

The Abbott Powdered Formula Scandal

After the global recall of potentially contaminated Abbott powdered formulas and one human milk fortifier, many questions remained unanswered. Abbott used the media to deny responsibility, deceive the public and denigrate critics.

It is important to place the facts on record before they are buried. Each question is answered by a summary of the facts and provides further evidence backed up by references from media reports, United Nations agencies and US government documents.

Questions are grouped together under three main headings: **Formula Recalls, Reducing Health Risks and Contaminated Factories.**

Formula Recalls

Q | Did you know why there is an infant formula shortage in the United States – and worldwide?

A | In February 2022, the largest US infant formula manufacturer Abbott recalled three brands of its powdered formula and one human milk fortifier.

The company shut down its main manufacturing facility in Sturgis, Michigan following reports of *Cronobacter* infections in infants who had consumed formula manufactured at the plant. Evidence points to contamination of the Abbott Nutrition formula factory by strains of this dangerous bacteria. A massive worldwide recall of powdered formula produced in this

factory emptied stores and left shelves bare. The subsequent scramble to import more formula into the USA led to further shortages in other countries:

<https://www.ibfan.org/wp-content/uploads/2022/05/2022-Action-Alert-2-REVISED-IBFAN-Calls-for-Action-Cronobacter-Salmonella-infections.pdf>

*“From September 2021 to February 2022, the US Centers for Disease Control and Prevention (CDC) received reports of cases of *Cronobacter* infection in infants in Minnesota, Ohio, and Texas ...These illnesses were ultimately linked by the CDC and US Food and Drug Administration (FDA) to the consumption of powdered formula produced by Abbott in its Sturgis, Michigan, factory.”*

<https://www.foodsafetynews.com/2022/05/publishers-platform-abbott-and-public-health-officials-have-failed-in-their-duty-to-protect-the-most-vulnerable/>

Q | Did you know how many babies died or suffered severe infections in the USA between December 2021 and March 2022?

A | Freedom of Information requests and whistleblower action revealed that not only two, but nine US infants were reported to have died after consuming powdered infant formula manufactured at the Abbott factory. These products were contaminated by *Cronobacter sakazakii* as well as by other pathogens: *Salmonella*, *Clostridioides difficile* and *Shigella*.

During the same period, 25 severe infections categorized as ‘*Life Threatening Illness/Injury*’ and 80 instances of ‘*Non-Life Threatening Illness/Injury*’ were reported among infants who were fed these formulas: “*Every one of the sick babies was fed an Abbott powdered formula.*”

Until *Cronobacter* infections require mandatory notification, the full number of cases of

illness or deaths will never be known. Nor will the extent be known in the 37 countries that imported the potentially contaminated Abbott formula.

<https://www.foodsafetynews.com/2022/06/nine-baby-deaths-reported-to-fda-during-abbott-nutrition-investigation/>

<https://efoodalert.files.wordpress.com/2022/06/abbott-complaints-spreadsheet-redacted.pdf>

https://en.wikipedia.org/wiki/Notifiable_diseases_in_the_United_States

Q | Did you know that powdered infant formula is not a sterile product?

A | Powdered infant formula is not a sterile product, unlike 'ready-to-feed' liquid infant formula which is packed in feeding bottles that are sterile until opened. The manufacturing process for powdered formulas does not include end-point sterilization and the powder may become infected with harmful bacteria present in the factory. This 'intrinsic contamination' means that microorganisms are present in unopened packages of powdered formulas, including pathogenic bacteria which can cause severe infections in vulnerable babies.

"Powdered infant formula (PIF) has been associated with serious illness and death in infants due to infections with Cronobacter/Enterobacter sakazakii. During production, PIF can become contaminated with harmful bacteria, such as Cronobacter/Enterobacter sakazakii and Salmonella enterica. This is because, using current manufacturing technology, it is not feasible to produce sterile PIF."

<https://apps.who.int/iris/handle/10665/43659>

https://apps.who.int/iris/bitstream/handle/10665/43659/9789241595414_eng.pdf?sequence=1&isAllowed=y

Q | Did you know why Enterobacter/Cronobacter is such a dangerous resistant super-bug?

