



ByHeart & Botulism: serious food safety failings expose online marketing risks

IBFAN is gravely concerned by the recent outbreak of potentially deadly infant botulism that seems to be linked to *Clostridium botulinum* contamination of powdered infant formula (PIF) manufactured by the new US-Based company ByHeart.¹ The US Food and Drug Administration (FDA) has determined that ByHeart's PIF is the source of at least 39 cases of infant botulism in an outbreak spread across 18 US states. All 39 of the infected babies have been hospitalised and another 70 cases are under investigation.² ByHeart has admitted that all of its products could be contaminated with *Clostridium botulinum* Type A and that it is focused on finding the root cause ... from suppliers and raw ingredients to packaging and transportation.^{3,4}

IBFAN is calling for full transparency, a rapid independent investigation, mandatory reporting of infections in national systems⁵ and a revision of Codex and WHO's Food Safety Guidelines.

This should be reinforced by a new World Health Assembly Resolution that highlights the food safety risks of online formula promotion, especially into the Global South and settings where the risks are greater and access to treatment is reduced.

IBFAN's thoughts are with the sick infants, affected families and the health workers caring for the children.

ByHeart's online marketing reaches the Global South with limited treatment options

ByHeart was launched in March 2022, during the US national formula shortage that followed the recall of contaminated **Abbott Nutrition** formulas. ByHeart capitalised on the Trump administration's agenda to *Make America Healthy Again*, using misleading and idealized claims that the products were purer and "filled with ingredients backed by breast milk science in every scoop."

Through subscriptions, direct marketing to consumers via on-line social media platforms such as Amazon, UBuy and Desertcart, ByHeart's formula market grew quickly, spreading to Canada, Africa, the Arab world, Asia and Latin America, exacerbating their use in the Global South where Botulism diagnosis and treatment is more difficult to access.⁶

Summary of ByHeart's Contamination problems

In 2022 the FDA led an investigation into ByHeart because of suspected *Cronobacter sakazakii* contamination.⁷ ByHeart's admission that a batch of PIF had tested positive for *Cronobacter* led to the recall of five batches in December 2022.⁸

In August 2023 the FDA warned ByHeart: "You did not establish a system of process controls covering all stages of processing that was designed to ensure that infant formula does not become adulterated due to the presence of microorganisms in the formula or in the processing environment, as required by 21 C.F.R. 106.55(a)." ⁹

December 2023 the FDA raised an **Official Action Indicated (OAI)** red flag, its highest tier of concern after finding multiple safety violations in ByHeart's Pennsylvania factory, including a leaking roof, mold in a water tank and 2,500 dead flies in a food production area.^{10 11}

November 2025: Dr. Erica Pan, a leading public health expert, noted an increase of infant botulism cases from August 1st. Dr. Pan said that the number of infected infants who had consumed ByHeart formula jumped out at her, because the company's sales account for only about 1 percent of the national formula market. "So that was a very disproportionate, very concerning signal of what's going on here". ByHeart initiated a nationwide recall of all its formulas following the multi-state

infant botulism outbreaks. The FDA investigated ByHeart's other facilities in Allerton, Iowa and Portland, Oregon. The FDA found that ByHeart's Pennsylvania factory violated its own rules for maintaining the temperatures needed to eliminate bacteria from the formula before it was sent for packaging. ByHeart also failed to report variations in temperature to a supervisor before the formula was sent out to be fed to its infant customers.^{12 13}

Congresswoman Rosa DeLauro,¹⁴ from Connecticut's Third Congressional District sent a letter to FDA Administrator Marty Makary, demanding that all inspection records of the company's infant formula manufacturing factories be released to Congress.¹⁵

Infant botulism must be treated as quickly as possible after symptoms appear

Clostridium botulinum is an anaerobic spore forming bacterium which produces the neuro-toxin *botulinum* that attacks nerve function causing paralysis. Botulism is potentially deadly and must be treated as quickly as possible. Botulism Immune Globulin (referred to as *BabyBig*) administered intravenously is the single treatment for infants under one year of age but is only available in the US. Access outside of the US is on 'a case-by-case evaluation basis.' International requests require the infant's physician to contact an on-call *BabyBig* physician for approval; after which a letter of authorization from the importing country's Medicine Regulatory Authority must be issued; payment made; customs cleared; all with a required international courier account and more. Clearly, access to treatment outside of the US, will be costly and time consuming, unavailable for the many and too late for an effective treatment.

IBFAN's Call to Action

1. A full, independent investigation with publication of findings: Governments must ensure public funding for routine environmental surveillance and commercial-free third-party testing of PIF manufacturing facilities. Independent public health experts must have full access and all findings, including negative results, should be made public and stored in a centralised data base.

