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Technical Bulletin

Date: Update: March 1, 2022
Topic: FDA Recall on Powdered Infant Formula and Multistate Investigation of *Cronobacter sakazakii* Infections Associated with Powdered Infant Formula
Contact: Melissa Peek-Bullock, State Epidemiologist, Division of Public and Behavioral Health
To: Consumers (Parents and Caregivers), Public Health Authorities, Health Care Providers, and Laboratories

Background:

The Nevada Division of Public and Behavioral Health (DPBH) is working with the U.S. Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration (FDA) to investigate cases of *Cronobacter-sakazakii* infection in multiple states linked to powdered infant formula that originated from a single Abbott Nutrition production facility in Michigan. Three brands of powdered infant formula were recalled on February 17, 2022, for possible *Cronobacter* contamination. FDA is investigating several consumer complaints about sick infants who were fed powdered formula.

From September through December 2021, FDA received four consumer complaints of infant illness due to *Cronobacter-sakazakii* (3) and *Salmonella Newport* (1) following consumption of powdered infant formula from Abbott Nutrition's Sturgis, Michigan facility. Cases currently span the following states: Minnesota, Ohio, and Texas. Limited patient information is available at this time; all four illnesses resulted in hospitalization, and *Cronobacter* may have contributed to death in one case. FDA inspection of the Sturgis Michigan facility yielded several positive *Cronobacter* results from environmental samples taken by FDA, and adverse inspectional observations by FDA investigators. Review of the firm's internal records also indicated prior environmental contamination with *Cronobacter sakazakii* and the firm's destruction of product due to the presence of *Cronobacter*. Abbott reported that testing of distributed powdered infant formula was negative for *Cronobacter sakazakii*. There have been no samples or past records indicating the presence of *Salmonella* in the facility; therefore, it is unclear if the *Salmonella Newport* infection was associated with the consumption of powdered infant formula.

As of February 28, 2022, CDC has announced one additional illness of *Cronobacter sakazakii* with exposure to powdered infant formula produced at Abbott Nutrition's Sturgis, MI facility. *Cronobacter* infection may have been a contributing cause of death for this patient. In total, this investigation includes four reports of *Cronobacter sakazakii* infections in infants (three from FDA complaints and one from a CDC case finding) and one complaint of a *Salmonella Newport* infection in an infant. All five (four *Cronobacter* infections and one *Salmonella Newport* infection) illnesses resulted in hospitalization and *Cronobacter* may have contributed to death in two patients.

The most recent patient was reported to have consumed Abbott Nutrition's Similac PM 60/40 product with the lot code 27032K800 prior to *Cronobacter sakazakii* infection. This is a specialty formula for certain infants who would benefit from lowered mineral intake and was not included in the previous recall. On February 28, 2022, Abbott Nutrition voluntarily recalled Similac PM 60/40 powdered infant formula with the lot code 27032K800. Please see the *What Patents and Caregivers Should Do* section below for additional information on recalled products.

Cronobacter sakazakii, formerly known as *Enterobacter sakazakii*, is an organism found naturally in the environment. It can live in dry foods, such as powdered infant formula, powdered milk, herbal teas, and starches. *Cronobacter* can cause diarrhea and urinary tract infections in people of all ages, but infection can be very serious in infants.

Cronobacter infections are rare, but they can be deadly in newborns. Infections in infants usually occur in the first days or weeks of life. About two to four cases are reported to CDC every year, but this figure may not reflect the true number of illnesses because most hospitals and laboratories are not required to report *Cronobacter* infections to health departments.

Cronobacter germs can cause a dangerous blood infection ([sepsis](#)) or make the linings surrounding the brain and spinal cord swell ([meningitis](#)). Infants two (2) months of age and younger are most likely to develop meningitis if they get sick from *Cronobacter*. Other infants more likely to get sick are those born prematurely and those less able to fight germs and sickness because of illness or medical treatment, such as infants receiving chemotherapy for cancer.

Cronobacter infection can also be serious for older people and for people whose immune systems are weakened by other illnesses or conditions, such as HIV, organ transplants, or cancer.

What Parents and Caregivers Should Do:

Recalled powdered infant formulas are **Similac, Alimentum, and EleCare. Do not use these brands if they meet all three of these conditions:**

- The first two digits of the code (lot number) are **22** through **37**, AND
- The code on the container contains "**K8**," "**SH**," or "**Z2**," AND
- The use by date (expiration date) is **4-1-2022 (APR 2022) or later.**

Abbott has also provided a website where consumers can check the lot number on their product to see if it is included in the above recall: <https://www.similacrecall.com/us/en/product-lookup.html>.