A | *Cronobacter sakazakii* was formerly called *Enterobacter sakazakii* but has been moved into a new genus *Cronobacter*, a name "derived from the Greek term 'Cronos', a Titan of ancient mythology who swallowed his infants when they were born, in fear of being replaced by them": <https://pubmed.ncbi.nlm.nih.gov/23538645/> The severity of invasive infections in infants caused by *Cronobacter* justifies its new name. These infections include meningitis, sepsis and necrotizing enterocolitis:

"According to the CDC, Cronobacter can cause severe, life-threatening infections or meningitis. Although Cronobacter infections are rare, they

can be deadly in newborns in the first days or weeks of life with a mortality rate between fifty and eighty percent.”

<https://www.foodsafetynews.com/2022/05/publishers-platform-abbott-and-public-health-officials-have-failed-in-their-duty-to-protect-the-most-vulnerable/>

Cronobacter and Salmonella infections are now increasingly resistant to antibiotics:

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6463179/>

These infections can be fatal and can also cause lasting neurological damage and developmental delays. Over the past 20 years there are many reports of life-changing disability in infants who do survive infections. This mother relates how her infant daughter sustained brain damage after drinking formula that had been given by the hospital as a free sample and was tainted with Cronobacter:

<https://www.washingtonpost.com/business/2022/09/06/cronobacter-sakazakii-bacteria-baby-formula/>

Q | Did you know why Cronobacter infections and contamination of powdered infant formulas are under-reported?

Q | Minnesota is the only state in the USA that mandates reporting of Cronobacter infections. If the CDC had not received notifications of cases of Cronobacter infections in this state, other cases in Ohio or Texas would have been missed.

<https://foodpoisoningbulletin.com/2022/minnesota-cronobacter-case-spurred-federal-investigation/>

According to Abbott, the company exported batches of potentially contaminated formula to 37 countries all over the world. There is no testing of the content of packages of powdered formula in most of these countries because few of them have the highly technical laboratory facilities to identify and investigate the origin of bacterial infections. Tests are needed of the blood and cerebrospinal

fluid of patients with meningitis or sepsis caused by these bacteria.

Even worse, even in high-income countries, cases of neonatal meningitis and sepsis are often attributed to common germs. In the absence of microbiological testing the signs and symptoms are the same. There should also be testing of household surfaces and the content of unopened formula packages, but many are discarded or not readily available. Testing of packaged powdered formula is challenging because Cronobacter can survive in dry products “for long stretches of time and can be unevenly distributed in formula powder, meaning that one scoop of formula could contain the organism and the next may not.”

<https://www.washingtonpost.com/business/2022/09/06/cronobacter-sakazakii-bacteria-baby-formula/>

<https://www.ibfan.org/wp-content/uploads/2022/05/2022-Action-Alert-2-REVISED-IBFAN-Calls-for-Action-Cronobacter-Salmonella-infections.pdf>

These reviews of outbreak history, infections and fatalities show the extent of under-reporting:

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6463179/>

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4662064/>

Reducing Health Risks

Q | Did you know how to reduce the risk to babies' health?

a | Your baby's immune system has not yet fully matured to fight off infections, thus increasing the risk of illness after exposure to harmful bacteria. If your baby is not breastfeeding, learning about relactation and milk banks are safer options. When preparing powdered formula you need to include a 'kill step' to inactivate any dangerous bacteria introduced at factory level and thus present even in sealed packages.

Cronobacter and Salmonella bacteria are resistant to heat and drought. Since there is no final

sterilization step for powdered formula, even small colonies of bacteria can survive in a vegetative state for long periods in the dry powder. When this formula is mixed with lukewarm water to feed the baby, any bacteria in the dried powder can multiply at a rapid rate – exponentially – because Cronobacter and Salmonella thrive in warm milk. Preparation of a powdered formula feed must include the 'validated kill step' of mixing the powdered formula with very hot water to inactivate these bacteria. This means first boiling the water and letting it cool to no less than 70°C before mixing the formula powder:

<https://www.enonline.net/attachments/542/safe-prep-bottle-feeding-leaflet.pdf>

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

Q | Did you know how breastfeeding protects babies' health?

a | The infant's immune system is not fully developed at birth. It is only after several months that the immune system matures and is robust enough to fight off infections. Powdered formulas contain no antibodies or anti-infective agents to protect against these infections.

