



Why There's a Baby Formula Shortage

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As the US continues to grapple with a nationwide infant formula shortage, Congress has passed a measure to help families in need. The Access to Baby Formula Act, which seeks to ensure that low-income families can buy more types of formula, was approved Thursday in the Senate by unanimous consent after passing the House. It now heads to President Joe Biden for his signature.

Another measure -- a \$28 million emergency spending bill intended to increase the number of FDA inspectors, prevent unapproved formula from entering the country and improve data collection on the industry -- was approved by the House on Wednesday. Its fate in the Senate, however, is less assured.

The problem dates back to a recall after possible contamination at a Sturgis, Michigan, factory owned by Abbott Nutrition, the maker of Similac and other popular baby formulas.

According to retail market analysis firm Datasembly, ongoing supply chain constraints, product recalls and inflation concerns have added to the shortage.

Here's what you need to know about the shortage of infant formula, including what caused it, why it's so serious and when it may end.

Why do we have a baby formula shortage?

In September 2021, an infant in Minnesota given formula manufactured in Abbott's Michigan factory was diagnosed with *Cronobacter sakazakii*, a potentially lethal bacteria.

Cronobacter is rare, but it can cause sepsis or meningitis and even lead to death in infants.

At least four more babies given formula from Abbott's Sturgis facility fell sick in the following months, three with *Cronobacter sakazakii* and one with *Salmonella newport*. Ultimately, two infants in Ohio died from *Cronobacter* infection. Another baby was hospitalized for three weeks before recovering.

As the infections were under investigation, the Food and Drug Administration received a report in October from an ex-employee alleging poor sanitation standards at the factory and the doctoring of records to hide inadequate quality checks.

After an FDA inspection of the facility in February, Abbott voluntarily recalled a number of batches of its Similac, Alimentum and EleCare infant formula brands. Abbott also ceased production at the factory.

In a May 16 statement, Abbott said it conducts microbiological testing on products before distribution "and no Abbott formula distributed to consumers tested positive for *Cronobacter sakazakii* or *Salmonella*." It added that an investigation by the Centers for Disease Control and Prevention found no link between Abbott formulas and infant illnesses.

Still, Abbott is the largest of only a handful of baby formula manufacturers in the US, and accounts for more than 40% of the market. Thus the recall and plant closure cratered supply.

The crisis has also fueled formula hoarding, which has made the deficit worse, along with reports of price gouging. Some stores, including CVS and Walgreens, have limited customers to three formula purchases per visit.

Why is the formula shortage such a big deal?

Less than half of newborns in the US are breastfed exclusively in the first three months of life, according to the CDC, and one in five are given formula in the first few days.

Some mothers or babies have difficulty breastfeeding, and infants may be given formula to encourage weight gain. Changing formulas suddenly can cause digestive issues, and babies with allergies or certain medical conditions require specific formulas.

"If your baby is allergic to standard formulas and you need a broken-down formula, then it's critical that you stick to that same type of formula," Steven Abelowitz, medical director of Coastal Kids Pediatrics in Orange County, California, told CNET previously.

The shortage isn't impacting all Americans equally, either.

"The families who have fewer resources, have fewer options, who aren't able to pay premium prices are going to be more at risk," Ann Kellams, board president of the Academy of Breastfeeding Medicine, told Vox.

The Special Supplemental Nutrition Program for Women, Infants, and Children, a federal program commonly known as WIC, provides food assistance to low-income families. Individual states dictate which brand of formula is covered by WIC, and Abbott Nutrition's Similac formula, the leading brand in the US, is one of the major suppliers to the WIC program.

That means parents of the estimated 1.7 million infants in WIC haven't had a lot of options.

What did the whistleblower accuse Abbott of doing?

The whistleblower's report, first detailed by Politico in late April and later shared by Rep. Rosa DeLauro, chair of the House Appropriations Committee, alleges:

- **Falsification of records.** Among other charges, the whistleblower alleged that Abbott shipped untested formula and falsified maintenance records.