2. An internationally available register of all infants diagnosed with suspected foodborne, bacterial or viral illness must be created for all concerned including parents.

3. Accountability and legal remedy for affected families: Any regulatory enforcement actions must be pursued swiftly and fairly and companies held accountable for the medical, financial and legal costs of the treatment of harmed infants and parental leave for their care.

4. The WHO/FAO INFOSAN network must continue to warn national safety authorities. The *WHO Guideline on the Safe preparation, storage and handling of powdered infant formula* must be updated to address the fact that 'the preparation step' (relating to pathogens such as *Enterobacteriaceae*, *Cronobacter* and *Salmonella* species) will not be effective in de-activating the heat-resistant spores of *Clostridium botulinum*. While the immediate feeding and discarding of unused formula remains critical, the reconstitution of PIF at the necessary high temperatures could negatively impact the nutrient content.

5. The Codex Committee on Food Hygiene (CCFH) must address the manufacturing issue. CCFH will meet in December 2025 and should update the *Code of Hygienic Practice on Powdered Formulae for Infants and Young Children*.¹⁶ The *Codex Code of Ethics in International Trade and*

*Food Aid*¹⁷ forbids the international trade of any food (including re-exported food) which is unsafe, unsuitable, poisonous, harmful or otherwise injurious to health or "is labelled or presented in a manner that is false, misleading or deceptive."

6. Member States should adopt a new World Health Assembly Resolution to highlight the food safety risks of online commercial promotion and sale of formula products that are not registered or regulated at national level. All transactions must fully comply with the *International Code of Marketing of Breastmilk Substitutes* and subsequent relevant WHA resolutions (referred together as the 'Code'). Code implementation, with appropriate warnings on labels and the removal of all idealisation and promotional claims is necessary beyond food safety. Misleading marketing practices undermine breastfeeding and increase the number of infants dependent on formula and exposed to its multiple risks.

7. Governments and health workers should implement the Code, the WHO/UNICEF *Global Strategy for Infant and Young Child Feeding*,¹⁸ the *Baby Friendly Hospital Initiative* (BFHI) and *Nurturing Care Framework in service provision*.¹⁹ Governments should also recognise parent's rights to maternity protection and leave.

8. Ensure preparedness and appropriate responses for the protection of Maternal Infant and Young Child Feeding in Emergencies following the *Operational Guidance on Infant Feeding in Emergencies*.²⁰ Build capacity for social behaviour change that protects breastfeeding, re-lactation, wet-nursing, human milk banking and cup feeding

9. Social media platforms must be required to maintain nationally domiciled legal entities that can monitor and pursue breaches of regulations. Licencing mechanisms must include Code compliance for all entities within their jurisdiction.

Legal Action so far

Currently, two families whose infants contracted infantile botulism after consuming ByHeart PIF are suing the company, alleging that the recalled formula was defective and that ByHeart was negligent in producing and in selling it. These families are seeking financial compensation for medical bills, emotional distress, and other damages.²¹ It is likely that more infants will contract botulism and more families may initiate lawsuits, with the potential of nationwide litigation, similar to the necrotizing enterocolitis (NEC) case.²² The Brazilian sanitary authority (ANVISA) has prohibited the importation and sale of ByHeart powdered formula 720 ml in Brazil. INFOSAN, the joint FAO/WHO network of the national food control authorities, issued a global alert warning about this issue on 19 November to all 190 INFOSAN food safety authority members and updates are being provided as new information becomes available. The FDA has put out warnings to a number of countries, but there has been no systematic global mandatory recall or warning system as yet. E-commerce makes the importation of individual orders much harder to trace.

Conclusion

This outbreak highlights again systemic failures in PIF production surveillance, regulatory oversight, recall systems and crisis communication, that are exacerbated by commercial promotion globally online. PIF is NOT sterile; it requires strict manufacturing controls, transparent testing and rapid warning and support for families.²³

IBFAN calls on ByHeart to cooperate with the FDA, State Health Departments and independent experts. To prevent repeated crises that leave large numbers of infants vulnerable to illness and death from contamination or from the growing shocks that disrupt formula supply chains, reliance on formula must be reduced and breastfeeding rates protected and increased through full implementation of the Code.

The US Government must act now to ensure that ByHeart and all US based companies are required to follow the Code, not only within the United States but also with regard to exports to other countries.

Why Breastfeeding is so important.

“Breastfeeding provides essential nutrition for infants and young children. It makes an irreplaceable contribution to their growth and development. It protects infants from respiratory infections, diarrhoeal diseases, and other potentially life-threatening ailments. Protecting and supporting breastfeeding is recognized as a critical component of securing children’s inalienable right to survival, development and the highest attainable standard of health.