Breastmilk and colostrum contain many substances with antibiotic properties. Breastmilk is a dynamic, living fluid with anti-infective agents as well as bioactive components. Breastfeeding is an interactive process between a mother and her

baby that has been called 'personalised medicine' as well as the perfect food.

"There is a wealth of evidence that breastfeeding reduces the risk of babies developing infectious diseases. There are numerous live constituents in breastmilk, including immunoglobulins, antiviral factors, cytokines and leucocytes, that help to destroy harmful pathogens and boost the baby's immune system."

[Infant Feeding During The Coronavirus Crisis](#)

<https://www.unicef.org.uk/babyfriendly/local-authorities-guide/>

[UN calls for stronger workplace policies for nursing mothers:](#)

<https://news.un.org/en/story/2015/08/505612>

Contaminated Factories

Q | **Did you know why powdered infant formula can be contaminated at factory level?**

a | Research shows that contamination by Cronobacter and Salmonella is not rare in dairy farms, the facilities where milk is produced for dried milk powders. The FDA conducted a sampling assignment in 2014 to understand the prevalence of Cronobacter spp. and Salmonella in 55 US dry dairy facilities. "Cronobacter was detected in 69 percent of the facilities..."

<https://www.food-safety.com/articles/7073-cronobacter-pathogen-considerations-beyond-salmonella-in-dairy-powders>

The milk powder is then processed into powdered formula in manufacturing facilities. These are factories and not laboratories. They are exposed to bacteria like any other commercial premises, and cleaning equipment, even vacuum cleaners may harbour bacteria.

Cronobacter, like Salmonella, is found everywhere in the environment and may be introduced at factory level even after the liquid milk coming from the farm is pasteurized. These factory premises are not sterile and sources of contamination are numerous. Contamination may occur during the drying process in huge towers or when heat-sensitive probiotic vitamin premixes

are added to the powder in large blenders. The WHO/FAO meeting report on *Enterobacter sakazakii* (now called Cronobacter) and Salmonella in Powdered Infant Formula describes how such contamination can occur in factories. Microbiological Risk Assessment Series (MRA) 10 (who.int) pages 23-24:

<https://www.who.int/publications/i/item/9241563311>

In 2018, Lactalis powdered formula manufactured in France was contaminated by Salmonella and exported to over 80 countries:

<http://www.babymilkaction.org/archives/15630>

More recently, Cronobacter contamination was found in Numil infant formula manufactured in the Czech Republic and exported to Moldova and in KetoCal formula manufactured in Europe and exported to Australia:

<https://www.foodsafetynews.com/2022/06/cronobacter-found-in-numil-infant-formula/>

For these reasons, strict internal sanitary measures and routine mandatory product testing are necessary, in addition to stringent external controls. In the case of the Abbott factory, "FDA inspectors uncovered a host of violations, including bacterial contamination, a leaky roof, and lax safety controls":

<https://www.craigslist.com/manufacturing/abbott-again-shuts-down-formula-production-michigan>

Q | Did you know about the unsanitary state of the Abbott factory?

Q | At the US Congressional Hearings held on May 25, 2022 FDA Commissioner Dr. Robert Califf stated “the Abbott manufacturing plant was egregiously unsanitary ...Frankly, the inspection results were shocking.” The conditions included “bacteria growing from multiple sites in the facility, cracks in key equipment, leaks from the roof, standing water and a previous citation for inadequate handwashing.”

