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Cereulide in infant formula

Following the recall of infant formula, the BfR compiles basic information

Several manufacturers of infant formula have recently recalled certain product batches 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. Below, the German Federal Institute for Risk Assessment (BfR) has compiled some general information about the pathogen and the toxin it produces.

The current recalls of infant formula are taking place because one of the ingredients supplied to the infant formula manufacturer may contain the toxin cereulide. This toxin can be produced by certain bacteria of the *Bacillus (B.) cereus* group, known as "emetic *Bacillus cereus*". The bacteria can form very stable peristant forms, known as spores. These are prevalent in food and are not a problem at low concentrations. However, if the spores germinate and the bacteria multiply, it is possible that cereulide is formed in the food. Germination and multiplication require suitable conditions in the food, particularly with regard to moisture content, pH value, salt content, available nutrients, competing microorganisms and storage temperature. In the current recall, however, it is not the bacterium itself in the infant formula that is the problem, but the toxin cereulide that it produces. This entered the affected infant formula products via a contaminated batch of the ingredient arachidonic acid oil.

Cereulide is not inactivated by heating, so boiling food does not eliminate the toxin. If cereulide is taken up with food, it can cause nausea and vomiting within 0.5 to 6 hours. These symptoms give rise to the term "emetic", which means "causing nausea". The symptoms are usually self-limiting within 24 hours. However, in rare cases of severe poisoning due to high concentrations of cereulide, organ damage can occur, particularly affecting the liver and kidneys. In the past, this has led to fatal illnesses in isolated cases.

The acute reference dose (ARfD) can be used as a basis for assessing the health risk posed by a substance in food, but also for the food law assessment of foodstuffs. The ARfD is the estimated maximum amount of a substance that a person can take up in one or more meals

over the course of a day without a detectable health risk. As infants are a particularly sensitive population group, the European Food Safety Authority (EFSA) has recently conducted an assessment of the ARfD for cereulide in infant food and published it at the following link: <https://www.efsa.europa.eu/en/news/efsa-provides-rapid-risk-assessment-cereulide-infant-formula>

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 Centres.

Separately from the current recall, the BfR is not aware of any reports to date of cereulide in infant milk powder in the scientific literature. However, emetic *B. cereus* has been found in infant milk powder in the past. Due to the low water content, the pathogen cannot multiply in the undissolved powder and therefore cereulide cannot be formed. However, if this powder is dissolved and stored at room temperature for several hours, the bacteria can multiply and cereulide can be formed. It is therefore important that powdered infant formula is always prepared immediately before consumption.

Further information on *Bacillus cereus* and foodborne diseases is available on the BfR website:

Topic page *Bacillus cereus*

<https://www.bfr.bund.de/en/food-safety/assessment-of-microbial-risks-in-foods/bacteria/bacillus-cereus/>

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>

Information for consumers: Protection against food-borne diseases caused by bacterial toxins

<https://www.bfr.bund.de/en/publication/protection-against-food-borne-diseases-caused-by-bacterial-toxins/>

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