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European Society for Paediatric
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Safety of Infant Milks: Contamination with Cereulide

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Since late 2025, several European manufacturers have undertaken precautionary recalls of specific batches of infant and follow-on formula due to contamination with cereulide, a heat-stable toxin produced by *Bacillus cereus*. Current evidence indicates that the source of contamination was an algal oil used to provide arachidonic acid (ARA), while no viable bacteria were detected in the affected products. Cereulide is resistant to both heat and digestion and can cause rapid-onset gastrointestinal symptoms, including vomiting, nausea, abdominal cramps, and occasionally diarrhea typically occurring within 15 minutes to 6 hours after ingestion. In most cases, symptoms are self-limiting; however, exposure to higher levels may lead to serious complications such as acute liver failure and multi-organ dysfunction.

The European Food Safety Authority (EFSA) has established a conservative acute reference dose (ARfD) of 0.014 µg/kg body weight per day of cereulide. Based on typical consumption patterns, cereulide concentrations below 0.054 µg/L in infant formula and 0.1 µg/L in follow-on formula are considered unlikely to pose a health risk. Surveillance data to date are reassuring, indicating that most tested samples show no detectable contamination, and when present, levels are generally below thresholds considered to pose no appreciable acute health risk based on EFSA risk assessment. Nevertheless, cereulide remains a biologically active toxin and should not be present in infant formula beyond analytically trace amounts. Continued improvements in analytical methods and quality control are therefore essential to ensure accurate exposure assessment and effective risk management.

Cases reported across several European countries have described infants presenting with gastrointestinal symptoms after consuming recalled products. However, such symptoms are common in infancy, particularly among formula-fed infants, and may arise from a variety of causes, making it difficult to establish a clear causal relationship.

Importantly, concerns about infant formula safety should not lead to the use of nutritionally inadequate alternatives such as unmodified cow's milk or plant-based drinks. In addition to being nutritionally inadequate for infants, these products do not comply with the strict compositional and safety standards required for infant nutrition and may pose significant health risks.

Another frequently raised point is that cereulide was detected in samples of ARA, which is not a mandatory component of infant formula under current EU regulations. However, ARA plays an important role in brain development, immune function, and overall growth. All infant and follow-on formulas marketed in Europe are required to contain n-3 docosahexaenoic acid (DHA) at 20–50 mg/100 kcal, while the addition of ARA is permitted but not mandatory. Both placental transfer and human milk provide DHA and ARA together, and during infancy, tissues accumulate more ARA than DHA. Given concerns about potential imbalances in tissue fatty acid composition when DHA is

provided without ARA, the European Academy of Pediatrics recommends including ARA alongside DHA in infant and follow-on formulas in at least equal amounts (up to ~0.64% of total fatty acids). Importantly, the reported contamination has been linked to a single supplier, while other safe and compliant sources of ARA are available.

Overall, the currently available evidence suggests that whilst it cannot be excluded that exposure to cereulide from infant formulas may have reached or exceeded EFSA's conservative exposure thresholds under high consumption scenarios, this is unlikely to have posed an acute or a sustained or long-term health risk. Nonetheless, the presence of cereulide in infant formula is not acceptable beyond minimal trace levels. Ensuring the highest standards of safety requires stringent control of raw materials, validated analytical approaches, and transparent communication. At the same time, risk management strategies must remain proportionate and should not compromise access to nutritionally appropriate infant formula.

While addressing these concerns, it is also important to emphasize that breastfeeding remains the safest and preferred method of infant feeding when available, as it provides optimal nutrition, supports immune protection, and is associated with numerous short- and long-term health benefits for both infants and mothers.

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