

GLOBAL ALERT!



March 1st 2022: “The United States Food and Drug Administration, FDA, warns against using another powdered baby formula after a 2nd death”:

<https://www.npr.org/2022/03/01/1083696031/fda-warns-against-using-another-powdered-baby-formula-after-a-second-death?t=1646207848860>

“A baby who used Abbott’s Similac PM 60/40 contracted a Cronobacter sakazakii infection and died”: [https://www.insider.com/more-infant-formula-recalled-after-another-baby-dies-2022-](https://www.insider.com/more-infant-formula-recalled-after-another-baby-dies-2022-3?utm_medium=social&utm_campaign=sf-bi-)

[3?utm_medium=social&utm_campaign=sf-bi-ti&utm_source=facebook.com&fbclid=IwAR3rp2WEkSfGiCVIDPr8MFpY0XvKg97kN51yI5EBsYvtNqqhW9sFVmbciHE](https://www.insider.com/more-infant-formula-recalled-after-another-baby-dies-2022-3?utm_medium=social&utm_campaign=sf-bi-ti&utm_source=facebook.com&fbclid=IwAR3rp2WEkSfGiCVIDPr8MFpY0XvKg97kN51yI5EBsYvtNqqhW9sFVmbciHE)

February 18th, 2022: Recall includes Similac Human Milk Fortifier:

<https://www.childrensdayton.org/the-hub/baby-formula-recall-what-you-need-know>

<https://www.therakyatpost.com/news/2022/02/24/kkm-recalls-2-similac-baby-formulas-due-to-bacteria-contamination/>

February 17th 2022: Similac, Alimentum and EleCare powdered infant formulas of Abbott Nutrition were recalled in the USA after the first reported death as well as several reported cases of severe illness in infants, caused by contamination with the dangerous bacteria *Cronobacter/Enterobacter sakazakii* and *Salmonella Newport*¹:

<https://www.cdc.gov/cronobacter/> <https://efoodalert.com/2022/02/20/cronobacter-and-powdered-infant-formula/amp/>²

These articles do not answer all the key questions about microbial contamination of powdered formulas. They do not propose mandatory measures to prevent further deaths and outbreaks of debilitating disease.

IBFAN calls for regulatory action that is long overdue. The ten questions below explain the reasons why.

IBFAN’s Call to Action

² See Frequently Asked Questions by the Centres for Disease Control, CDC, in the USA: <https://www.cdc.gov/cronobacter/technical.html>

IBFAN calls for mandatory warnings and information on labels and product websites that powdered formulas and human milk fortifiers are not sterile: IBFAN members' submissions to a 2020 international survey showed that there are still very few countries where manufacturers and distributors must provide mandatory warnings on labels and information that the products are not sterile and may be contaminated by harmful bacteria.

IBFAN calls for clear and prominent information on labelling that extra care must be taken in preparation, storage and handling, and must include the lethal decontamination step.

IBFAN calls for *Cronobacter/Enterobacter* and *Salmonella* infections to become reportable as a mandatory notifiable disease in all countries. The only State in the USA that has mandatory reporting is Minnesota, and this is where the first case of *Cronobacter* infection was reported in the USA. If there had been no consumer reports then the public would never have known about the dangers of contaminated powdered formulas.

1. Why is IBFAN calling for action? ³

Because *Cronobacter sakazakii* and *Salmonella* are dangerous bacteria that thrive in lukewarm milk made with powdered formula. They can multiply and cause severe infections in babies.

This photo shows multiplication on a plate culture of reconstituted powdered formula at room temperature. In lukewarm⁴ milk the bacterial growth of yellow-staining *Enterobacter sakazakii*, now called *Cronobacter sakazakii*, is exponential.



This trypticase soy agar plate culture of E. sakazakii is showing mucoid flat colonies after three days growth at 25° C. Photo credit: CDC/Dr. J. J. Farmer

2. How serious are the infections caused?

These infections can cause severe invasive infections that may be fatal.

³ IBFAN's websites provide information in 3 languages: In English, French and Spanish: <https://www.gifa.org/en/international-2/contaminants2/> Further articles in English: <https://www.ibfan.org/contaminants-in-baby-foods/>

⁴ Lukewarm or tepid means 100°-110°F and 36.5°-40.5°C

The three products recalled by Abbott in February 2022 caused an outbreak of severe infections in the USA with at least four children hospitalised. “Three of the infections are from *Cronobacter sakazakii* (formerly *Enterobacter sakazakii*) and one is from *Salmonella*. One death is being investigated by US officials.”⁵

The second recall by Abbott Nutrition concerned the specialty product Similac PM 60/40: « an infant who consumed the Similac specialty product died after testing positive for *Cronobacter sakazakii*. It was the second reported fatal case linked to powdered baby formula since September. » See FDA Alert, March 1st 2022.

