

CONTAMINATED COMMERCIAL MILK FORMULA: A GLOBAL RESPONSE IS NEEDED

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CORE CONCERN

A BROKEN SAFETY NET: PROTECTING FORMULA-DEPENDENT INFANTS IN EMERGENCIES



The evidence: a shift in the safety landscape. The safety profile for commercial milk formula safety has been altered due to the emergence of heat-stable contaminants.¹ Recalls in 2025 and 2026 across over 100 countries are linked to heat-stable botulism and cereulide toxins. Market observations show a lack of WHO preparation guidance on labels.² Regulators, researchers and policymakers observe widespread use of non-essential ingredients.³ Taken together, these factors point to a system with severe and growing vulnerabilities.

ADVOCACY INSIGHT:

Addressing Systemic Risk: In humanitarian crises, where basic hygiene breaks down⁵ and lot-number traceability is often impossible, the uncontrolled donation and distribution of commercial infant formula becomes a lethal risk. To protect infants, young children and their families, **Member States must act** immediately. In emergencies, commercial milk formula-dependent infants are the most vulnerable.

Member States must prioritize breastfeeding as a primary protective intervention. By actively reducing the number of commercial milk formula-dependent infants in high-risk environments, we create a barrier against supply chain contamination. Breastfeeding becomes a risk-mitigation strategy.

Member States must strictly regulate commercial milk formula procurement in line with UNICEF guidance,⁶ ensure that breast milk substitutes are distributed only within managed, supportive settings,⁷ and fully implement recommended infant and young child feeding in emergencies (IYCF-E) practices.⁸

It is now imperative that **Member States integrate** the Operational Guidance for Infant and Young Child Feeding in Emergencies (OG-IFE v3.0) into national emergency plans -- **before the next crisis strikes**.

TWIN POLITICAL COMMITMENTS

The systemic failures exposed at the IBFAN/ILCA, Burundi, Panama and Ecuador WHA79 event: *Contaminated Commercial Formula – the Need for a Global Response* are more than regulatory gaps.⁴ For infants and young children in emergencies and their families, these are existential threats. The call for **Twin Political Commitments** underscores the dual approach needed to mitigate risk.

The Will to Make Commercial Formula as Safe as It Can Be Mandatory independent oversight and the rejection of “flexible labelling” in emergencies are critical to ensure families that need commercial milk formula are not receiving deregulated, unregistered products. In humanitarian and crisis settings, traceability and transparency are live-saving prerequisites.

The Will to Enable and Support Breastfeeding

In emergencies, breastfeeding is a systemic risk-mitigation strategy. It is the only first-food supply that is resilient to supply chain failures, shortages and global contamination outbreaks. By enabling families and removing barriers, Member States create a safety net that reduces reliance on an industrial system that has proven to be fragile and prone to failure

¹ Official updates document outbreak numbers (WHO 2026; US-CDC 2026) and confirm involvement of heat-stable toxins. (US-FDA 2026). World Health Organization, “International Food Safety Event: Infant Formula and Products Containing Arachidonic Acid Oil Contaminated with Cereulide Toxin - Multi-Country,” Disease Outbreak News, World Health Organization, March 13, 2026, <https://www.who.int/emergencies/disease-outbreak-news/item/2026-DON596>; US Centre for Disease Control, “Investigation Update: Infant Botulism Outbreak, November 2025,” Botulism, US Centre for Disease Control, March 4, 2026, <https://www.cdc.gov/botulism/outbreaks-investigations/infant-formula-nov-2025/investigation.html>; Human Foods Program, “Outbreak Investigation of Infant Botulism: Infant Formula (November 2025),” US-FDA, February 26, 2026, <https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-infant-botulism-infant-formula-november-2025>.

