

Maximum levels of cereulide toxin in foods for infants

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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

What is changing and why?

The European Union (EU) plans to introduce new maximum limits for cereulide in infant formulae, follow-on formulae, and foods for special medical purposes intended for infants. The proposed limit for infant food is set at 0.1 µg/kg. This relates to products placed on the market during their shelf-life.

The new rules are driven by the detection of cereulide toxin in infant foods and reports of severe gastrointestinal symptoms in infants.

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.

Timeline

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

For more information see the full record on the AGRINFO website – where you can also view the latest AGRINFO Update newsletters and search the database.

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