Exclusive breastfeeding has the single largest impact on child mortality of any preventive intervention. Globally, poor breastfeeding practices, including not breastfeeding exclusively, contribute to an estimated 11.6% of mortality in children under five years of age.²⁴ Breastfeeding also has health benefits for the mother and can reduce the mother’s risk of breast and ovarian cancer, type 2 diabetes, and high blood pressure.²⁵

Footnotes

- 1 ANSES (the French Agency for Food, Environmental and Occupational Health & Safety) and FDA (The US Food & Drug Administration) refer to 'intestinal toxæmia botulism' "Because their intestinal flora is not fully formed or fully functional, infants under the age of 12 months are prone to intestinal toxæmia botulism. This form is rare in France, but it is the most common form of botulism in the United States." <https://www.anses.fr/en/content/botulism-how-can-you-prevent-it>.
- 2 More infants sick in outbreak traced to ByHeart formula. 3 December 2025. Food Safety News <https://tinyurl.com/mrxkbjz23>
- 3 More than 100 babies have received treatment for botulism in relation to ByHeart formula outbreak By Coral Beach on November 25, 2025 #
- 4 ByHeart says all of its products likely contaminated with Clostridium botulinum Food Safety News, Coral Beach on November 26, 2025 <https://www.foodsafetynews.com/2025/11/byheart-says-all-of-its-products-likely-contaminated-with-clostridium-botulinum/>
- 5 Such as About National Notifiable Diseases Surveillance System | National Notifiable Diseases Surveillance system (NNDSS) | CDC <https://www.cdc.gov/nndss/about/index.html>
- 6 ByHeart Infant Formula went to 21 Countries. Are infants ill? Are they getting the BabyBIG botulism anti-toxin? Bill Marler, Nov 29, 2025 <https://www.marlerblog.com/case-news/byheart-infant-formula-went-to-21-countries-are-infants-ill-are-they-getting-the-babybig-botulism-anti-toxin/>
- 7 <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/byheart-inc-653854-08302023#>
- 8 <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/byheart-inc-653854-08302023#>
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- 10 <https://www.nytimes.com/2025/11/13/health/infant-formula-botulism.html#>
- 11 https://www.foodsafetynews.com/2025/11/inspectors-found-multiple-problems-at-byheart-infant-formula-production-plants/?utm_source=daily.foodsafetynews.com&utm_medium=newsletter&utm_campaign=byheart-infant-formula-plant-violations-exposed-moringa-powder-salmonella-recall-expands
- 12 <https://www.nytimes.com/2025/11/13/health/infant-formula-botulism.html>
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- 14 <https://delauro.house.gov/about-rosa>
- 15 <https://delauro.house.gov/sites/evo-subsites/delauro.house.gov/files/evo-media-document/letter-from-ranking-member-delauro-11.14.25.pdf>
- 16 Code of Hygienic Practice on Powdered Formulae for Infants and Young Children CAC/RCP 66/2008
- 17 Codex Code of Ethics for International Trade in Food
- 18 <https://www.who.int/publications/i/item/9241562218#>
- 19 Nurturing Care Framework in service provision
- 20 Infant Feeding in Emergency Core Group.
- 21 <https://www.nbcnews.com/news/us-news/families-sue-byheart-two-babies-sickened-infantile-botulism-rcna243773>
- 22 <https://abcnews.go.com/US/nutrition-companies-parents-clash-court-cause-infant-intestinal/story?id=111617194>
- 23 Code of Hygienic Practice on Powdered Formulae for Infants and Young Children CAC/RCP 66/2008
- 24 Global nutrition targets 2030: breastfeeding brief, WHO UNICEF 22.10.2025. <https://www.who.int/publications/i/item/B09382>
- 25 US Centres for Disease Control and Prevention. May 2025 <https://www.cdc.gov/breastfeeding/features/breastfeeding-benefits.html>

The International Baby Food Action Network (IBFAN) is a global coalition of over 300 civil society organisations working in 114 countries to protect maternal and infant and young child health from commercial misinformation. The high mortality of bottle-fed babies in the 1970s prompted shareholder actions, legal trials, a consumer boycott and a US Senate Hearing into the marketing activities of the baby food industry. A joint WHO/UNICEF meeting on infant and young child feeding in 1979 recommended an international code to regulate the marketing of baby feeding products. IBFAN has worked since then to help governments bring that Code into legislation to protect support and promote breastfeeding, optimal complementary feeding and maternal and child health.



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