² While clinical guidance to reconstitute powdered formula at 70°C remains a baseline defense, field assessments indicate systemic failures in both labeling and adherence. Studies in Europe and Malaysia have documented that manufacturers frequently omit these critical safety instructions from product labels, contributing to inconsistent preparation practices (Beary et al. 2025; Sani et al. 2013). Maria Amalia Beary et al., “Assessing Hot Water Reconstitution Instructions and Labeling of Powdered Infant Formula to Ensure Cronobacter Spp. Reduction,” Journal of Food Protection 88, no. 9 (2025): 100571, <https://doi.org/10.1016/j.jfp.2025.100571>; N. Abdullah Sani et al., “Microbiological Assessment and Evaluation of Rehydration Instructions on Powdered Infant Formulas, Follow-up Formulas, and Infant Foods in Malaysia,” Journal of Dairy Science 96, no. 1 (2013): 1–8, <https://doi.org/10.3168/jds.2012-5409>.

³ Scientific and regulatory bodies have raised significant concerns regarding the complexity of modern formula composition. The European Union’s EFSA Panel (2014) concluded there is “no necessity” to add substances such as nucleotides or taurine, noting that excessive nutrient levels may “put a burden on the infant’s metabolism.” Analysis by Munblit et al. (2020) establishes that health and nutrition claims for these non-essential ingredients are poorly substantiated and potentially harmful to public health efforts, a finding confirmed by a 2023 international cross-sectional survey showing that 80% of such claims lacked robust clinical trial evidence (Cheung et al. 2023). EFSA Panel, “Scientific Opinion on the Essential Composition of Infant and Follow-on Formulae,” EFSA Journal (IT), no. 2014;12(7):3760 (n.d.), <https://doi.org/10.2903/j.efsa.2014.3760>; Daniel Munblit et al., “Health and Nutrition Claims for Infant Formula Are Poorly Substantiated and Potentially Harmful,” BMJ, May 6, 2020, m875, <https://doi.org/10.1136/bmj.m875>; Ka Yan Cheung et al., “Health and Nutrition Claims for Infant Formula: International Cross Sectional Survey,” BMJ 380 (February 2023): e071075, <https://doi.org/10.1136/bmj-2022-071075>.

⁴ WHA79: Contaminated Commercial Formula – the Need for a Global Response – IBFAN, January 30, 2025, <https://www.ibfan.org/ibfan-wha79-contaminated-commercial-formula-2026/>.

⁵ Lack of access to clean water, fuel for boiling water to sterilize and prepare feeds, inability to clean equipment and hands, etc.: FE Core Group, Operational Guidance on Infant and Young Child Feeding in Emergencies (OG-IFE) Version 3.0 (Emergency Nutrition Network, 2017).

⁶ “UNICEF Standard Operating Procedure on the Procurement and Use of Breastmilk Substitutes in Humanitarian Settings | IYCF,” accessed May 20, 2026, <https://iycfhub.org/document/unicef-standard-operating-procedure-on/>.

⁷ The IYCF-E (Infant and Young Child Feeding in Emergencies) joint statement is a multi-agency declaration used in humanitarian crises to protect child health. It mandates breastfeeding support and restricts inappropriate distribution of breastmilk substitutes. Per UNICEF, WHO, WFP and UNHCR: “Infants who are dependent on infant formula should be urgently identified, assessed and targeted with a package of essential support (including sustained breastmilk substitute supply, equipment and supplies for safe preparation, individual-level, context specific advice, practical training on safe preparation and regular follow up), to minimise risks to both breastfed and non-breastfed children.” “Model Joint Statement on IFE | ENN,” January 1, 2017, <https://www.enonline.net/resource/ife/model-joint-statement-ife>.

⁸ The IFE Core Group’s Operational Guidance on Infant and Young Child Feeding in Emergencies (OG-IFE) is the definitive global, inter-agency standard for emergency preparedness, response, and recovery to minimize infant mortality and maximize child nutrition globally. It provides policy-makers and responders with practical directives to safely manage infant feeding while ensuring strict compliance with international humanitarian standards, the WHO Code, and relevant WHA resolutions. IFE Core Group, Operational Guidance on Infant and Young Child Feeding in Emergencies (OG-IFE) Version 3.0 (Emergency Nutrition Network, 2017).