<https://www.cnn.com/2022/05/25/watch-live-house-grills-fda-commissioner-abbott-executive-on-baby-formula-shortage.html>

The FDA had earlier released its inspection report on March 18, 2022, after the closure of the Abbott factory on February 15. “It found *Cronobacter* bacteria on multiple surfaces in the plant, and other conditions that increase the risk of contaminated products, including cracks in processing equipment, multiple water leaks and moisture, and puddles of water on the floor.”

[https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(22\)01049-2/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(22)01049-2/fulltext)

These faults had previously been reported by the whistle-blower, an employee of Abbott who suffered retaliation by the company. This report contains 6 serious violations needing to be investigated:

<https://www.marlerblog.com/?s=Redacted-Confidential-Disclosure-re-Abbott-Laboratories-10-19-2021>

The UK Guardian reports “the federal whistle-blower complaint alleged some of the Sturgis plant’s equipment that caused the bacteria to get in the product “was failing and in need of repair”, and company management was aware of the issue for up to seven years ahead of the outbreak. When in June, 2022 flooding caused the closure of the Michigan Abbott factory after it had briefly reopened, the faults previously reported by the whistle-blower show how flood waters could easily spread the bacterial contamination noted in his report. :

<https://www.marlerblog.com/?s=abbott>

“A number of product flow pipes were pitting and leaving pinholes. This allowed bacteria to enter the system and, at times, led to bacteria not being adequately cleaned out in clean-in-place washes,” the report reads. “This, in turn, caused product flowing through the pipes to pick up the bacteria that was trapped in the defective areas of the pipe.” The problems are not only limited to ageing equipment, according to the whistle-blower’s report. “Management at the plant also falsified records, improperly trained employees, and successfully hid health and safety risks from the Food and Drug Administration auditors in 2019.”

<https://www.theguardian.com/environment/2022/may/20/abbott-baby-formula-shareholder-profits>

<https://www.craigslist.com/manufacturing/abbott-again-shuts-down-formula-production-michigan>

Q | Did you know that Abbott Nutrition repeatedly failed to clean up their act?

A | “In September 2019 the US Food and Drug Administration, FDA, inspected the facility and cited Abbott for failing to test an adequate amount of formula to assure that it met “the required microbiological quality standards.” In September 2021, the FDA returned to Abbott and found the company had “failed to maintain a building used in the manufacture, processing, packing or holding of infant formula in a clean and sanitary condition.”

<https://www.foodsafetynews.com/2022/05/publishers-platform-abbott-and-public-health-officials-have-failed-in-their-duty-to-protect-the-most-vulnerable/>

<https://www.cnn.com/2022/05/25/watch-live-house-grills-fda-commissioner-abbott-executive-on-baby-formula-shortage.html>

“Abbott has repeatedly failed to meet even the most basic food safety standards, resulting in product recall after product recall of a life-sustaining product that families desperately need. This must change...”

<https://www.foodsafetynews.com/2022/10/abbott-nutrition-puts-up-500-million-for-new-state-of-art-baby-formula-production/#:~:text=Food%20Safety%20News-,Abbott%20Nutrition%20puts%20up%20%24500%20million%20for,of%20art%20baby%20formula%20production&text=Abbott%20>

Q | Did you know why it took the US Food and Drug Administration (FDA) so long to take action?

A | The FDA had already been warned that Abbott Nutrition ignored the findings of the whistle-blower who exposed the dirty conditions in the Sturgis factory, and then discredited and fired this employee. During the US Congressional Hearings, Representative Rosa de Lauro explained that the whistle-blower report was submitted to the FDA on October 20, 2021. [For her statement see page 11.](#)

The FDA had then interviewed the whistle-blower in late December of 2021. The FDA inspected the Abbott manufacturing facility on January 31, 2022. The FDA recalled the products on February 17, 2022. It took the FDA 4 months to shut down the Abbott plant.

