Global Food Regulatory Science Society

FLASH INFO

Public Health Monitoring Bulletin

Subject	
Multi-country health event related to contamination of infant formula with *Bacillus cereus* toxin (cereulide)	
Period	December 2025 – February 2026
Keywords	Infant formula – *Bacillus cereus* – cereulide toxin – food safety – recalls
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Executive Summary

A multi-country food safety event has recently led to the withdrawal and recall of several infant formula products due to the presence or suspected presence of cereulide, a heat-stable toxin produced by certain strains of Bacillus cereus. Scientific assessments conducted at the international level indicate that even very low concentrations of this toxin may pose an acute health risk to infants. As a result, authorities have adopted a precautionary approach, including recalls, and reinforced control measures, in order to ensure a high level of health protection.

1. Background

Infant formula is a highly sensitive food product intended for infants, a population group particularly vulnerable to foodborne hazards. As a substitute for breast milk, it must meet the highest standards of safety and quality.

In early 2026, an international health alert was triggered following the detection of **cereulide toxin** in certain batches of infant formula. This toxin, produced by specific strains of *Bacillus cereus*, is of particular concern because it is resistant to heat and can remain biologically active even after standard processing or preparation. Clinical manifestations associated with exposure include severe vomiting and gastrointestinal disturbances, which can have serious consequences in infants.

The event affected several countries and resulted in precautionary recalls between December 2025 and February 2026, involving multiple international brands. Preliminary investigations into the origin of the contamination suggest a common upstream source, likely associated with a shared ingredient (arachidonic acid – ARA oil) used in the manufacturing process. This

highlights the importance of monitoring not only final products but also raw materials and supply chains.

The hazard identified in this event is dual. It involves, on the one hand, a biological agent (*Bacillus cereus*), a bacterium commonly present in the environment, and, on the other hand, a toxin of biological origin (cereulide), which is responsible for the observed adverse health effects.

A key aspect of this risk is that only certain strains of *Bacillus cereus* produce cereulide, and the presence of the toxin is not necessarily correlated with the number of bacteria present in the food. This means that standard microbiological analyses may not be sufficient to detect the risk, as the toxin can remain in the product even if the bacteria are no longer viable.

2. Situation overview and timeline

The event has been closely monitored by international authorities and organizations. In the European Union, the European Food Safety Authority (EFSA) conducted a rapid risk assessment to establish toxicological reference values and support risk management decisions. In the United Kingdom, the Food Standards Agency (FSA) issued official alerts concerning specific batches of infant formula. At the global level, the Food and Agriculture Organization (FAO) and the World Health Organization (WHO), through JEMRA, initiated scientific work focusing on spore-forming pathogens in powdered infant formula.

The timeline of events indicates that the first detections and precautionary recalls occurred in early December 2025. On January 5, 2026, recalls were officially confirmed in different countries, accompanied by public communication and product traceability information. On February 2, 2026, EFSA published its rapid risk assessment, providing key scientific benchmarks. Shortly thereafter, on February 5, 2026, FAO/WHO launched a call for experts and data to further investigate the risks associated with such contaminants.

3. Risk assessment

Key points:

According to EFSA, an acute reference dose (ARfD) of **0.014 µg per kg of body weight** has been established for infants. Considering the high consumption of infant formula relative to body weight, exposure can occur even at very low concentrations of the toxin. EFSA estimates that concentrations exceeding **0.054 µg/L in infant formula** and **0.1 µg/L in follow-on formula** may lead to an exceedance of this reference dose. These findings underline that even minimal contamination levels can result in a significant acute risk for infants, thereby justifying the precautionary measures adopted.

Following the multi-country recalls of infant formula contaminated with cereulide, the European Food Safety Authority (EFSA) conducted a **rapid risk assessment (2026)** to characterize the hazard, assess exposure, and support risk management decisions.

The assessment focused on infants as the most vulnerable population and adopted a conservative approach based on high consumption scenarios. It highlighted the specific risk posed by cereulide, a **heat-stable toxin that may be present even in the absence of viable bacteria**, and established a toxicological reference value to guide decision-making.

Table – Summary of EFSA risk assessment

Risk assessment step	Parameter	Value / Assumption	Interpretation
Hazard identification	Cereulide toxin	Produced by *Bacillus cereus*	Heat-stable, independent of viable bacteria
Hazard characterization	$BMDL_{10}$	4.2 µg/kg bw	Dose associated with emetic effect
Hazard characterization	Uncertainty factor	300 (100 × 3)	Accounts for variability and infant sensitivity
Reference value	ARfD	**0.014 µg/kg bw (24 h)**	Acute reference dose for infants
Exposure assessment	Infant formula	260 mL/kg bw/day	High consumption (P95)
Exposure assessment	Follow-on formula	140 mL/kg bw/day	High consumption (P95)
Risk characterization	Infant formula threshold	**0.054 µg/L**	ARfD may be exceeded
Risk characterization	Follow-on formula threshold	**0.10 µg/L**	Potential acute risk

4. Regulatory interpretation

Currently, there is no specific international regulatory limit established for cereulide in infant formulas. In this context, the reference values proposed by EFSA constitute the primary scientific basis for risk management.

Given the vulnerability of the target population and the severity of potential health effects, authorities apply a **near-zero tolerance approach**. This means that any detection of cereulide is considered potentially unacceptable and may trigger immediate risk management actions, including product recalls and public alerts.

This situation also highlights the need for further international work to establish harmonized standards and regulatory benchmarks.

5. Public health implications

This event has significant implications for public health, particularly due to the vulnerability of infants and the widespread use of infant formula. It also underscores the challenges

associated with globalized food supply chains, where a single contaminated ingredient can affect multiple products and countries.