In addition to the above recalled products, on February 28, 2022, Abbott Nutrition voluntarily recalled Similac PM 60/40 powdered infant formula with the lot code 27032K800. This is a specialty formula for certain infants who would benefit from lowered mineral intake and was not included in the previous recall. At this time, Similac PM 60/40 with lot code 27032K80 (can)/27032K800 (case) are the only type and lots of this specialty formula being recalled.

Do not feed infants recalled powdered formula. Throw it away or return it for a refund. Visit [FDA's website](#) for more information.

The first [symptom of Cronobacter](#) infection in infants is usually a fever, accompanied by poor feeding, crying, or very low energy. **You should take an infant with these symptoms to the doctor.**

Follow these five guidelines to protect your baby from *Cronobacter*:

1. Breastfeed.
2. Clean, sanitize and store feeding items and breast pump parts safely.
3. Consider using liquid formula when possible.
4. Prepare and store powdered infant formula safely.
5. Keep hands clean.

For more information about each of these five guidelines, please visit: <https://www.cdc.gov/cronobacter/infection-and-infants.html/>

What Public Health Authorities Should Do:

On Feb. 16 and 17, 2022, CDC issued a call for cases through various channels including Epi-X and the Emerging Infections Network (EIN). DPBH is working with CDC and FDA to identify any potentially associated cases in Nevada.

Please report any infants (<12 months old) with laboratory-confirmed *Cronobacter sakazakii* infections since November 2020 to dpbhepi@health.nv.gov.

If an isolate of *Cronobacter sakazakii* is available, please hold the isolate for potential molecular strain typing.

What Health Care Providers and Laboratories Should Do:

Cronobacter multi-species complex is a group of gram-negative bacteria that exists in the environment and which can survive in very dry conditions. The natural habitat for *Cronobacter* is not known. It has been found in a variety of dry foods, including powdered infant formula, skimmed milk powder, herbal teas, and starches, as well as in wastewater. *Cronobacter sakazakii* rarely causes human illness but can cause infant septicemia and severe meningitis that typically results in long-term neurological consequences or death in infants (<12 months old), *Cronobacter* usually causes sepsis or severe meningitis. Some infants may experience seizures. Those with meningitis may develop brain abscesses or infarcts, hydrocephalus, or other serious complications that can cause long-term neurological problems. Diagnostic evaluation and treatment should be guided by the clinical presentation.

Healthcare providers and laboratories should report infections with *Cronobacter sakazakii* from infants (<12 months of age) and/or if they become aware of an infant that consumed formula from a recalled lot and subsequently become ill, but does not have a laboratory diagnosis to their respective local health department:

Health Department	County	Phone Number to Report
Southern Nevada Health District (SNHD)	Clark	(702)-759-1300 (24 hours)
Washoe County Health District (WCHD)	Washoe	(775)-328-2447 (24 hours)
Carson City Health and Human Services (CCHHS)	Carson City, Douglas, Lyon, and Storey	(775)-887-2190 (M-F 8:00 AM to 5:00 PM) (775)-887-2190 (after hours)
Nevada Division of Public and Behavioral Health (DPBH)	All other Counties	(775)-684-5911 (M-F 8:00 AM to 5:00 PM) (775) 400-0333 (after hours)

The local health departments will facilitate any necessary testing of the product.

Questions:

For updated guidance, please review the DPBH Technical Bulletin [website](#) and Nevada’s Health Response [website](#) regularly. Please email dpbhepi@health.nv.gov for other questions regarding *Cronobacter sakazakii*.

References:

CDC *Cronobacter* information: <https://www.cdc.gov/cronobacter/infection-and-infants.html>

FDA Health Advisory: <https://www.fda.gov/food/outbreaks-foodborne-illness/fda-investigation-cronobacter-and-salmonella-complaints-powdered-infant-formula-february-2022>; <https://www.fda.gov/news-events/press-announcements/fda-warns-consumers-not-use-certain-powdered-infant-formula-produced-abbott-nutrition-facility>

Abbott recall information:

https://www.similarecall.com/us/en/home.html?gclid=EAIaIQobChMI7_P1rI2X9gIVEyCtBh3EngA2EAAAYASAAEgKUPfD_BwE&gclid=aw.ds



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