CONTAMINATED COMMERCIAL INFANT FORMULA: A GLOBAL RESPONSE IS NEEDED

CASE STUDY 1: THE GLOBALIZED THREAT THE 2026 CEREULIDE TOXIN CRISIS AND THE LIMITS OF CURRENT SAFETY GUIDANCE



Background

The Cereulide toxin crisis resulted in product recalls in more than 100 countries,⁹ with 144 suspected and confirmed illness cases.¹⁰ In Southeast Asia, Indonesia reported that up to 33% of premium commercial milk formula brands were removed from shelves, while Singapore recalled approximately 5% of its total imported stock.¹¹

Cereulide toxin is heat-stable.¹² For decades, WHO guidance to boil water and cool it to above 70°C before reconstituting powdered infant formula has served as the baseline defence against long-standing concerns like Cronobacter and Salmonella.¹³ This standard remains absolutely critical and must be upheld. However, the emergence of cereulide and similar toxins highlights a new limitation: hygiene and high-temperature preparation alone can no longer be relied upon to control all forms of contamination.

The sheer scale of the 2026 cereulide toxin crisis has exposed the cascading vulnerabilities of a globalized commercial milk formula supply chain.

Impact on low-resource settings

Even with standard hygiene practices, these toxins remained in products, including in low-resource settings. Commercial milk formula ingredients are sourced and exported globally, which means contamination originating in high-resource production facilities exported to low-resource settings.¹⁴

Advocacy Insight

In emergency and low-resource contexts, the assumption that risks can be mitigated at the point of preparation is no longer valid. Heat-stable toxins cannot be neutralised through boiling or reconstitution above 70°C. When biological contamination cannot be eliminated at the point of use, the burden of safety must shift upstream. Strict supply chain controls, combined with the capacity to execute rapid, targeted and effective recalls, become the only remaining safeguards. Most importantly, breastfeeding support becomes a critical upstream intervention.

This crisis makes one point unequivocally clear: when safety fails at production, there is no downstream fix.

ACTIONABLE STEPS

MEMBER STATES - ACT NOW *Immediate policy measures to reduce unmanageable risks in IYCF-E*

The conditions facing formula-dependent families in emergencies are inherently high-risk. To protect these infants, and to preserve the protective baseline provided by breastfeeding, Member States must take immediate, decisive action:

Adopt strict procurement controls: Breast milk substitutes must only be procured and distributed through UNICEF mechanisms or in full compliance with UNICEF procurement guidelines and Operational Guidance on Infant and Young Child Feeding (OG-IFE). Corporate donations must cease immediately.

Create and mandate fully supported environments: Any targeted distribution of breast-milk substitutes must occur only within controlled settings and must include a comprehensive package of essential support services for caregivers.

See Case Study 2 for more actions

⁹WHO's last updated list in March 2026 listed 99 confirmed countries impacted, and the real-time reports on the European Union's Rapid Alert System for Food and Feed. (RASFF) show as many as 130 countries impacted with reports as late as May 2026. World Health Organization, "International Food Safety Event: Infant Formula and Products Containing Arachidonic Acid Oil Contaminated with Cereulide Toxin - Multi-Country," Disease Outbreak News, World Health Organization, March 13, 2026, <https://www.who.int/emergencies/disease-outbreak-news/item/2026-DON596>; European Union, "Rapid Alert System for Food and Feed," accessed May 20, 2026, <https://webgate.ec.europa.eu/rasff-window/screen/search?searchQuery=eyJkYXRJlp7InNOYXJ0UmFuZ2U0iitiLCJlbmRSYW5nZSI6Ij9LCjB3VudHJpZXMtOnt9LCJ0eXB1jp7fSwibm90aWZpY2F0aW9uU3RhdHVzIjp7fSwicHJvZHVjdCI6e30sInJpc2siOnt9LCJyZWZlcmVuY2UiOiitiLCjzdWJqZWNOIjoIY2VyZXVsaWRlIn0%3D>.

¹⁰World Health Organization, "International Food Safety Event: Infant Formula and Products Containing Arachidonic Acid Oil Contaminated with Cereulide Toxin - Multi-Country," Disease Outbreak News, World Health Organization, March 13, 2026, <https://www.who.int/emergencies/disease-outbreak-news/item/2026-DON596>.

