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Answer given by Mr Várhelyi
on behalf of the European Commission
(18.6.2026)

The European Food Safety Authority's (EFSA) mandate is to scientifically assess the risk of hazards linked to food, not to manage them. This separation between risk assessment and risk management is enshrined in EU food law¹ to ensure independent, evidence-based advice without political or industry influence. EFSA was tasked by the Commission on 27 January 2026 to provide an urgent assessment regarding cereulide toxicity levels in infants, and safe consumption thresholds for infant formula. EFSA's assessment, alongside Commission's recommendations, were promptly disseminated to Member States on 30 January 2026, providing essential guidance on acceptable exposure levels and standardised testing methods.

In its 2016 scientific opinion on *Bacillus cereus*, EFSA did not evaluate the acute toxicity of cereulide, nor did it establish any safety thresholds for its presence in food. The European Union's Rapid Alert System for Food and Feed (RASFF) was immediately activated once evidence of potential cereulide contamination in infant formula emerged, prompting the withdrawal and recall of the affected products. When it became clear that Member States required harmonised guidance, particularly to inform recall decisions, the Commission urgently requested EFSA to determine an acute reference dose (ARfD) for cereulide. EFSA delivered its assessment within three days.

The Commission remains committed to protecting consumer health and enforcing EU food safety laws and intends to conduct a lessons-learned exercise to evaluate communication protocols, information flows, and identify potential improvements. Moreover, discussions with Member States are expected to begin shortly to establish permanent legal limits for cereulide in infant formulas, ensuring infant long-term protection.

¹ <http://data.europa.eu/eli/reg/2002/178/oj>.