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Infant food security and formula safety in the UK

Recommendations from the cereulide toxin
formula contamination and recall event

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GLOSSARY

Commercial milk formula: A term used to describe a range of different products marketed for use in place of breastmilk, up to 36 months of age. These include infant formula, follow-on formula, growing up and toddler milks and some specialised formulas regulated as FSMP (see below) but sold over the counter (e.g. comfort milks). The term ‘commercial milk formula’ and ‘formula’/‘formula milk’ are used interchangeably in this briefing.

Donor human milk: Breastmilk that has been expressed and provided freely by a donor to a human milk bank to be fed to another mother's child.

Follow-on formula: Commercial milk formula products marketed as suitable from 6-12 months of age. They offer no extra nutritional benefits for young children and are not recommended by the NHS.

Infant formula: Also termed first infant formula, commercial milk formula products that can be used from birth until 12 months of age, although marketed for use up to 6 months of age. Infant formulas are the primary concern in the context of food security and formula safety, because infant formula is the only safe alternative to breastmilk for healthy infants under 6 months of age. Prescribable specialised formulas regulated as foods for special medical purposes (FSMP) are also a concern for infants who have a diagnosed medical need for an alternative to infant formula.

Prescribable specialised formula: Formula milks designed for infants with specific medical conditions for whom standard infant formula is inappropriate. These products are regulated as Foods for Special Medical Purposes (FSMP).

ACRONYMS

CMA	Competition and Markets Authority	ECDC	European Centre for Disease Prevention and Control	JEMRA	Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment
DEFRA	Department for Environment, Food and Rural Affairs	EFSA	European Food Safety Authority	OPSS	Office for Product Safety and Standards
DHSC	Department of Health and Social Care	FSA	Food Standards Agency	SACN	Scientific Advisory Committee on Nutrition
DWP	Department for Work and Pensions	HMT	His Majesty's Treasury	UKHSA	UK Health Security Agency
		INFOSAN	International Food Safety Authorities Network	WHO	World Health Organization

Executive summary

This policy briefing describes the recent cereulide toxin formula contamination and recall event in the UK, including the scale of the incident, the official public health response, and the effects on formula supply chains and market stability. It considers the wider implications for infant food safety and infant food security, and makes recommendations for government.

The recalls followed the detection of cereulide, a bacterial toxin produced by *Bacillus cereus*, in a range of commercial milk formula products, including many infant formulas. Cereulide contamination can cause rapid-onset gastrointestinal illness and dehydration*, which can become life-threatening in young infants if not recognised and treated promptly. Its detection in formula milks available in the UK retail chain exposed important weaknesses in the safety and security systems governing infant foods.

The detection of cereulide toxin in formula milks exposed important weaknesses in the safety and security systems governing infant foods.

Although the UK public health assessment now claims that the likelihood of infant exposure to cereulide toxin is low, evidence suggests that contaminated products may have been on the UK market from May 2025¹ until the first Food Standards Agency alert on 5 January 2026.² This raises questions about the adequacy of existing regulatory oversight, surveillance and incident response arrangements.

More than 60 formula milk batches were implicated in UK recalls,³ and 61 reports of symptoms consistent with cereulide poisoning were identified among children who had consumed affected products across the UK and Crown Dependencies.⁴ The true number of affected infants is likely to be higher, and the incident remains under investigation.

The incident also highlighted a structural vulnerability in the manufacture and distribution of infant formula, which is currently the only recommended alternative to breastmilk during the first year of life. It highlights how ingredient sourcing, market concentration and globalised production can turn a contamination event into both a public health risk and a supply risk, endangering infant health and disrupting access to a product that the majority of UK infants rely on as their primary food source in the first six months of life.

Although the total volume of recalled formula milk has not been made public, the affected brands together accounted for approximately 85% of the UK commercial milk formula market.⁵ At the peak of the disruption, 28.4% of formula milk products were out of stock,⁶ and some products saw sharp retail price increases.⁷ These impacts demonstrate the close relationship between formula safety, affordability and availability. Neither infant formula supply or breastfeeding support are currently included in UK food security assessments, limiting preparedness for future disruption.⁸

Public health communications during the recall were also insufficient. Families were not consistently provided with clear, consolidated and practical guidance on how to maintain safe and appropriate infant feeding practices while avoiding affected formula milk products.

* Cereulide poisoning typically presents with nausea, vomiting, diarrhoea and abdominal cramps occurring shortly after consumption. See UK Health Security Agency, "HPR Volume 20 Issue 1: News (29 January and 5 February 2026)," GOV.UK, 5 March 2026, <https://www.gov.uk/government/publications/health-protection-report-volume-20-2026/hpr-volume-20-issue-1-news-29-january-2026-january-2026>.



Policy recommendations

NON-REGULATORY RECOMMENDATIONS

1 The UK Health Security Agency of the Department of Health and Social Care should strengthen safeguards for infant health by improving surveillance and evidence on foodborne risks linked to infant formula.

To ensure that government action is proportionate to the risks facing infant health, UKHSA should strengthen surveillance of food poisoning symptoms in infants aged 0–6 months. Enhanced monitoring would provide a more accurate picture of the scope and scale of preventable gastrointestinal illness linked to formula feeding and help identify emerging threats earlier.

This should include improving the collection and testing of stool samples for pathogens and toxins that may be linked to infant formula, including *Cronobacter* species, *Salmonella*, *Listeria monocytogenes*, *Bacillus cereus* and cereulide toxin, and other relevant microbiological hazards identified through risk assessment.

2 The Department of Health and Social Care and the Food Standards Agency should urgently improve public messaging during infant formula crises, with a clearer focus on safe and appropriate infant feeding[†].