¹¹Brandotors, "Penjelasan Publik | Badan Pengawas Obat dan Makanan," accessed May 20, 2026, <https://www.pom.go.id>; Singapore Food Agency, "Recall of Two Additional Infant Formula Products Due to Presence of Cereulide Toxin," Default, January 30, 2026, <https://www.sfa.gov.sg/news-publications/newsroom/recall-of-two-additional-infant-formula-products-due-to-presence-of-cereulide-toxin>.

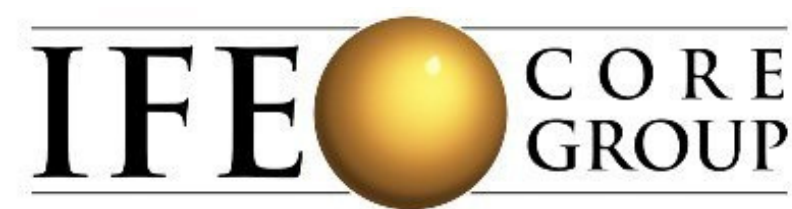
¹²World Health Organization, "International Food Safety Event: Infant Formula and Products Containing Arachidonic Acid Oil Contaminated with Cereulide Toxin - Multi-Country," Disease Outbreak News, World Health Organization, March 13, 2026, <https://www.who.int/emergencies/disease-outbreak-news/item/2026-DON596>.

¹³Concerns regarding intrinsic contamination of powdered infant formula are longstanding. In 2005, Member States adopted WHA58.32 following findings from a joint FAO/WHO expert consultation concluding that intrinsic contamination of powdered infant formula with Enterobacter sakazakii (now Cronobacter sakazakii) and Salmonella had caused severe illness and death in infants. The Resolution further recognized the need for caregivers to be informed of evidence-based public health risks associated with intrinsic contamination and emphasized safe preparation, handling, storage, and warning messages on packaging. Subsequent WHO guidance introduced recommendations including reconstitution with water above 70°C to reduce microbiological risks. Safe Preparation, Storage and Handling of Powdered Infant Formula: GuidelinesCronobacter spp (World Health Organization, 2007).

¹⁴Phillip Baker et al., "Globalization, First-Foods Systems Transformations and Corporate Power: A Synthesis of Literature and Data on the Market and Political Practices of the Transnational Baby Food Industry," Globalization and Health 17, no. 1 (2021): 58, <https://doi.org/10.1186/s12992-021-00708-1>.

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CASE STUDY 2: BOTULISM RECALL - COMPOUNDED BY DONATIONS WHEN PRODUCTS ENTER INFORMAL DISTRIBUTION CHAINS, RECALL BECOMES IMPOSSIBLE



Background

In 2025-26, the United States saw the full recall of the ByHeart commercial milk formula product line following a catastrophic failure in lot-number traceability and recall execution.¹⁵ The situation was further compounded by the company's own donation program, through which thousands of contaminated products were distributed via informal channels, including homeless shelters, church basements, diaper banks and domestic violence centres.¹⁶ The consequences of this recall were severe: dozens of infants were hospitalized.¹⁷

Compounding the crisis, **the response was also critically delayed**. The U.S. FDA reported that retailers failed to remove recalled products efficiently, with contaminated product still documented on retail shelves as late as April 2026.¹⁸

The impact on low-resource settings: On the ground reports from recent responses in Pakistan, Ukraine, Turkiyë and Gaza, indicate large-scale commercial milk formula donation remains common. A recent series of case studies from UNICEF explores unsolicited and untargeted donations in a number of countries including Lebanon and Sudan.

Advocacy insight: This case demonstrates two central failures: once products enter informal or unregulated distribution systems, the core safety mechanism - traceability - is lost. Without traceability, effective recall becomes functionally impossible, leaving the most vulnerable infants exposed to life-threatening contamination. It also reinforces a critical point: severe safety failures are not confined to weak systems. They can, and do, occur within highly regulated, high-resource environments. At present, safety relies upon voluntary industry recall systems to intercept hazards that cannot be mitigated at the point of preparation, such as heat-stable toxins or botulism contamination. In emergency settings, this effectively translates into attempting product-by-product verification in the middle of a crisis, an approach that is neither realistic nor sufficient.

