Maximum levels of cereulide toxin in foods for infants

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EU to set maximum levels for cereulide toxin in infant formulae, follow-on formulae, and foods for special medical purposes intended for infants

Draft Commission Regulation amending Regulation (EC) No 2073/2005 as regards the cereulide toxin in infant formulae, follow-on formulae and foods for special medical purposes intended for infants

Draft Annex

Update

Multiple manufacturers have recently detected cereulide toxin in infant foods. European Union (EU) Member States have reported cases of infants experiencing severe gastrointestinal symptoms after consuming such products. The European Commission therefore proposes to set maximum limits for cereulide in infant formulae, follow-on formulae, and foods for special medical purposes intended for infants.

Stakeholders have an opportunity to comment on the draft Regulation via the EU's Have your say consultation until **29 September 2026**.

Impacted products

Infant formulae, follow-on formulae, and foods for special medical purposes intended for infants

What is changing?

The European Commission proposes to set maximum levels for cereulide – a toxin produced by strains of *Bacillus cereus* – in infant formulae, follow-on formulae, and foods for special medical purposes intended for infants. The proposed limit for infant formulae, follow-on formulae and foods for special medical purposes intended for infants is set at 0.1 µg/kg. This relates to products placed on the market during their shelf-life.

These limits will be included in Regulation 2073/2005, which sets microbiological criteria for foodstuffs. Information on sampling is included in Annex I.

Why?

Between December 2025 and May 2026, multiple manufacturers detected cereulide toxin in infant foods. Several EU Member States reported cases of infants experiencing severe gastrointestinal symptoms after consuming products that were later recalled from the market. Following a rapid risk assessment in February 2026, the European Food Safety Authority established an acute reference dose (ARfD) and acceptable cereulide concentrations in foods intended for infants (EFSA 2026).

Timeline

Stakeholders have an opportunity to comment on the draft Regulation via the EU's Have your say consultation until **29 September 2026**.

What are the major implications for exporting countries?

Exporting countries will need to comply with stricter EU safety standards by ensuring that levels of cereulide in infant foods remain within the new limits. This may require adjustments in production processes, quality control systems, and testing capacity.

The new rules could lead to higher compliance costs due to the need for additional laboratory analysis, staff training, and quality assurance systems.

Recommended Actions

Producers of foods intended for infants should review their current practices. Cereulide contamination can be fully prevented through rigorous manufacturing practices and hygiene controls.

All interested stakeholders are invited to give feedback via the European Commission's Have your say platform until **29 September 2026**. Stakeholders wishing to respond must be registered. Those who are not will first need to create an EU login account, then register their organisation on the EU Transparency register.

Background

Cereulide is an emetic toxin produced by certain strains of *Bacillus cereus*. Infants are particularly vulnerable to the effects of cereulide due to their low body weight and limited ability to metabolise and eliminate toxins. Their exposure to even low levels of this toxin can lead to severe illness, including persistent vomiting, dehydration, and electrolyte imbalances. In some cases, it may be fatal.

Regulation 2073/2005 sets microbiological criteria (food safety and process hygiene) for foodstuffs, as well as rules for sampling and preparing test samples.

Resources

Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs

EFSA (2026) Rapid risk assessment on acute reference dose (ARfD) of cereulide in infants and information on acute consumption of infant formulae. EFSA Journal, 24(1): e9941.

Sources

Draft Commission Regulation as regards the cereulide toxin in infant formulae, follow-on formulae and foods for special medical purposes intended for infants

Draft Annex

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