- **Lack of traceability.** According to the report, the factory's automatic labeler frequently failed to work properly, making it difficult to track down potentially contaminated products.
- **An atmosphere of retaliation.** The whistleblower maintained that "despite an admirable employment record at Abbott and elsewhere," he was terminated after raising concerns repeatedly.

In addition, the FDA's investigation found that Abbott "did not ensure that all surfaces that contacted infant formula were maintained to protect infant formula from being contaminated by any source."

How has Abbott responded to the allegations?

Abbott did not respond to a request for comment. The company said in an April 28 statement that its focus "has, is and always will be to ensure safe food for families who rely on us for our high-quality nutrition products."

It maintains infant formula produced at the Sturgis facility "is not likely the source of infection."

No products from the plant tested positive for *Cronobacter sakazakii* or "any known infant illness," according to Abbott.

Inspectors found evidence of *Cronobacter* bacteria in the plant, but not in any areas in contact with formula, Abbott said, and the strains that were detected did not match those found in the infected children.

According to the release, the former employee had been "dismissed due to serious violations of Abbott's food safety policies."

Can the US import formula from other countries?

The FDA requires manufacturers to meet specific nutritional standards for infant formula that differ from guidelines in Canada, Europe and elsewhere. That makes bringing in formula from other countries difficult.

At a May 16 briefing, FDA Commissioner Robert Califf said the agency was loosening restrictions on imported infant formula products to improve supply "efficiently and safely."

"We anticipate that those products that can quickly meet safety and nutrition standards could hit US stores in a matter of weeks," Califf said.

In addition to setting health standards, the US government also levies heavy tariffs on imported baby formula -- up to 17.5%, according to the Cato Institute. And as part of a trade agreement negotiated by President Donald Trump in 2020, Canada agreed to impose a \$7.26-per-pound surcharge if its global formula exports surpassed 44,620 tons annually.

Infant formula accounted 22% of all US dairy imports into Canada last year-- the largest product in the category -- but the US didn't import any from our neighbor to the north.

When will the baby formula shortage end?

Abbott Nutrition announced an agreement with the FDA on May 16 that will allow it to resume production in the Michigan factory in about two weeks, meaning formula produced there could hit supermarket shelves in about six to eight weeks.

By that time, imported formula should also be available in US stores. (Abbott is also flying formula in from its plant in Ireland.)

In addition, President Biden on May 18 invoked the Defense Production Act to force suppliers to prioritize the production of infant formula and authorized the Pentagon to use commercial flights to import supplies from abroad.

On May 19, the White House announced the first transport will bring to bring Nestle formula from Switzerland to Indiana, where it will then be distributed to areas nationwide with the worst shortages. According to White House, the effort will bring "up to 1.5 million 8-ounce bottles of three formulas -- Alfamino Infant, Alfamino Junior, and Gerber Good Start Extensive HA -- all of which are hypoallergenic formulas for children with cow's milk protein allergy."

A senior White House official told CBS News that the Switzerland transport could begin "within days."

What is being done to prevent future shortages?

The \$28 million emergency funding bill would help prevent future shortages, according to Rep. DeLauro, who is also challenging the FDA for reacting "far too slowly" in addressing possible contamination at the Michigan facility.

"Why did the FDA not spring into action?" DeLauro said in a statement on April 28. "Why did it take four months to pull this formula off store shelves? How many infants were fed contaminated formula during this time?"

DeLauro, who is on the House Appropriations subcommittee that oversees the FDA, has requested the Department of Health and Human Services' Inspector General's office investigate the agency's actions.

She also indicated hearings will be held "to find answers into how this happened and how we can prevent it from ever happening again."

Speaker of the House Nancy Pelosi told reporters on May 17 that there "might be a need for indictment[s]" in the wake of the FDA investigation into Abbot Nutrition, but did not specify who might be charged.

"The baby formula emergency also serves as a critical reminder of the urgent need to invest in strengthening our supply chains," Pelosi added.