Public health messaging should include clear, practical information such as:

- What parents/carers should do with recalled formula products;
- That there is no increased health risk from switching between infant formula brands, or from switching from follow-on formula to infant formula;
- Which alternative products are suitable during supply disruption, including when clinical advice is needed for prescribable specialised formulas, and reassurance that the Government can maintain a reliable supply of suitable infant formula for all infants who need it;
- The distinction between the nutritional equivalence of infant formula brands and the wider protective components of breastmilk, including immune support;
- Practical support for parents/carers who are mixed feeding and wish to increase breastfeeding;
- The importance of preparing powdered formula in line with NHS guidance, including using water hot enough to kill bacteria that may be present, because powdered infant formula is not sterile and cannot be made sterile. Parents and carers should also be advised that many formula preparation devices may not heat water to the minimum temperature required to kill bacteria present in the powder;
- Guidance on safer formula feeding in emergency situations involving disruption to power or water supplies where it may be difficult to follow usual preparation guidance.

[†] Noting that parents and carers should be directed to clear, independent public health guidance rather than to formula companies, whose commercial interests make them inappropriate sources of impartial advice

3 DHSC, FSA, and the Office for Product Safety and Standards should review current NHS guidance on formula preparation and associated risks

DHSC should commission an independent review of current NHS formula preparation guidance to assess whether it is sufficient to protect infant health. This review should be informed by an FSA-led assessment of bacterial risks associated with powdered infant formula. In parallel, OPSS should ensure the safety and regulatory compliance of all products used in formula preparation, including at-home preparation devices. Where any risks are identified, DHSC should consider regulating the marketing or sale of such devices.

4 The Department for Environment, Food and Rural Affairs and the DHSC should recognise infant feeding as a critical component of UK food security

4.1 DEFRA should incorporate both infant formula supply and safer formula use, alongside breastfeeding support, into the UK food security assessment. This should include greater transparency across formula supply chains to help ensure reliable access to infant formula and prescribed specialised formulas. Infant feeding, including both formula feeding and breastfeeding, must also be included in emergency planning, with the protection, promotion and support of breastfeeding recognised as essential to building resilience.

4.2 DHSC should investigate means of widening access to donor human milk (DHM) as part of emergency planning for infant food security. Human milk banks can play an important role during crises by

providing DHM for infants where breastfeeding is not possible and infant formula supply is disrupted. Wider access to DHM, alongside high-quality breastfeeding support, can also help mothers establish or continue breastfeeding, strengthening resilience and reducing avoidable reliance on formula. The forthcoming EU *Substances of Human Origin (SoHO)* regulation, which will reclassify human milk as a regulated SoHO in Northern Ireland from 7 August 2027, reinforces essential safety and quality standards. These protections should be extended across the whole of the UK to strengthen national readiness for future supply shocks and to ensure consistent governance that protects infants from contamination related ill health.

5 The Scientific Advisory Committee on Nutrition should review infant feeding recommendations in light of infant formula supply risks

SACN should re-evaluate the evidence supporting the recommendation to give formula milks rather than cows' milk to non-breastfed infants aged 6 to 11 months, with or without iron supplementation, in line with global recommendations.⁹ Public health recommendations should reflect the changing risk–benefit balance following recent formula recalls (and price rises)⁷ and prioritise infant health, recognising that cows' milk can be pasteurised, is produced locally (so any contamination affects a far smaller population group), and contains fewer ingredients and processing steps where contamination can occur.

REGULATORY RECOMMENDATIONS

A reluctance to introduce regulatory measures perceived to be disproportionate to risk and need, is leaving important gaps in protections for infant health. The stronger regulations recommended below are required to safeguard infant health.

6 The Food Standards Agency, DHSC and Office for Product Safety and Standards should strengthen oversight of infant formula safety and preparation risks

- 6.1 The FSA should strengthen regulatory oversight through mandating final product testing (including implementing European Food Safety Authority (EFSA)-linked thresholds for cereulide), defining testing schedules, regular inspections of manufacturing sites, independent audits of manufacturers own testing, clear penalties for non-compliances and regularly updating microbiological risk assessments guided by emerging evidence. Manufacturers should also be held accountable for timely emergency management.
- 6.2 The FSA should continue to actively support and drive forward the work initiated at the 55th Session of the Codex Committee on Food Hygiene to strengthen Codex standard CXC 66-2008. This should include advocating for improved safety standards in infant formula manufacture, with particular attention to microbiological risks, including cereulide and botulism.



7 The Department of Health and Social Care should ensure a coordinated government response to protect families during infant formula supply disruptions and price shocks. This should include better regulating commercial milk formula marketing which undermines safe and appropriate infant and young child feeding practices

7.1 DHSC should implement the jointly agreed programme of work set out in the Government's response to the Competition and Markets Authority market study, aimed at reducing infant formula supply risks associated with the dominance of a small number of brands. DHSC should clarify its approach for evaluating the impact of its work in implementing the selected CMA recommendations.

7.2 DHSC and His Majesty's Treasury should assess the risks, design and implementation of government-led price controls on infant formula, such as profit caps, while closely monitoring infant formula price changes in line with the 2025 recommendations of the Competition and Markets Authority.⁵

7.3 DHSC should clarify the next steps for strengthening labelling and advertising rules, in line with the

2025 recommendations of the CMA. Regulation should be brought into closer alignment with the International Code of Marketing of Breastmilk Substitutes and subsequent resolutions, supported by effective enforcement mechanisms. This should include mandatory front-of-pack warnings on powdered formula milks stating they are not sterile, clear labelling on safer preparation, and stronger consumer protections governing the marketing of all formula milks and formula preparation devices.

7.4 DHSC should commission an independent review of Regulation (EU) No 609/2013 and Commission Delegated Regulation (EU) 2016/127, reassessing the permissibility of optional ingredients in formula milks that may offer limited health and nutrition benefits while increasing production complexity and contamination risk.

8 The DHSC and the Department for Work and Pensions should embed breastfeeding and infant feeding support as a core component of maternal and child health policy, recognising breastfeeding as the safest and most resilient method of infant feeding.