<https://delauro.house.gov/media-center/press-releases/icymi-delauro-shares-whistleblower-report-contaminated-infant-formula>

Q | Did you know that the FDA had to legally require Abbott to stop formula production?

a | In May 2022, the US Food and Drug Administration entered into a legally binding consent agreement that enjoins Abbott from manufacturing infant formula at its Sturgis plant and lays out steps required before resuming productions. This is the Justice Department Files Complaint and Proposed Consent Decree to Ensure Safety of Abbott Laboratories' Infant Formula:

<https://www.justice.gov/opa/pr/justice-department-files-complaint-and-proposed-consent-decree-ensure-safety-abbott>

This Complaint for Permanent Injunction to “permanently enjoin Abbott Nutrition from violating US law” legally orders Abbott to stop producing powdered formula in the Sturgis, Michigan plant. The Plaintiff is the UNITED STATES OF AMERICA versus the Defendants ABBOTT LABORATORIES, a corporation doing business as ABBOTT NUTRITION:

https://www.docketalarm.com/cases/Michigan_Western_District_Court/1--22-cv-00441/United_States_of_America_v._Abbott_Laboratories_et_al/1/

Under the consent agreement the company is required to take specific measures designed to increase safety and ensure compliance with federal laws. “The company will - among other things - permit unannounced FDA inspections and hire an independent expert to ensure that formula is free of contaminants.” In June, 2022 the FDA allowed operations to restart at the Michigan plant after meeting initial requirements of the consent decree.

[https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(22\)01049-2/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(22)01049-2/fulltext)

“The U.S. Attorney sued Abbott and several employees. In the complaint, filed by the U.S. Department of Justice on behalf of the FDA, the government alleges that powdered infant formula products manufactured at Abbott Nutrition’s Sturgis facility were adulterated because they were made under unsanitary conditions and in violation of current good manufacturing practice requirements.... Abbott essentially confessed to the violations in the consent decree. Under the consent decree, Abbott Nutrition will be required to retain an independent expert to review the Sturgis facility’s operations to ensure compliance with the law. “

‘Abbott essentially confessed to the violations’

Abbott confessed to these violations to be allowed to reopen its Sturgis factory. This is an admission of guilt, despite repeated denials of responsibility by the company’s executives.

<https://www.foodsafetynews.com/2022/06/the-death-of-another-baby-linked-to-abbott-infant-formula-apparently-under-investigation/>

This article is annexed with links to the key documents related to the complaint lawsuit and consent decree.

Q | Did you know how many court cases are pending against Abbott?

a | There are now over 30 court cases throughout the USA: “After its recall of formula this year, Abbott has been sued at least 30 times in federal courts. The amount of evidence that has recently entered the public domain includes a lawsuit that the Justice Department filed against Abbott and

the whistle-blower complaint submitted to the FDA by a former employee”. Will the lawyers who represent parents of infants who fell sick or died be more successful than in previous cases?

<https://www.nytimes.com/2022/09/06/business/abbott-baby-formula-lawsuits-jones-day.html>

We do not know the outcome for these families who need long-term care for their severely disabled children, but we know that these key documents exist as evidence and that they must remain accessible in the public domain.

Annex

This article contains links to the key documents related to the lawsuit and consent decree. The links are repeated below in case the original article is subsequently made inaccessible.

<https://www.foodsafetynews.com/2022/06/the-death-of-another-baby-linked-to-abbott-infant-formula-apparently-under-investigation/>

Here is the 2021 inspection report at the plant: [APPLIED – FOI II – BR Abbott Nutritions- FEI# 1815692 9-2021 EIR.](#)

Here are the whistleblower documents: [Redacted Confidential Disclosure re Abbott Laboratories – 10-19-2021_Redacted \(1\)](#)

Here is the 2022 inspection report at the plant: [Updated Final Applied_Unapplied Redactions Abbott Nutrition Sturgis FEI 1815692 FDA 483 1-31022 to 3-16-22 – ISSUED_Redacted](#)

Here is the complaint: [abbott_complaint_0](#)

Here is the consent decree: [abbott_proposed_consent_decree_0](#)

The infant Formula Shortage: What are we Really Short On? Walker, Marsha, RN, IBCLC.

