

Abbott Reaches Agreement With Department Of Justice To Resolve Claims Relating To 2022 Infant Formula Recall

- Settlement does not represent any finding of fault or liability
- As the government has previously indicated, it has closed its criminal investigation on this matter
- Tests by government regulators of unopened product from the homes of the infants under investigation at the time of the 2022 recall were negative for *Cronobacter sakazakii*
- No unopened, distributed Abbott infant formulas have ever tested positive for *Cronobacter sakazakii*

ABBOTT PARK, Ill., Sept. 14, 2026 /PRNewswire/ -- Abbott (NYSE: ABT) has reached an agreement to resolve the previously disclosed investigation and lawsuit brought by the United States Department of Justice, as well as lawsuits filed by certain relators and the Attorneys General of several states, relating to Abbott's manufacturing and 2022 recall of powdered infant formula at its facility in Sturgis, Mich.

Abbott will pay a total of \$385 million to resolve the claims. The settlement does not represent any finding of fault or liability.

Additionally, as the government has previously indicated, it has closed its criminal investigation regarding this matter.

Importantly, no unopened, distributed Abbott infant formulas have ever tested positive for *Cronobacter sakazakii*. Consistent with this, the FDA confirmed in early March 2022 that the unopened product from the homes of the infants under investigation at the time of the 2022 recall tested negative for *Cronobacter sakazakii*. The CDC later concluded there was no definitive link between the Sturgis facility and the clinical cases under investigation at that time. Read more details below in Frequently Asked Questions.

Nothing matters more than the safety and quality of Abbott's products. We make infant formula with the same care we would for our own families and are deeply committed to earning and maintaining caregivers' trust. As we move forward, Abbott remains focused on serving the families who depend on us every day.

Frequently Asked Questions:

What is *Cronobacter*, and where is it commonly found?

- *Cronobacter* is a ubiquitous bacterium that is known to harbor in homes (especially kitchens), bottled water and unsanitized feeding equipment (like breast pumps), as well as all infant formula manufacturing facilities.
- A [study published in July 2024 in the American Society for Microbiology's Applied and Environmental Microbiology](#) journal showed that out of 263 households in the U.S., 36% had at least one environmental positive swab for *Cronobacter* spp. and 25% had *Cronobacter sakazakii*, confirming its ubiquity. And those findings were based on an average of just 10 swabs per house.

Were the lots of the products consumed by these infants tested for *Cronobacter sakazakii*?

Yes, they were tested. No unopened, distributed Abbott infant formulas have ever tested positive for *Cronobacter sakazakii* or *Salmonella Newport*.

Additionally:

- Abbott retains samples from all lots of all products distributed.
- Samples from the lots that corresponded to those that were consumed by the infants were tested. All tested negative.
- Genetic sequencing on the available samples from two of the ill infants did not match the strains of *Cronobacter* found in the plant. Nor did the available samples from the infants match one another, indicating that the two cases did not have a common source. That's important because microbiologists tell us that the DNA sequence is a critical element for determining origin. Institutions performing the testing of the other three infants did not retain or provide the clinical sample for Whole Genome Sequencing (WGS). The lack of this data is not a miss from Abbott Nutrition.

What did government regulators' testing of the formula linked to the reported infant illnesses reveal?

In all five cases, the state, FDA, and/or CDC tested samples of the Abbott formula that was used by the child.

- In all five cases, all unopened containers tested negative.
- Open containers from the homes of the infants were also tested in four of the five cases; three of the four tested negative.
- The one positive was from an open container from the home of the infant, and it tested positive for two different strains of *Cronobacter sakazakii*, neither of which were found in the Sturgis plant. In fact, one matched the strain that caused the infant's infection, and the other matched a strain found on a bottle of distilled water in the home used to mix the formula. Notably, these findings are significant because it was these five complaints that ultimately were the reason for the recall.
- Further, FDA testing of product batches and retained product samples collected from the Sturgis facility during the inspection were all negative for *Cronobacter sakazakii* and *Salmonella*.
- We later learned in March 2023 through a CDC report that *Cronobacter sakazakii* was recovered from breast pump parts used in the home of one of the four infants the FDA was investigating in 2022.

Has the CDC commented on Abbott's recall in Sturgis?

In a [video posted by the National Academies](#), CDC scientists look back on the Sturgis recall; in particular, Dr. Julia Haston explains (presentation beginning at approximately 1:03), among other things:

- The cases did not meet the definition of an "outbreak."
- There was "no definitive link" between the Sturgis facility and the cases investigated.
- One of the four cases was "linked to PIF [powdered infant formula] that was likely contaminated in the home after the formula was opened."
- CDC's investigation found five invasive *Cronobacter* infections unrelated to the Sturgis facility.
- Powdered infant formula investigations "most often suggest that contamination [with *Cronobacter*] occurs in the home."
- "For *Cronobacter*, most cases linked to infant formula are not associated with an outbreak."

Have other infant formula manufacturers experienced similar issues?

Yes. Following Abbott's 2022 recall, [multiple infant formula manufacturers](#) have reported *Cronobacter*-related findings in manufacturing facilities, [and in one instance](#), in finished, distributed product.

What should parents and caregivers take away?

The [CDC](#) states:

- *Cronobacter* bacteria are found naturally in the environment.
- *Cronobacter* bacteria can contaminate dry foods, including powdered infant formula, and feeding items like breast pump equipment.
- To prevent babies from getting *Cronobacter* infection:
 - Breastfeed if you can.
 - Clean, sanitize and store infant feeding items safely.
 - Keep hands and surfaces clean.
 - Prepare and store formula safely.

About Abbott:

Abbott is a global healthcare leader that helps people live more fully at all stages of life. Our portfolio of life-changing technologies spans the spectrum of healthcare, with leading businesses and products in diagnostics, medical devices, nutritionals and branded generic medicines. Our 122,000 colleagues serve people in more than 160 countries.

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