This should include sustained, high-quality breastfeeding and infant feeding training for all relevant NHS staff; long-term, dependable funding for quality-assured support through neonatal, maternity, health visiting, Children's Centre and Family Hub services; stronger legal protections for breastfeeding women returning to work; and upgraded, properly enforced UK legislation to prevent the inappropriate marketing of commercial milk formula, bottles and teats, in line with the International Code of Marketing of Breastmilk Substitutes and subsequent World Health Assembly resolutions.



1 Overview and scale of the cereulide toxin formula contamination and recall

The UK public was first notified of commercial milk formula recalls linked to possible cereulide toxin contamination between 5 January and 6 February 2026, through a series of FSA food alerts.³

More than 60 formula milk batches were affected in the UK, spanning multiple product lines. These included Danone products marketed under the *Aptamil* and *Cow & Gate* brands, and Nestle products sold under the *SMA* and *Little Steps* brands.³ Although the total volume of recalled products is unknown, batch expiry dates ranged from June 2026 to December 2027. The UKHSA estimated that contamination occurred no earlier than May 2025,¹ suggesting that affected products may have been on the UK market for at least eight months before the first UK recall notice. Delays in product recalls are central to a criminal complaint filed in Paris.¹⁰

EU-derived microbiological standards require testing for presumptive *Bacillus cereus*, but sampling frequency is determined by manufacturers.¹¹ This leaves oversight substantially dependent on self-testing and self-reporting and raises questions about whether current monitoring and enforcement arrangements are sufficient for products consumed by infants given the risks and their vulnerability.

The contaminated ingredient was identified as arachidonic acid (ARA), a long-chain polyunsaturated fatty acid supplied by Cabio Biotech¹². ARA oil is produced through fermentation using the fungus *Mortierella alpina*. It is thought that *Bacillus cereus* contaminated the production process and that, because both ARA and cereulide are lipophilic, the toxin was extracted alongside the oil.¹³ All infant formulas sold in the UK currently contain ARA, and its inclusion is often used to make claims about supporting infant growth, brain development and overall health.^{14,15} However, there is no UK regulatory requirement to add ARA to infant formula.¹⁶ UK regulations classify ARA as an optional ingredient, and EFSA has concluded that it is not necessary to meet infants' nutritional needs or support growth and development.¹⁷ While ARA is optional, Codex standards recommend including ARA in infant formulas that also contain DHA (docosahexaenoic omega-3 fatty acid). DHA has been required in UK infant and follow on formula since 2016 through legislation



Toxin contaminated formula milks may have been on the market for at least eight months before the first UK recall notice.

derived from Commission Delegated Regulation (EU) 2016/127.¹⁶ This creates a complex regulatory environment in which optional ingredients may become effectively normalised in the market despite limited independent evidence of benefit¹⁸.

The UKHSA and partner agencies identified 61 reports of symptoms consistent with cereulide poisoning among children who had consumed affected formula milk batches, across the UK and Crown Dependencies.⁴ This figure is likely to underestimate the true number of adverse reactions because of limitations in surveillance and diagnostic capacity. First, until late 2023 there was no reliable assay to detect cereulide toxin in leftover food and clinical samples,¹⁹ and UK capacity for detecting cereulide in human clinical samples remains limited.⁴ Second, the symptoms of cereulide toxicity are non-specific and overlap with common seasonal viral infections. This is further complicated by the frequency with which infants present to primary care with gastrointestinal symptoms linked to normal developmental physiology and common functional disorders such as colic and constipation^{20,21}. This is despite the possibility that some of these symptoms may be related to formula use, preparation practices or contamination of infant formula. Third, testing for cereulide only began in January 2026, although >>

contamination may have been present from May 2025. Without enhanced surveillance and expanded diagnostic capacity, distinguishing routine infant illness from contamination-related cases will remain difficult.

In February 2026, EFSA identified concentrations of cereulide in reconstituted infant and follow-on formula that raised safety concerns, informing recall

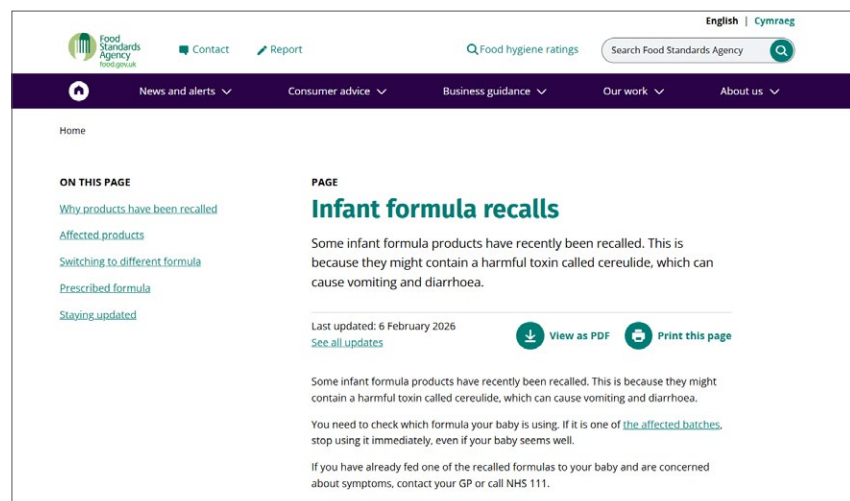
and risk-management activity across the European Union.²² However, it is not clear if the FSA has adopted these EFSA-linked values as mandatory routine legal thresholds for infant formula testing in the UK. The UK Government has also indicated that it has no current plans to introduce mandatory testing for cereulide or other toxins in formula milks.²³

1.1 Official public health response to the cereulide toxin formula contamination and recall

The UK has established arrangements for managing microbiological foodborne disease outbreaks through coordinated action across multiple agencies. These agencies include the UKHSA, FSA, counterpart public health and food safety bodies in the devolved nations, local authorities, environmental health officers and public health consultants. Within this framework, the UKHSA leads on surveillance, risk assessment (alongside the FSA's Advisory Committee on the Microbiological Safety of Food), and clinical guidance. The FSA is responsible for food safety risk management, including investigations and the coordination of product withdrawals and recalls.