Furthermore, the event highlights the limitations of conventional control approaches based solely on microbiological criteria, as they may not adequately capture toxin-related risks. It emphasizes the importance of adopting an integrated risk assessment approach that considers the relationship between hazards, toxins, and production processes.

6. Recommendations for consumers

Consumers, particularly parents and caregivers, are advised to remain vigilant and informed. It is important to check product information, including brand names, batch numbers, and expiration dates, and to follow official announcements issued by competent authorities.

Products subject to recall should not be used under any circumstances. In case of doubt or concern, consumers are encouraged to seek advice from healthcare professionals or pharmacists.

Maintaining awareness and adhering to official guidance are key measures to ensure the safety of infants.

7. Actions taken by authorities

Competent authorities have implemented a series of measures to address this event and prevent further risks. These include strengthening import and market surveillance systems, prioritizing controls on high-risk products such as infant formula, and enhancing analytical capabilities to detect cereulide using advanced methods such as LC-MS/MS.

In addition, efforts have been made to improve traceability across the supply chain, particularly regarding critical ingredients. Authorities have also ensured transparent communication with the public and stakeholders, including timely dissemination of recall information.

8. Risk-based Action Levels (EFSA / Belgium – AFSCA)

Based on the EFSA toxicological reference value (ARfD) and exposure scenarios, **risk-based action levels** were derived to support operational risk management. These values represent concentrations above which the acute reference dose may be exceeded and therefore trigger risk management actions such as product withdrawal or recall.

Belgium (AFSCA) has adopted the same thresholds, translating EFSA scientific outputs into **practical operational tools for rapid decision-making**, ensuring a harmonized and precautionary approach at the European level.

Table – EFSA / AFSCA risk-based action levels

Product category	Reconstituted milk (µg/L)	Powder equivalent (µg/kg)	Interpretation
Infant formula (IF)	**0.054 µg/L**	**0.43 µg/kg**	Exceedance → ARfD likely exceeded → product considered unsafe
Follow-on formula (FOF)	**0.10 µg/L**	**0.80 µg/kg**	Potential acute risk
FSMP (<16 weeks)	Same as IF	Same as IF	Highest vulnerability
FSMP (4–12 months)	Same as FOF	Same as FOF	Exposure-adjusted

Interpretation for risk management:

- These values are **not regulatory limits**, but **action levels based on risk**
- Exceedance indicates that **acute exposure may surpass safe levels**
- They serve as a **scientific basis for immediate measures** (recall, withdrawal, reinforced controls)

9. Current Status of the Event (Update)

The contamination event involving cereulide in infant formula remains a **recent and evolving food safety issue**, initially identified between December 2025 and February 2026. Rapid actions taken by national and international authorities, including product recalls and risk communication, have contributed to limiting immediate consumer exposure.

At present, no widespread new incidents have been publicly reported beyond the initial recall period. However, the event is still considered **highly relevant from a risk management and vigilance perspective**, due to several key factors:

- The **root cause (upstream contamination via a shared ingredient)** highlights structural vulnerabilities in global supply chains.
- The **nature of the hazard (heat-stable toxin)** means that conventional microbiological controls may not be sufficient to ensure safety.
- The **absence of harmonized international regulatory limits** (e.g., Codex standards) requires reliance on scientific reference values such as those provided by EFSA.
- Ongoing international activities (e.g., FAO/WHO JEMRA work) indicate that the issue is still under scientific evaluation.

As a result, the event should be considered **ongoing from a vigilance and risk assessment standpoint**, even if the acute crisis phase has subsided.

10. References (key sources)

The information presented in this bulletin is based on scientific and regulatory work conducted by recognized international organizations, including:

1. **European Food Safety Authority (EFSA) (2026)**
   Rapid risk assessment on cereulide in infant and follow-on formulae. EFSA Journal.
   Available at: https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2026.9941
2. **Food Standards Agency (FSA) (2026)**
   Infant formula recalls and official alerts (SMA / Nestlé products).
   Available at: https://www.food.gov.uk/news-alerts

   https://www.food.gov.uk/search?keywords=cereulide

   FSA-PRIN-07-2026: Danone recalls several Aptamil and Cow & Gate First Infant Milk and Follow on Milk formula products sold in Northern Ireland because of the possible presence of cereulide (toxin)

   FSA-PRIN-05-2026: Danone recalls several Aptamil and Cow & Gate First Infant Milk and Follow on Milk formula products because of the possible presence of cereulide (toxin)
3. **UK Health Security Agency (UKHSA) (2026)**
   UK Health Security Agency (UKHSA), investigation reports (2026)
   https://www.gov.uk/government/publications/health-protection-report-volume-20-2026/hpr-volume-20-issue-1-news-29-january-2026
4. **World Health Organization (WHO) / Food and Agriculture Organization (FAO) (2026)**
   Call for experts and data on microbiological risk assessment of powdered infant formula (JEMRA).
   Available at: https://www.who.int/news-room/articles-detail/call-for-experts-and-data-on-microbiological-risk-assessment-on-powdered-formulae-for-infants-and-young-children
5. **ANSES (2021)**
   Bacillus cereus – Hazard profile (Fiche de danger).
   Available at: https://www.anses.fr/fr/system/files/BIORISK2016SA0075Fi.pdf

ADVISORY KEY MESSAGE AND OFFICIAL GUIDANCE IMPLICATION:

Stay informed – Protect infant health – Follow and continued monitoring, strengthened controls (particularly at import level), and integration of cereulide into risk-based surveillance programs are essential to prevent recurrence and ensure sustained protection of infant health.