In infants less than 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. The mortality rate for *Cronobacter* meningitis may be as high as 40%.”⁶ See endnote 1.

3. How long did the CDC know about this bacterial contamination at factory level?

At least since 2008. The products implicated are manufactured at a production facility in Sturgis, Minnesota, USA. Abbott’s history during the 27 inspections since 2008 is examined in this article.⁷ It makes chilling reading. Inspectors found positive results for *Cronobacter* in samples taken, as well as repeated failures in basic hygiene, pest control, building maintenance, particle filters, temperature controls. “A review of the firm’s internal records also indicate environmental contamination with *Cronobacter sakazakii* and the firm’s destruction of product due to the presence of *Cronobacter*.”

These environmental ‘adverse inspectional observations’ resemble those found at the Lactalis factory in Craon, France, where *Salmonella* Agona introduced during the manufacturing process contaminated powdered formulas and baby foods.⁸

4. Where were the recalled products exported?

According to the firm (Abbott Nutrition), recalled products were distributed to the following countries: Australia, Bahrain, Barbados, Bermuda, Canada, Chile, China, Colombia, Costa Rica, Dominican Republic, Ecuador, Egypt, Guam, Guatemala, Hong Kong, India, Indonesia, Israel, Jordan, Kuwait, Lebanon, Malaysia, Mexico, New Zealand, Oman, Peru, Puerto Rico,

⁵ <https://www.foodsafetynews.com/2022/02/multiple-countries-received-recalled-infant-formula-linked-to-deadly-outbreak/?fbclid=IwAR27tDozRKzt9yP3ByaTd53bqIEC3EVZrE8zO0ekuz65Yeg-RyFSkE1-Qe0>

⁶ <https://www.cdc.gov/cronobacter/technical.html>

⁷ <https://efoodalert.com/2022/02/20/cronobacter-and-powdered-infant-formula/amp/>

⁸ This recalls the 2017-2018 Lactalis scandal when the drying towers in one factory were contaminated. See endnote 2.

Qatar, Saudi Arabia, Singapore, South Africa, Sudan, Taiwan, Thailand, United Arab Emirates, United Kingdom, and Vietnam ANI South.

5. What is the danger of using these recalled products?

These risks are clearly explained in “The Food and Drug investigation of *Cronobacter* and *Salmonella* complaints: powdered infant formula, 17.02.22”⁹

“Recalled powdered infant formulas have the potential to be contaminated with *Cronobacter*, a bacterium that can cause severe foodborne illness primarily in infants. *Cronobacter* infections are rare but are especially high risk for newborn infants ... *Cronobacter* bacteria can cause severe, life-threatening infections (sepsis) or meningitis (an inflammation of the membranes that protect the brain and spine). Symptoms of sepsis and meningitis may include poor feeding, irritability, temperature changes, jaundice (yellow skin and whites of the eyes), grunting breaths, and abnormal movements. *Cronobacter* infection may also cause bowel damage and may spread through the blood to other parts of the body.” This invasive infection can cause bacteraemia, also known as septicaemia, in older infants.

Salmonella includes several species of bacteria causing gastrointestinal illness and fever with symptoms of diarrhoea, abdominal cramps. “More severe cases of salmonellosis may include a high fever, aches, headaches, lethargy, a rash, blood in the urine or stool, and in some cases, may become fatal.”¹⁰

“In the United States, the incidence of salmonellosis (from all sources) among infants (121.6 laboratory-confirmed infections per 100,000 infants) was ~8 times greater than the incidence among other age groups”.¹¹

The USFDA Alert¹² reports a law suit filed by the parents after their infant daughter « was infected with Salmonella after consuming Alimentum. Their child developed severe illness, which the lawsuit says was a "direct result" of consuming the formula. The child continues to experience gastrointestinal and bowel problems, the law firm said in a release last week. «¹³

⁹ <https://www.fda.gov/food/outbreaks-foodborne-illness/fda-investigation-cronobacter-and-salmonella-complaints-powdered-infant-formula-february-2022>