In February 2026, healthcare professionals in England were advised to notify suspected cases of cereulide poisoning to the UKHSA. The UKHSA also recommended that individuals presenting to hospital with compatible symptoms should receive a clinical assessment and that faecal samples should be collected for cereulide testing.¹

There were 61 reports of symptoms consistent with cereluide poisoning among children who had consumed affected formula batches, but this is likely an underestimate.



Targeted testing of recalled formula milk samples linked to notified cases was also advised.

From early January 2026, DHSC's National Supply Disruption Response acted as the single point of contact for the medical supply industry and worked with the Food Standards Agency to manage supply issues affecting infant formula and prescribable specialised formula milks.²⁴ Its response focused on protecting the clinical needs of the most vulnerable infants, including

by securing unaffected stock for redistribution in hospital and home settings and working with industry to identify suitable alternative products.

The global nature of the supply chain meant that the recall affected multiple countries. UK data informed a joint rapid outbreak assessment by the European Centre for Disease Prevention and Control and EFSA, which concluded that the overall risk of infant exposure was low because of large-scale recalls, suspension of the contaminated ARA ingredient and public warnings across affected markets.²⁵ In response, the International Food Safety Authorities Network has developed a standardised case definition to support consistent >>

case identification in the current outbreak and future incidents, with scope for adaptation across different settings.²⁶ WHO has also issued a call for experts and data to inform the microbiological risk assessment of powdered formulae for infants and young children, and is establishing an expert group to support the Joint FAO/WHO Expert Meeting on Microbiological Risk Assessment.²⁷

Parents were advised not to use affected formula products, even in the absence of symptoms. They were also advised to return recalled items for a refund, contact manufacturer helplines, and seek advice from healthcare professionals, including GPs or NHS 111, where concerns arose.

However, public-facing guidance focused primarily on product safety and recall compliance, with less

affected. In the absence of a consolidated official list, some non-governmental and media sources collated recalled products in one place, highlighting a gap in official emergency communication for a product that may be the sole source of nutrition for young infants.

There was also limited explicit reassurance that the infant formula products from different brands can be used interchangeably, given that all must meet the same UK nutrition compositional standards. This omission was significant because supply disruption may require families to switch products quickly. This can be made more difficult by formula company marketing, which may encourage brand loyalty or imply nutritional differences between products. Families using specialised formulas affected by the recalls, including anti-reflux, lactose-free and amino acid products, were particularly affected because suitable alternatives are more limited. Infants who are prescribed these products require clinical input to ensure an appropriate and safe replacement. However, the ready availability of some specialised formulas on supermarket shelves may contribute to overdiagnosis and overuse, creating avoidable vulnerability among infants who do not have a clinical need for these products^{18,28}.

Public-facing guidance focused on product safety and recall and less on supporting families to maintain safe and appropriate infant feeding practices.

Official communications were delivered through multiple channels, including FSA food alerts and product recall information notices, manufacturer communications from Nestlé and Danone, retail and point-of-sale notices, and online platforms. Some NHS organisations and local health trusts also communicated with healthcare practitioners, and the UKHSA issued a proactive press release and official statement to national media. At the direct request of health professionals, civil society and non-governmental organisations working in early years nutrition, including First Steps Nutrition Trust and the Breastfeeding Network, also sought to address the absence of direct public health messaging for families and carers on NHS infant feeding webpages.

emphasis on supporting families to maintain safe, appropriate and nutritionally adequate infant feeding practices. No reassurance was provided to healthcare practitioners or parents that government could maintain a reliable supply of suitable infant formula for all infants who needed it. This contributed to anxiety about whether appropriate products would remain available and affordable[†].

Official information was issued through separate recall notices as details became available, rather than through a single consolidated source covering all affected products and batch numbers. This created an additional burden for parents/carers and healthcare professionals, who had to consult multiple sources to determine whether specific products were

[†] Personal correspondence: parents contacted First Steps Nutrition Trust by email between February and March 2026 to raise concerns related to the formula recalls.

1.2 Market impacts of the cereulide toxin formula contamination and recall

The UK commercial milk formula market is highly concentrated, with Danone and Nestlé accounting for an estimated 85% of market share across the *Aptamil*, *Cow & Gate*, *SMA* and *Little Steps* brands.²⁹ At the peak of the recall, 28.4% of formula products, or 98 out of 335 products, were out of stock.⁶ This demonstrates how reliance on shared global ingredient supply chains can spread disruption quickly across multiple products, brands and markets, even where the contamination originates from one ingredient. Some retailers had visibly reduced stock, with sections of infant formula shelves left empty. One affected product was among the lowest-cost options on the market, reducing access to more affordable infant formula. Where families were unable to afford the full quantity needed at a higher price, there is a risk that they may have resorted to unsafe feeding practices, such as over-dilution or early introduction of unsuitable products.^{30, 31}

At the peak of the recall, 28.4% of formula products (98/335) were out of stock, and the prices of some products increased by up to 45% between January and February 2026.

To protect infant health, risk management measures prioritised the recall of contaminated and potentially contaminated products. However, they did not fully address the need to maintain access to safe and nutritionally appropriate infant formula or to encourage ongoing or increased breastfeeding for babies who were mixed fed. Alongside availability challenges, prices for some formulas increased by up to 45% between January and February 2026.³² Recent price increases follow several years of price increases and growing evidence that infant formula is unaffordable for some families, with implications for infant and maternal health and wellbeing.^{7,33,8} Although Danone stated that the 2026 price increases were not linked to the recalls³⁴, Danone's *Aptamil* and *Cow & Gate* brands accounted for 84.1% of the recorded price rises³² during a period when families were seeking safe alternatives.