<https://connect.springerpub.com/content/sgrc/early/2022/10/01/cl-2022-0018>

“The infant formula shortage has dominated the headlines and caused frustration and anxiety among parents who rely on infant formula or specialty formulas to feed their infants or children. The Federal government has taken steps to ease this shortage but has been a major contributor to the problem. Most of the discussion has centered around increasing the formula supply but little has been discussed regarding reducing the demand for infant formula. This commentary explores the background to the infant formula shortage and encourages breastfeeding advocates to speak up and step up to decrease the pervasive creep of infant formula use”.

Racial capitalism and the US formula shortage: A policy analysis of the formula industry as a neocolonial system.

<https://www.frontiersin.org/articles/10.3389/fsoc.2022.961200/full>

Congresswoman Rosa DeLauro, the United States House of Representative's top food safety advocate, shares a whistleblower Report on how contaminated infant formula led to hospitalizations and deaths. The Report shows falsification of records, untested Infant Formula and hiding of information during 2019 FDA Audit.

"The whistleblower report lays out a damning list of allegations of wrongdoing at this factory, including:

- Falsification of records relating to testing of seals, signing verifications without adequate knowledge, failure to maintain accurate maintenance records, shipping packages with fill weights lower than what was on the label, and more;*
- Releasing untested infant formula;*
- Hiding information during a 2019 FDA audit;*
- Lax practices associated with clean in place procedures;*
- Lack of traceability of the product;*
- Failure to take corrective measures once the company knew their testing procedures were deficient;*
- An atmosphere of retaliation against any employee who raised concerns about company practices.*

And these are just a few of the allegations laid out in the report. I want to remind everyone we are talking about infant formula. Parents trust that formula will be safe and healthy for their newborn babies – it should be the most regulated of any product... Why did the FDA not spring into action? Why did it take four months to pull this formula off store shelves? How many infants were fed contaminated formula during this time, by parents who trusted that the formula they were buying was safe? How many additional illnesses and deaths were there due to FDA's slow response?

I am deeply concerned about the practices at this Abbott facility and their apparent failure to implement and enforce internal controls at this facility. We need to know exactly who in the company was aware of this failure and the alleged attempts to hide this information from the FDA.

I am equally concerned that the FDA reacted far too slowly to this report. The report was submitted to the FDA on October 20, 2021. The FDA did not interview the whistleblower until late December 2021. According to news reports, FDA did not inspect the plant in person until January 31, 2022, and the recall was not issued until February 17, 2022.

Why did the FDA not spring into action? Why did it take four months to pull this formula off store shelves? How many infants were fed contaminated formula during this time, by parents who trusted that the formula they were buying was safe? How many additional illnesses and deaths were there due to FDA's slow response?

I have already requested that the HHS Inspector General look into this and I can assure you this Committee will also carry out its oversight role to find answers into how this happened and how we can prevent it from ever happening again.

I want to say thank you to this brave whistleblower for coming forward with this critical information... If Abbott cannot guarantee the safety of infant formula purchased through the WIC program, the federal government should not be in business with them."

<https://delauro.house.gov/media-center/press-releases/icymi-delauro-shares-whistleblower-report-contaminated-infant-formula>



For a PDF of this Q&A and more briefing click [here](#)

www.ibfan.org

[IBFAN GIFA Contaminants and Residues \(multi-lingual site\)](#)

[Environment chemical and microbiological contamination of infant feeding products](#)

[Green Feeding - action on climate change](#)

[Human Milk Patent Blog](#)

The International Baby Food Action Network (IBFAN) is a worldwide network of more than 148 public interest groups in over 108 countries. Members are diverse and include health worker, parent and consumer organisations. Social justice, human rights and environmental protection underscore all our work.

IBFAN does not seek or accept financial or other supports from manufacturers or distributors (or their trusts or foundations) of infant and young child feeding and related products. IBFAN is also cautious about funding from any for-profit entities since this can lead to loss of reputation and raise questions about IBFAN's integrity.

IBFAN's work on breastfeeding and young child feeding is just one element in the global action to ensure an environment in which children can survive and reach the highest attainable standard of health.

This Q&A was prepared by IBFAN's global working group on Environment Climate and Health.