¹⁰ <https://www.foodsafetynews.com/2009/11/bacteria-in-formula-poses-risk-for-infants/>

¹¹ <https://academic.oup.com/cid/article/46/2/268/457688?login=false>

¹² “The United States Food and Drug Administration, FDA, warns against using another powdered baby formula after a 2nd death”: <https://www.npr.org/2022/03/01/1083696031/fda-warns-against-using-another-powdered-baby-formula-after-a-second-death?t=1646207848860>

¹³ <https://www.prnewswire.com/news-releases/schlesinger-law-offices-pa-fights-for-families-in-toxic-baby-formula-class-action-lawsuit-against-abbott-laboratories-301487952.html>

Long-term disabilities

The risks and dangers of such infections caused by contaminated powdered formulas cannot be underestimated. Babies may suffer fatal illness, or long-term brain damage leading to life-long disabilities. In the USA, parents have taken companies to court and have received compensation to cover the costs of caring for a severely disabled child.

But no amount of money can compensate for the loss of a child or caring for a disabled child forever.

6. Are these infections a rare occurrence?

No. They are seldom reported. IBFAN calls for mandatory reporting, to make Cronobacter and Salmonella infections reportable diseases in all countries.

Baby food manufacturers repeatedly claim that cases of microbial infection caused by intrinsic contamination are rare. This is because even in the USA it is not mandatory to report Cronobacter/Enterobacter infections. However, Salmonellosis (infections caused by Salmonella) is a reportable foodborne disease.¹⁴ In other countries there may be no or few reporting systems for food-borne illness.

The CDC admits that these infections are under-reported: “CDC typically receives reports of 2–4 infections in infants per year, although reporting is not required except in one state, Minnesota. As a result, rates of *Cronobacter* infection in the USA are not well understood.”¹⁵

Worse still, these infections remain unidentified: there are few facilities to perform tests on body fluids of sick babies and correlate these with the content of unopened powdered formula packages. Often this packaging is discarded, and the evidence disappears. Complex testing is needed to prove a causal link with the serious infections in infants and young children to powdered formula. If this is the case in the USA, then how many countries and settings lack such facilities? Even in 2002, it was noted that “*Enterobacter sakazakii* could be recovered from 20 out of 141 samples (14%).”¹⁶

7. Is there an increase in these infections caused by contaminated products?

Yes. In many countries global heating caused by climate change produces higher ambient temperatures. Warm, humid conditions increase the multiplication of any dangerous bacteria present in the reconstituted powdered formula, especially when bottles are carried around by care givers or unfinished formula bottles are kept at room temperature and consumed by babies. Increasing anti-microbial resistance makes these serious food-borne

¹⁴ <https://www.cdc.gov/salmonella/reportspubs/surveillance.html>

¹⁵ <https://www.cdc.gov/cronobacter/technical.html>

¹⁶ <https://corpora.tika.apache.org/base/docs/govdocs1/980/980335.html>

infections harder to treat. The impact of these microbial infections can include neurological damage causing life-long disabilities.

8. Are there any steps to reduce the risk of infections caused by harmful bacteria in powdered formula?

Yes. But powdered formula feeding can never be made safe. It is only possible to reduce, but not eliminate the risks. In the 2007 WHO and FAO published **“New Safety Advice” with the clear and direct message: “Powdered infant formula is not sterile. It may contain bacteria that can cause serious illness in infants. By preparing and storing powdered infant formula correctly, you can reduce the risk of illness.”**¹⁷

These Guidelines on Safe preparation, storage and handling of powdered infant formula published the same year recommend a decontamination preparation phase to **kill harmful bacteria**: the water should be first boiled and then cooled to a temperature of not less than 70° Celsius before mixing it with the powder and left to cool down before feeding the bottle to the baby. Bottled water should also be boiled and left to cool to no less than 70°. The remaining formula in the bottle should be disposed of and not reused.

This **decontamination or lethal step** is critical because both *Cronobacter* and *Salmonella* species are heat-resistant, also called thermo-tolerant. After introduction at factory level during ultra-processing, these bacteria can survive in dry state in unopened formula packages. This is called intrinsic contamination. Then, when the powdered formula is reconstituted with lukewarm water, these bacteria multiply exponentially and rapidly reach dangerous levels for infant health.

9. Why is this lethal step to inactivate dangerous pathogens so critical?

It is imperative to protect infants and young children who are at particular risk of severe infections because their immune systems are immature. Those who are not breastfed do not receive the antibodies and anti-infective agents present in breastmilk. These build the infant’s protective microbiome to boost the immune system and fight off disease.

