European outbreak case definition

In order to harmonise the investigations related to the cereulide contamination of infant formula products (EpiPulse event 2025-FWD-00107), the following European outbreak case definition is proposed:

A possible outbreak case:
An infant presenting with acute gastrointestinal symptoms, with vomiting as the predominant symptom but diarrhoea also possible, from October 2025 and onwards. Onset within 8 hours* after consumption of any infant formula product, and with no other cases of gastrointestinal infection in the household within two days before and after the onset of symptoms in the infant, and with no other GI pathogens are detected in stool samples from the infant.

A probable outbreak case:
An infant presenting with acute gastrointestinal symptoms, with vomiting as the predominant symptom but diarrhoea also possible, from October 2025 and onwards, onset within 8 hours* after consumption of recalled infant formula product.

A confirmed outbreak case:
An infant presenting with acute gastrointestinal symptoms, with vomiting as the predominant symptom but diarrhoea also possible, from October 2025 and onwards, onset within 8 hours* after consumption of any infant formula product,

AND

1. Detection of cereulide in stool samples from the infant
   OR
2. Detection of cereulide in the same batch of infant formula as the one consumed by the infant

* When prolonged exposure is suspected, the incubation time is not a strict criterion

The following has been taken into consideration when developing the outbreak case definition related to the event with cereulide contamination of infant formula products (EpiPulse event 2025-FWD-00107):

- **Exposure** to infant formula has been included in this outbreak case definition, as the aim is to identify infants who are linked to contaminated batches of infant formula, rather than finding the source of the outbreak. The aim is to estimate the number of children affected, as well as being able to quickly identify additional contaminated batches, if other batches than the ones already subjected to the recall are involved.
- In foodborne outbreaks caused by cereulide, cases are usually identified based on an **epidemiological link**, meaning that people develop symptoms shortly after consuming a food product that later tests positive for the toxin. **Laboratory confirmation** through stool testing is not routinely performed, as methods to detect cereulide in faecal samples are not widely available in clinical microbiological laboratories. In this event however, a limited number of cases have been laboratory-confirmed even though this is not commonly done. Both epi-link to a product that contains cereulide, and laboratory confirmation of clinical samples are included in the definition for a confirmed outbreak case.
- The **symptoms** of cereulide intoxication, such as nausea, vomiting and diarrhoea, closely resemble common viral gastrointestinal infections, which are widespread in Europe during the winter season. However, cereulide intoxication is not transmitted to other people within the household. Occurrence of secondary cases within the household is therefore added as an exclusion criterion for a possible outbreak case, i.e. to increase the specificity of the outbreak case definition when no laboratory testing has been conducted on formula and/or clinical samples, and the formula/batch is unknown or not part of the recall. In addition, with the aim to increase the specificity for a possible outbreak case, no other GI pathogens are detected in stool samples from the infant.
- ECDC has one report of a case with symptoms before December 2025. For this outbreak case definition, the **time** is defined form October 2025 and onwards to increase the sensitivity of the outbreak case definition.

- The outbreak case definition may be **updated** if the situation changes.
- Link to the joint ECDC-EFSA Rapid Outbreak Assessment: Multi-country foodborne event caused by cereulide in infant formula products