⁸ Forthcoming research led by Professor Amy Brown, Swansea University, including three papers on the impact of infant formula affordability on parental wellbeing, financial security and safe feeding practices in the UK; 1) Infant formula affordability negatively impacts parental wellbeing, financial security and safe feeding practices in the UK 2) Expenditure on infant formula, brand decisions and marketing in the UK: Inequitable impacts upon low-income families 3) What are the solutions to the infant formula milk affordability crisis in the UK? Parent and professional perspectives

2 Structural vulnerabilities in infant formula safety and supply

2.1 Infant formula contamination risks from production to consumption

Infant formula is the only safe alternative to breastmilk for infants during their first six months, and current UK recommendations advise its use up to 1 year of age for non-breastfed infants. Because infants have underdeveloped immune systems, the safety and nutritional adequacy of their food is critical. Powdered formula milks, including infant formula, are not sterile, making them vulnerable to food safety risks. In a concentrated and globalised market, contamination of a single ingredient can create widespread risks. Microbial contamination may be present in approximately one-third of infant formulas at the point of consumption,³⁵ and contamination can occur at any stage from production to feeding. Because symptoms can resemble common gastrointestinal illnesses, contamination may remain undetected.



Powdered formula milks, including infant formula, are not sterile, making them vulnerable to food safety risks.

Powdered formula production involves complex, multi-stage processing, including the addition of vegetable/fish oils, vitamins and minerals.³⁶ Infant formula powders generally contain more than 40 individual ingredients. Each additional ingredient and processing step creates further opportunities for microbial

contamination.³⁵ While some ingredients are required to meet nutritional standards, others are optional under EFSA guidance and are often included to support health or nutrition claims, despite limited robust clinical trial evidence²⁷.

Their inclusion may therefore introduce additional risk without clearly demonstrated health or nutritional benefit. Manufacturers may also use these optional ingredients to support marketing claims, position products as premium, and justify higher prices^{18, 37}.

Home preparation introduces additional contamination risks from bacteria present in the powder and from the surrounding environment. NHS guidance recommends sterilising equipment and adding freshly boiled tap water to the powder, cooled to no less than 70 °C, to reduce bacterial contamination.³⁸ However, this guidance does not protect against cereulide toxin. Although water at 70 °C can kill bacteria, cereulide is highly heat stable, can survive temperatures above 120 °C, and can remain active after *Bacillus cereus* cells are destroyed.

Water in at-home formula preparation devices, used by as many as half of formula feeding parents in the UK, may not reach temperatures sufficient to eliminate bacteria.³⁹ Formula prepared using these devices can also contain higher microbial loads.³⁵ Reported contaminants associated with automated devices include *Candida* species and *Cupriavidus pauculus*, organisms not previously linked to powdered infant formula, indicating that these devices may introduce new contamination risks beyond those traditionally associated with formula production and preparation. NHS guidance recommends checking that water from these devices reaches the appropriate temperature when combined with formula, but it is unclear how well this guidance is understood or followed by parents and carers.

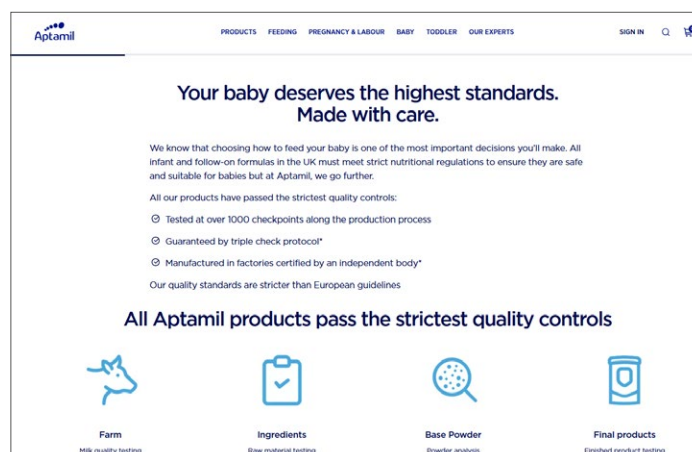
Popular rapid-cooling devices raise a further concern, as quickly cooling prepared formula may reduce the effectiveness of heat treatment in killing bacteria.³⁵

2.2 Regulatory gaps affecting the safety of infant formula and feeding practices

Current EU-derived microbiological standards require infant formula sold in the UK to be tested for *Listeria monocytogenes*, *Salmonella* and *Cronobacter sakazakii*. Other potential contaminants of dried infant formula, including Enterobacteriaceae and presumptive *Bacillus cereus*, including strains capable of producing cereulide toxin, are left to manufacturers' own risk assessments.¹¹ These criteria are set out in Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs,⁴⁰ which applies Hazard Analysis and Critical Control Point principles and good hygiene practices. Manufacturers must comply with the microbiological criteria, but beyond the prescribed minimum sample sizes, the frequency and extent of sampling are not mandated. This places responsibility on manufacturers to determine appropriate sampling plans. This also enables manufacturers to market their products as “safe” using statements such as “we carry out a large number of microbiological tests to ensure the formula meets our strict specifications”⁴¹, despite there being no meaningful regulatory basis for such claims. Codex standard CXC 66 2008 similarly sets criteria for *Salmonella* and *Cronobacter sakazakii* in powdered infant formula but does not include specific limits for cereulide, presumptive *Bacillus cereus*, botulism or *Clostridium botulinum*⁴². It also does not require fixed testing frequencies, leaving manufacturers to determine testing through their own risk assessments.

This reliance on manufacturer self-regulation creates regulatory vulnerability. Limited routine product testing, combined with the fact that contamination symptoms may resemble common gastrointestinal illnesses, as described above, increase the risk that formula contamination can remain undetected for extended periods. The cereulide recall illustrates this risk. Other toxins that are not routinely monitored in infant formula also warrant consideration, including those associated with botulism, which was linked to the hospitalisation of 58 infants in the United States during a formula-implicated outbreak in 2025.⁴³

Although commercial milk formula recalls appear to be becoming more frequent globally, manufacturer accountability remains limited. A list of infant formula recalls reported internationally over the last decade is provided in the [annex](#). This illustrates that the recent cereulide contamination event is not an isolated incident, but part of a wider pattern of recurring risks to infant health and food security.