Despite all these alerts on intrinsic contamination, manufacturers of powdered formulas and baby cereals still do not place warnings on their products. Instead, the industry opposes action at every step. Due to the opposition of the manufacturing and exporting countries the discussion in the Codex Alimentarius Committee on Food Hygiene could not reach consensus to impose mandatory warnings on labelling.

10. Why still no warnings that powdered formulas are not sterile and “may contain bacteria that can cause serious illness in infants”?¹⁸

¹⁷ <https://www.who.int/publications/i/item/9789241595414> These 2007 Guidelines need revision to include all powdered formulas and to remove the word ‘safe’ because there is no such thing as safe formula feeding.

¹⁸ <https://www.who.int/publications/i/item/9789241595414>

It is now 20 years since the US Food and Drug Administration, FDA, issued an alert to health care professionals about contamination of powdered formulas by *Enterobacter sakazakii*. These harmful bacteria cause severe and potentially fatal infections in premature and newborn infants.¹⁹

It is over 40 years since John J. Farmer²⁰ documented the outbreaks of illness in babies after discovering bacteria called '*Enterobacter cloacae*' in his dog's feeding bowl. The name 'cloacae' refers to the fecal origins of these bacteria which underwent a name change to disguise their origin, becoming first *Enterobacter sakazakii* in 1980 and then *Cronobacter sakazakii* in 2007.

It is 17 years since the 2005 outbreaks of *Salmonella* infections in babies in France caused 148 babies to fall sick and 45% to be hospitalised.²¹ The scandal of Lactalis products contaminated by *Salmonella* Agona hit the headlines in 2018. Potentially contaminated formulas were exported worldwide to over 83 countries. These batches were manufactured in the same facility in France where there was at least one contaminated drying tower. In the same way the batches of Abbott Similac and other powdered formulas are manufactured at their facility in Sturgis and marketed in several States and at least 37 countries.

It is now 15 years since the warning issued in the 2007 Guidelines published by WHO and FAO. Their "**New Safety Advice**" also issued in 2007 carries the clear and direct message: "**Powdered infant formula is not sterile. It may contain bacteria that can cause serious illness in infants. By preparing and storing powdered infant formula correctly, you can reduce the risk of illness.**" But how many manufacturers place these warnings on labels? How many governments mandate warnings on labelling? How many labels include the critical decontamination or lethal step? See endnote 3.

How much longer will babies fed powdered formulas have to wait?

All these years and still no action. Babies cannot wait.

Endnotes:

1. <https://corpora.tika.apache.org/base/docs/govdocs1/980/980335.html>
Even way back in 2002, the USFDA Letter to health professionals cites reports of severe invasive infections caused by *Enterobacter sakazakii* that "described neonates

¹⁹ <https://corpora.tika.apache.org/base/docs/govdocs1/980/980335.html>

²⁰ My 40-year history with *Cronobacter/Enterobacter sakazakii* – lessons learned, myths debunked, and recommendations
<https://www.frontiersin.org/articles/10.3389/fped.2015.00084/full>

²¹ EuroNews - The tip of the Iceberg: <https://www.euronews.com/2018/01/17/lactalis-scandal-is-a-tip-of-the-iceberg-the-international-baby-food-action-network-says>

with sepsis, meningitis or necrotizing enterocolitis as a consequence of the infection, with case-fatality rates reported to be as high as 33%.”

2. In 2018 the Lactalis scandal hit the headlines when 12 million batches of powdered formulas contaminated by *Salmonella* bacteria were exported to over 83 countries. IBFAN groups and contacts publicised the dangers of contaminated powdered formulas, monitored those on display or on sale, complained to health authorities and reported on any action taken: <http://www.babymilkaction.org/archives/15630>

3. The original text of the USFDA Letter to health professionals was revised in the same year, 2002, to omit reference to using boiling water to prepare powdered formula. The baby food industry strongly opposed this step because they claimed that boiling water would destroy heat-sensitive additives to formula. Vitamin premixes and probiotics are added after the dried milk powder has been sterilised and these ingredients can introduce microbial contamination. The addition of these ingredients has been shown to be unnecessary and serves merely to justify unfounded nutritional and health claims. See <https://www.foodsafetynews.com/2009/11/bacteria-in-formula-poses-risk-for-infants/>