understaffing in the agency's mailroom.

On Jan 31, 2022, 3 months after receiving the complaint, the FDA inspected the Sturgis facility, despite Abbott's multiple requests for a delay because of an outbreak of COVID-19 at the plant.

By February, the FDA had received a total of four reports of infants infected with *Cronobacter sakazakii* bacteria after consuming formula from the Sturgis plant. Two of the children died and *Cronobacter* may have contributed to their deaths, said Califf. As a result of these cases and the January inspection, the FDA asked Abbott to recall its products.

Abbott voluntarily ceased production at the plant on Feb 15 and agreed to recall its infant formula on Feb 17. The same day, the FDA issued an advisory warning consumers not to buy certain formula products made by Abbott.

More than 3 months after the whistleblower's complaint and 2 months after the January inspection, the FDA released its inspection report on March 18, 2022. It found *Cronobacter* bacteria on multiple surfaces in the plant, and other conditions that increase the risk of contaminated product, including cracks in processing equipment, multiple water leaks and moisture, and puddles of water on the floor.

Califf called the findings "shocking" and admitted that it took too long to inspect the plant after receiving the whistle-blower's complaint.

Abbott's Christopher Calamari, Senior Vice President, US Nutrition, testified

before the same committee about the precautions that the company takes to ensure its formula is safe. He also described its efforts to increase supply, including airlifting millions of cans of formula from its FDA-registered facility in Ireland. He blamed supply-chain disruptions for the formula shortage.

However, he also told the committee, "we let you down and we are going to do everything we can to earn your trust". Asked for details, Calamari said that the company has installed non-porous floors and increased employee training. "We are going to learn from this."

Calamari's remarks did little to mollify the committee. "I'm actually livid at what happened at Abbott's Sturgis plant", said Representative Jan Schakowsky, an Illinois Democrat. Instead of apologising to Congress, she told him, "you owe an apology to the parents of children who got sick and... to all the families out there who are really struggling and suffering because they can't get the product that you produce so much of".

An Abbott representative later confirmed that there is no date for resuming production of non-specialty infant formula, in a written statement to *The Lancet*. The official did not respond to questions about why the company was seeking to fill as many as 97 positions in Michigan.

### Changing the system

In May, 2022, legislation that DeLauro introduced to provide US\$28 million in emergency funding to the FDA passed in the Senate by a voice vote, and the House approved it without a single Republican vote. About \$22 million will be used as a long-term investment to hire up to 75 people to inspect infant formula facilities and to review applications from companies to sell formula in the USA, according to a source familiar with the matter. The remaining \$6 million will target immediate needs, including boosting the infant formula supply. Representative Buddy Carter, a Georgia

Republican who is also a pharmacist, opposed the measure, even though his 7-month-old granddaughter depends on infant formula. He said that his wife has appealed to extended family members across the country for help finding it.

"The FDA had the tools to predict and prevent this crisis; instead, they did nothing", Carter said. He blamed the shortage on regulations that prevent importation of formula. "Sending another \$28 million to the FDA will not put formula on the shelves—it merely pumps more money into a broken system with zero accountability or safeguards to prevent a similar future crisis."

"I don't want to throw more money into a broken system, that's why I want to change the system", said DeLauro. On June 3, she proposed legislation intended to close several of the regulatory gaps that the formula shortage has uncovered. It would allow the FDA to conduct unannounced inspections and make *Cronobacter sakazakii* a reportable disease. It would also require companies to provide microbial test results during inspections, direct producers of infant formula and other essential medical foods to report potential shortages to the FDA, and mandate the FDA to maintain an updated list of manufacturing facilities that could be used to make infant formula.

DeLauro is also planning to reintroduce a bill to create a separate food safety agency to conduct independent investigations, much like the Transportation Safety Board investigates plane crashes. Without one responsible agency, DeLauro said, "you have people pointing fingers at one another".

And without independence, DeLauro said, Califf's decision to appoint someone from inside the FDA to review the agency's role in the formula shortage is like putting "the fox in the henhouse".

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