Commercial milk formula recalls appear to becoming more frequent while manufacturer accountability remains limited.

Manufacturers have faced serious allegations and lawsuits concerning infant disease and deaths in other countries^{10, 44}, but there appear to be no widely reported cases in which a manufacturer has been successfully sued and found liable for infant deaths in the UK. In the UK, legal action is constrained by limited testing for cereulide in clinical samples and the discretionary nature of testing recalled formula.⁴ At the time of writing, there is limited publicly available evidence of legal action brought in the UK by government bodies or non-governmental organisations, against industry or regulators in relation to infants potentially harmed by cereulide-contaminated formula. One legal firm has announced that it has begun litigation on behalf of clients against Nutricia and Nestlé UK following reports of contaminated products^{45, 46}, and another firm is offering support to parents seeking compensation if they believe they have been affected by the recall.⁴⁷ Prosecutors in Paris have opened investigations into Nestlé, Lactalis, Danone, Babybio and La Marque en moins over possible criminal wrongdoing in the distribution of ‘baby formula’ that may have been contaminated with cereulide.⁴⁸

Regulatory gaps in the marketing of commercial milk formulas also risk undermining breastfeeding and weakening public health messaging on formula safety. Current UK legislation restricting the marketing of >>

infant formula is weaker than global guidance.⁴⁹ In practice, the marketing of commercial milk formulas, including infant formulas, continues to influence infant feeding decisions and practices.^{50,51} Many formula companies do not clearly communicate at the point of sale that powdered formula is not sterile, and instead promote products as similar to breastmilk.⁵² This framing may contribute to an assumption that powdered infant formula is inherently safe, weakening the perceived importance of safer preparation guidance and obscuring the risks associated with bacterial contamination. In the UK, this may help explain why safer preparation guidance is not always followed consistently, and why some parents and carers may have limited understanding of the potential microbiological risks associated with powdered infant formula³⁹.

Breastfeeding remains the safest method of infant feeding, providing optimal nutrition and immune protection. It is also resilient to contamination, supply chain disruption, and disruption to water or power supplies. Because breastfeeding is portable and requires no special equipment, it is particularly protective in emergency situations.

Marketing practices that undermine informed infant feeding decisions and breastfeeding increase reliance on formula and, as a result, can amplify exposure to contamination and supply risks in the event of an emergency.

2.3 Risks to infant food security arising from formula milk contamination

The recent recall exposed significant vulnerabilities in infant food security. While most mothers in the UK intend to breastfeed, systemic societal and financial barriers prevent many from achieving their breastfeeding goals, leaving the majority of infants partly or wholly dependent on formula from the first weeks and months of life.⁵³ For infants reliant on formula as their sole source of nutrition, any supply disruption has immediate food security implications.

These risks are intensified by the structure of the infant formula market. Infant food security is particularly vulnerable in a concentrated market dominated by a small number of brands and dependent on global, profit-driven supply chains. The recall demonstrates that infant food security depends not only on the availability

of finished formula products, but also on the resilience and transparency of the ingredient supply chains behind them.³⁶ Market concentration leaves supply chains vulnerable to disruption, while weak and poorly enforced marketing regulations reinforce brand loyalty, create barriers to entry for new

suppliers⁵⁴, and further erode resilience during events such as recalls.

During the recall, families experienced several dimensions of food insecurity, including reduced infant formula availability, perceived scarcity and rising costs. Mothers who wished to breastfeed but lacked adequate support also experienced distress at their dependence on formula. Parents reported concerns about infant health, alongside anxiety about whether suitable products would remain available and affordable^{55,56}. As noted above, the affected brands represented a substantial share of the UK commercial milk formula market⁵, meaning concerns about availability were well founded. Early in the recall, there were also concerns that additional brands could be affected >>



⁵⁵ Personal correspondence: parents contacted First Steps Nutrition Trust by email between February and March 2026 to raise concerns related to the formula recalls.

through shared ingredient supply chains. Even after manufacturers confirmed alternative suppliers of the contaminated ingredient, uncertainty remained about whether unaffected brands could meet increased demand.

Affordability further compounded these access concerns. As noted in section 1.2, the recall coincided with price increases of up to 45% for some formula products. In food security terms, this matters because families affected by reduced availability may also have faced higher costs when seeking alternatives.³² One affected infant formula product was among

the lowest-cost options on the market, further reducing access to affordable formula for families already under financial pressure.

Pricing, marketing and public messaging are closely connected. A lack of clear public messaging on the nutritional equivalence of infant formula brands, the safety of switching products where clinically appropriate, and the importance of supporting continued breastfeeding for mixed-fed babies may have made it harder for families to identify safe, suitable and affordable alternatives. These gaps were reinforced by marketing strategies that encouraged brand

loyalty and implied the nutritional superiority of particular formula milks⁵.

Infant formula supply is not currently included in the UK's food security assessments⁸ limiting emergency preparedness and contributing to inadequate mitigation planning during unexpected events such as recalls. This gap represents a broader risk for future crises, particularly given ongoing weaknesses in the regulatory oversight of formula safety and the vulnerability of supply chains to contamination events.

2.4 Other infant feeding options when infant formula supply is reduced

Infant formula is the most commonly used replacement for breastmilk. However, alternative options may be relevant in some circumstances, including donor human milk.

Experience from the US shows that when formula supply is disrupted, hospitals and families may turn to human milk banks as a source of food for newborns and other infants, including sick and preterm babies.⁵⁶ In the UK, however, human milk banks are not currently resourced or funded to respond to sudden increases in demand. This limits their ability to maintain routine provision while also responding to emergency requests and prioritising supplies of pasteurised donor human milk.