Breastfeeding is a protective intervention and this case shows we must shift scarce resources away from managing product recalls and towards skilled counselling and relactation support during emergencies.

When traceability breaks down, so does the entire safety system.

ACTIONABLE STEPS

MEMBER STATES - ACT NOW
Immediate policy measures to reduce unmanageable risks in IYCF-E

Fully implement WHA 63.23 (2010) and 71.9 (2018): Member States must urgently integrate the OG-IFE into national emergency preparedness and response plans, with dedicated funding and enforcement.

Reject weakened labelling standards: Member States must oppose any effort to relax labelling requirements for infant and young child foods in emergencies. Instead, manufacturers must be required to clearly and prominently display current WHO preparation guidelines. The pursuit of "flexible labelling" for infant foods in emergencies must stop. In crisis settings, strong labelling requirements and full traceability are essential to protect infants and young children.

See Case Study 1 for more actions

¹⁵ Human Foods Program, "Outbreak Investigation of Infant Botulism: Infant Formula (November 2025)," US-FDA, February 26, 2026, <https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-infant-botulism-infant-formula-november-2025>; Office of the Commissioner, "FDA Takes Action to Improve Recall Effectiveness Following Infant Botulism Outbreak Investigation Linked to ByHeart Infant Formula," FDA, FDA, December 15, 2025, <https://www.fda.gov/news-events/press-announcements/fda-takes-action-improve-recall-effectiveness-following-infant-botulism-outbreak-investigation>.

¹⁶ Traceability failure in informal CMF donations was exposed during the 2025/26 botulism crisis, where ByHeart's "OpenHearted Initiative" sent 24,000 cans of formula (ByHeart 2025), including contaminated units into distribution via community initiatives such as diaper banks and shelters, and outside the formal tracking system (HealthBeat 2025). This prompted US Rep. Rosa DeLauro (D-CT) to label the lack of oversight a "nightmare scenario" (April 29, 2026) and propose the Infant Formula Safety Modernization Act of 2026 (H.R. 7867), which seeks to close these gaps by mandating comprehensive lot-level traceability for all infant formula throughout the supply chain. ByHeart, "OpenHearted Initiative - ByHeart," November 12, 2025, <https://web.archive.org/web/20251112160145/https://byheart.com/pages/openhearted?srltid=AfmBOopoHghxslEOvHl3sfcTO0qqRtpfLRrPPVQl00xM8mOmTmBK9Y9>; Rosa L. [D-CT-3. Rep. DeLauro, "Text - H.R.7867 - 119th Congress (2025-2026): Infant Formula Safety Modernization Act of 2026," legislation, September 3, 2026, 2026-03-09, <https://www.congress.gov/bill/119th-congress/house-bill/7867/text>; Rosa L. [D-CT-3. Rep. DeLauro, "H.R.7867 - 119th Congress (2025-2026): Infant Formula Safety Modernization Act of 2026," legislation, September 3, 2026, 2026-03-09, <https://www.congress.gov/bill/119th-congress/house-bill/7867>.

¹⁷ Human Foods Program, "Outbreak Investigation of Infant Botulism: Infant Formula (November 2025)," US-FDA, February 26, 2026, <https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-infant-botulism-infant-formula-november-2025>.

¹⁸ The FDA first recommended a volunteer recall in November 2025, and issued a warning in December to retailers after finding the product still for sale "for over three weeks in one case, in over 175 locations across 36 states." Office of the Commissioner, "FDA Takes Action to Improve Recall Effectiveness Following Infant Botulism Outbreak Investigation Linked to ByHeart Infant Formula," FDA, FDA, December 15, 2025, <https://www.fda.gov/news-events/press-announcements/fda-takes-action-improve-recall-effectiveness-following-infant-botulism-outbreak-investigation>.