German Federal Institute for Risk Assessment

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Product recalls following the detection of cereulide in infant formula

The BfR provides an overview of the situation and compiles key information

Since the beginning of December last year, several manufacturers of infant formula have recalled certain batches of their products as a precautionary measure because they may contain the bacterial toxin cereulide. Cereulide can cause nausea and vomiting, and in rare cases, severe, life-threatening poisoning. In this communication, the BfR provides an overview of the contamination incident and compiles some basic information on the toxin cereulide.

Since December 2025, various manufacturers worldwide have recalled certain batches of infant formula and follow-on formula as a precautionary measure, as the products may be contaminated with the toxin cereulide (https://www.lebensmittelwarnung.de, in German). This toxin can be produced by some *Bacillus cereus* strains and can cause nausea and vomiting within 0.5 to 6 hours. The symptoms usually subside on their own within 24 hours. However, in rare cases of severe poisoning caused by high concentrations of cereulide, organ damage may occur. Cereulide is not inactivated by heating, so even boiling food does not eliminate the toxin.

Origin and detection of the toxin

In the current incident, the toxin entered the infant formula products via the ingredient arachidonic acid oil (ARA oil). Arachidonic acid is an omega-6 fatty acid that is added to infant formula for nutritional reasons. According to the information on product packaging, the oil is derived from the fungus *Mortierella alpina*. The contaminated ARA oil was produced by a Chinese company. In response, the European Commission has decided to implement stricter import controls on ARA oil from China from 26 February 2026 (DG Health and Food Safety, 2026). In addition, the responsible local authorities in Germany have increased the testing of samples of infant formula for food monitoring. In this context, the standard method for the detection of cereulide in infant formula has been optimised in

testing laboratories to achieve the lowest possible limit of quantification, in order to be able to detect and quantify even very low levels of contamination.

Health risk assessment

For the toxicological assessment of the health risk posed by substances that exhibit adverse effects shortly after intake (acute effects), the so-called acute reference dose (ARfD) is used. The ARfD indicates the estimated maximum amount of a substance that can be taken up with food over the course of a day, either in a single meal or across several meals, without any recognisable health risk. By comparison, the assessment of chronic toxicity considers the amount of a substance that can be ingested orally on a daily basis throughout a person's lifetime without any recognisable health risk (e.g. acceptable daily intake (ADI) or tolerable daily intake (TDI)).

To assess the risk posed by the (mostly low) concentrations of cereulide in affected infant formula, the EFSA calculated the ARfD for cereulide in infants in a Rapid Risk Assessment. In this assessment, the cardinal symptom of vomiting was considered as the acute, adverse effect. Based on an animal study using shrews and taking into account a general uncertainty factor of 100 and an additional uncertainty factor of 3 for infants, an ARfD for cereulide of 0.014 micrograms per kilogram of body weight (µg/kg$_{\text{body weight}}$) was determined for infants. Threshold levels at which the ARfD would be reached were also calculated based on specific consumption assumptions. These thresholds are 0.054 µg/litre (L) and 0.1 µg/L for liquid infant and follow-on formulae, and 0.43 µg/kg and 0.8 µg/kg for powdered infant and follow-on formulae (EFSA, 2026). Whether there are chronic effects beyond the acute effects resulting from long-term intake of cereulide concentrations below the ARfD cannot be assessed on the basis of the currently available scientific data. As early as 2013, an ARfD for cereulide was calculated in a Dutch risk assessment (Wijnands et al., 2013). However, as this assessment did not consider the particularly sensitive group of infants, both the ARfD of 0.03 µg/kg $_{\text{body weight}}$ and the deduced threshold for food, 1.8 µg/kg, were higher than the values now applicable to infant formula.

To assess the health impacts, EFSA and ECDC have also carried out a Rapid Outbreak Assessment. This compiled cases of illness in various European countries that may be linked to cereulide in infant formula. However, the identification and attribution of cases is complicated by the unspecific symptoms, the lack of a reporting mechanisms for individual cases of cereulide poisoning, and the absence of routine testing for cereulide in clinical samples. According to ECDC & EFSA (2026), the risk of exposure to infant formula and follow-on formula contaminated with cereulide is low due to the extensive product recalls. Should any recalled products still be present in consumers' households, these products should no longer be used.

The BfR is monitoring the situation very closely and is in close contact with other national and international authorities as well as the German poison information centres.

Further advice on the preparation of infant formula

Independent of the current recalls, the BfR is not aware of any reports of cereulide in infant formula from the scientific literature to date. However, *Bacillus cereus* strains capable of producing cereulide have been found in infant formula in the past. To minimise

contamination with *Bacillus cereus* as much as possible, there is a legally established process hygiene criterion (European Commission 2005 and 2007). Due to the low water content, the pathogen cannot multiply in the powder and therefore no cereulide formation is possible. However, if this powder is dissolved and stored at room temperature for several hours, bacterial growth and cereulide formation are possible. It is therefore important that powdered infant formula is always prepared immediately before consumption in accordance with basic hygiene rules, and that any unused infant formula is discarded.

References

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ECDC & EFSA, 2026. Multi-country foodborne event caused by cereulide in infant formula products; https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2026.9984

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European Commission (2005). COMMISSION REGULATION (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for food

European Commission (2007). COMMISSION REGULATION (EC) No 1441/2007 of 5 December 2007 amending Regulation (EC) No 2073/2005 on microbiological

Further information on Bacillus cereus

Topic page on Bacillus cereus
https://www.bfr.bund.de/en/food-safety/assessment-of-microbial-risks-in-foods/bacteria/bacillus-cereus/

BfR-Press Release: Infant formula in baby bottles to be prepared as fresh as possible
https://www.bfr.bund.de/en/press-release/infant-formula-in-baby-bottles-to-be-prepared-as-fresh-as-possible/

About the BfR

The German Federal Institute for Risk Assessment (BfR) is a scientifically independent institution within the portfolio of the German Federal Ministry of Agriculture, Food and Regional Identity (BMLEH). It protects people's health preventively in the fields of public health and veterinary public health. The BfR provides advice to the Federal Government as well as the Federal States ('Laender') on questions related to food, feed, chemical and product safety. The BfR conducts its own research on topics closely related to its assessment tasks.

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