Greater attention should be given to how milk banks could be supported during formula supply disruptions, to support safe and appropriate infant feeding. Consideration could also be given to developing a breastmilk reserve, including the potential role of freeze-dried human milk, to strengthen resilience in emergencies involving interruptions to infant formula supply.

Based on the 2023 WHO Guidelines for complementary feeding of infants and young children aged 6–23 months⁹, cows' milk and other animal milks may have a role as accessible alternatives to formula milks in some circumstances. However, their suitability depends on the age, health and nutritional needs of the child, and



on the wider context in which they are used. Further consideration is therefore needed of whether, and in what circumstances, public health guidance in the UK should recognise animal milks as a suitable alternative to breastmilk for infants aged 6-11 months.

3 Cross-cutting principles for policy action

Infant formula is currently an essential food for many UK infants. Its safety, availability and affordability should therefore be protected, particularly during contamination incidents or supply disruptions. In line with the precautionary principle, infant food safety systems should prioritise prevention where credible risks to infant health are identified, rather than waiting for complete evidence of harm before strengthening safeguards. This requires stronger regulatory oversight and corporate accountability, including mandated final product testing, regular manufacturer inspections, independent government audits, clearer testing requirements, defined penalties and updated microbiological risk assessments.

Parents who use formula to feed their babies should receive accurate and impartial information about formula at appropriate opportunities in line with the Unicef UK

Baby Friendly Initiative and the International Code of the Marketing of Breastmilk Substitutes and World Health Assembly Resolutions which informs it. This should include guidance on preparing powdered formula safely, clear information that infant formula is suitable up to 12 months (and follow-on formula is not necessary), that no formulas are needed beyond 12 months, and that all infant formulas are nutritionally equivalent, meaning that switching between brands is safe.

At the same time, acknowledging public health recommendations on infant feeding and the superiority of breastfeeding for maternal, infant and child outcomes, the economy and the environment, Government policy should also prioritise the protection and promotion of, and support for, breastfeeding. Breastfeeding reduces unnecessary and potentially risky reliance on commercial milk formulas.



Conclusion

The cereulide toxin recall highlights the fragility of infant food security in the UK. High levels of formula feeding, market concentration and globally sourced supply chains mean that formula contamination can have significant public health and food security implications. Although the current risk of toxic exposure is assessed as low, the full extent of exposure remains uncertain, including how many families may still hold contaminated products.

The incident demonstrates the need for systems that can detect infant formula contamination rapidly, maintain reliable and affordable supply, communicate clearly with families about safe and appropriate infant feeding practices during crises, and regulate a market that provides a critical source of nutrition for many UK infants during the first 6-12 months of life. Strengthening these systems is essential to protect infant health and safeguard food security in the UK, alongside protecting, promoting and supporting breastfeeding as optimal for maternal, infant and young child health, the economy and the environment.

Our recommendations to Government are set out on pages 3 to 6.



About us

First Steps Nutrition Trust is an independent public health nutrition charity working to improve nutrition from pre-conception to age five. We fill practical and policy-relevant information gaps by influencing policies to better support optimal, safe and appropriate infant and young child feeding, and providing conflict of interest-free resources for professionals supporting pregnant women and parents and carers of babies and children up to school age.

Our resources are developed by nutrition experts, regularly updated, available as free PDF downloads, and can be used in Unicef UK Baby Friendly Initiative accredited settings. We also maintain www.infantmilkinfo.org, a dedicated website providing independent information on infant milks marketed in the UK, for professionals supporting families who use formula to feed their babies.

FIRST STEPS NUTRITION TRUST 

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ANNEX 1. International infant formula recalls linked to microbiological contamination over the past decade

Year	Country/ region affected	Manufacturer/ product(s)	Identified risk / hazard	Recall summary	Source
2017	France; products distributed to 48 countries/ territories	Lactalis Nutrition Santé (Picot SL (Lactose Free), Pepti Junior SL (Lactose Free) & Milumel Bio)	<i>Salmonella</i> Agona	35 confirmed infant cases in France (under 6 months of age). - Lactalis recalled over 600 batches, more than 7,000 tonnes, with an expanded recall of products from the Craon plant.	World Health Organization (2017). Salmonellosis – France. WHO. Available at: https://www.who.int/emergencies/disease-outbreak-news/item/22-december-2017-salmonella-agona-infections-france-en
2018	Chile	Wyeth (S-26 Gold)	<i>Bacillus cereus</i>	3 infants hospitalised	24 Horas (2018). At least three cases of poisoning from contaminated milk have been registered in the capital. 24Horas. Available at: https://www.24horas.cl/nacional/al-menos-tres-casos-de-intoxicacion-por-leche-contaminada-se-han-registrado-en-la-capital-2694065
2018	France	Nestlé (Guigoz)	“Enterobacter-type contamination	Manufacturer recall due to possible contamination	Ouest-France (2018). Infant milk. Nestlé recalls as a "precaution" boxes of Guigoz 1st age. https://www.ouest-france.fr/sante/lait-infantile-nestle-rappelle-38-boites-guigoz-1er-age-5880448
2018	Chile	Nestlé (NAN Premature formula)	<i>Staphylococcus aureus</i>	Manufacturer recall due to contamination	Ministerio de Salud Chile (2018). Minsal decrees new extension of Food Alert to NAN Premature Infant formula. Minsal. Available at: https://www.minsal.cl/minsal-decreta-nueva-ampliacion-de-alerta-alimentaria-a-formula-nan-prematuros/
2018	Singapore	Dumex (Mamil Gold)	<i>Cronobacter sakazakii</i>	Agri-Food and Veterinary Authority (AVA) recalled product after bacteria found in test samples	The Straits Times (2018). AVA recalls batch of Dumex infant formula. Available at: https://www.straitstimes.com/singapore/health/ava-recalls-batch-of-dumex-infant-formula
2018– 2019	France	Modilac (three rice-based products, produced in a Spanish factory)	<i>Salmonella</i> Poona	14 cases (2-19 months), 7 hospitalised for salmonellosis. - Modilac recalled its entire range of rice protein-based infant nutrition products and, more broadly, all products manufactured at the affected Spanish production site.	Santé publique France (2019). Cases of Salmonella Poona in Infants: Update as of February 8, 2019. Santé publique France. Available at: https://www.santepubliquefrance.fr/en/les-actualites/cases-salmonella-poona-infants-update-february-8-2019 >>

Year	Country/ region affected	Manufacturer/ product(s)	Identified risk / hazard	Recall summary	Source
2022	United Kingdom	Abbott Nutrition (Elecare Similac and Alimentum Similac)	Potential <i>Salmonella Newport</i> and <i>Cronobacter sakazakii</i>	Manufacturer recall due to possible contamination	Food Standards Agency (2022). Abbott recalls two infant formula powders because of the possible presence of Salmonella. FSA. Available at: https://www.food.gov.uk/news-alerts/alert/fsa-prin-11-2022
2022	United States; international implications	Abbott Nutrition (Similac, Alimentum, EleCare products)	<i>Cronobacter sakazakii</i>	4 confirmed cases in infants, 2 deaths. - Manufacturer recalled specific batches of products according to lot code.	US Centers for Disease Control and Prevention (2022). Cronobacter Outbreak Linked to Powdered Infant Formula. CDC. Available at: https://www.cdc.gov/cronobacter/outbreaks/formula-2022/index.html
2022	United States	ByHeart (Whole Nutrition Infant Formula product)	Potential <i>Cronobacter sakazakii</i> cross-contamination	“None of the distributed ByHeart product has tested positive for any contaminants. No consumer complaints received that would indicate any illness”. - ByHeart recalled five batches due to potential Cronobacter cross-contamination.	U.S. Food & Drug administration (2022). ByHeart Issues Voluntary Recall of Five Batches of Its Infant Formula Because of Possible Health Risk. FDA. Available at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/byheart-issues-voluntary-recall-five-batches-its-infant-formula-because-possible-health-risk
2023	United States	Reckitt (Enfamil ProSobee)	Potential <i>Cronobacter sakazakii</i> cross-contamination	“Product tested and confirmed negative for contaminants. No reported adverse consumer reactions to date.” - Reckitt recalled two batches, around 145,000 cans, due to possible Cronobacter cross-contamination.	U.S. Food & Drug administration (2023). Reckitt Recalls Two Batches of Prosobee 12.9 oz Simply Plant Based Infant Formula Because of Possible Health Risk. FDA. Available at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/reckitt-recalls-two-batches-prosobee-129-oz-simply-plant-based-infant-formula-because-possible
2023	United States	Perrigo Company plc (Gerber Good Start & SoothePro Infant formula products)	Potential <i>Cronobacter sakazakii</i>	“No distributed product has tested positive for the presence of this bacteria, no adverse events have been reported.” - Perrigo recalled certain Gerber Good Start and SoothePro powdered infant formula batches due to potential Cronobacter contamination.	U.S. Food & Drug administration (2023). Perrigo Announces Voluntary Recall of Limited Quantity of Gerber® Good Start® SoothePro™ Powdered Infant Formula. FDA. Available at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/perrigo-announces-voluntary-recall-limited-quantity-gerber-good-start-sootheprotm-powdered-infant

Year	Country/ region affected	Manufacturer/ product(s)	Identified risk / hazard	Recall summary	Source
2023	United States (distributed in 19 countries)	Reckitt / Mead Johnson Nutrition (Nutramigen hypoallergenic infant formula)	Possible <i>Cronobacter sakazakii</i>	“No illnesses have been reported”. - Reckitt / Mead Johnson Nutrition recalled Nutramigen powdered formula after Israeli border testing confirmed <i>Cronobacter sakazakii</i>; related products were distributed in multiple countries.	U.S. Food & Drug administration (2023). Reckitt/ Mead Johnson Nutrition Voluntarily Recalls Certain Nutramigen Hypoallergenic Powdered Infant Formula Products. FDA. Available at: https://www.fda.gov/food/hfp-constituent-updates/reckittmead-johnson-nutrition-voluntarily-recalls-certain-nutramigen-hypoallergenic-powdered-infant
2024	United Kingdom	Reckitt Mead Johnson Nutrition (Nutramigen LGG Stage 1 Hypoallergenic Formula and Nutramigen LGG Stage 2 Hypoallergenic Formula)	Possible <i>Cronobacter sakazakii</i>	Manufacturer recall due to possible contamination	UK Health Security Agency (2024). Event: Recall of infant formula product due to possible contamination with <i>Cronobacter sakazakii</i> . UKHSA. Available at: https://www.selondonics.org/wp-content/uploads/UKHSA-20240111_01_Recall-of-infant-formula-product-due-to-possible-contamination-with-Cronobacter-sakazakii_v1.00.pdf
2025– 2026	United States (distribution to over 20 countries)	ByHeart (Whole Nutrition Infant Formula)	<i>Clostridium botulinum</i> / botulinum toxin type A	28 cases of confirmed infant botulism and 20 cases of probable infant botulism (48 hospitalisations). - FDA described this as the first documented US outbreak of botulism attributed to contaminated infant formula. - All ByHeart infant formula products recalled.	U.S. Food & Drug administration (2023). Outbreak Investigation of Infant Botulism: Infant Formula (November 2025). FDA. Available at: https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-infant-botulism-infant-formula-november-2025
2025– 2026	Multi-country; 99 countries and territories	Multiple infant formula products containing contaminated ARA oil	Cereulide toxin, produced by some strains of <i>Bacillus cereus</i>	144 suspected and confirmed cases were reported across ten countries in three WHO Regions, with investigations ongoing– 13 March 2026.	World Health Organization (2026). International food safety event: Infant formula and products containing arachidonic acid oil contaminated with cereulide toxin - Multi-country. WHO. Available at: https://www.who.int/emergencies/disease-outbreak-news/item/2026-DON596

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