EUROPEAN
COMMISSION

Brussels, XXX
SANTE/1373/2026 CIS
(POOL/G5/2026/1373/1373-EN CIS.docx)
[…](2026) XXX draft

COMMISSION REGULATION (EU) …/…

of XXX

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

(Text with EEA relevance)

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This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

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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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs[1], and in particular Article 4(4) thereof,

Whereas:

(1) Commission Regulation (EC) No 2073/2005[2] lays down the microbiological criteria for certain micro-organisms and the implementing rules to be complied with by food business operators in respect of the general and specific hygiene requirements referred to in Article 4 of Regulation (EC) No 852/2004. In particular, Regulation (EC) No 2073/2005 lays down food safety criteria, which define the acceptability of a product, or a batch of foodstuffs applicable to products placed on the market.

(2) Cereulide is an emetic toxin produced by certain strains of *Bacillus cereus*. It is resistant to common heat treatments, including pasteurisation and sterilisation, and therefore may remain in food until the moment of consumption. Food contamination primarily arises from deficiencies in manufacturing practices, such as inadequate temperature control or poor hygiene in production facilities, which allow *Bacillus cereus* to proliferate and produce the toxin. Additionally, cereulide may enter the food chain through contaminated ingredients introduced during processing. Infants are particularly vulnerable to the effects of this toxin due to their lower 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, and may be fatal in some cases.

(3) Between December 2025 and May 2026, the detection of the cereulide toxin in infant foods from multiple manufacturers triggered large-scale recalls across multiple Member States and non-EU countries. Several Member States reported cases of infants experiencing severe gastrointestinal symptoms after consuming products later included in the recalls.

[1] OJ L 139, 30.4.2004, p. 1., ELI: http://data.europa.eu/eli/reg/2004/852/oj.
[2] OJ L 338, 22.12.2005, p. 1., ELI: http://data.europa.eu/eli/reg/2005/2073/oj.

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(4) On 2 February 2026, at the urgent request of the Commission, the European Food Safety Authority (the 'Authority') published a rapid risk assessment[3] establishing an acute reference dose (ARfD) for cereulide in infants and providing data on acute consumption levels of infant formulae. The assessment determined cereulide concentrations in infant formulae, follow-on formulae, and foods for special medical purposes intended for infants that may lead to an exposure~~could~~ exceeding the ARfD for infants consuming these products, and enabled Member States to have scientifically grounded provisional action thresholds to support the implementation of harmonised risk management measures in response to the ongoing incident.

(5) The Authority's assessment also highlighted critical analytical considerations for cereulide analysis using ISO 18465 which is the reference analytical method for this toxin. Specifically, the assessment stressed the necessity of sufficient sample hydration before acetonitrile extraction to ensure efficient toxin recovery and reliable results when analysing dried matrices with ISO 18465.

(6) To minimise the risk of similar incidents recurring, a permanent food safety criterion for cereulide should be established in infant formulae, follow-on formulae and foods for special medical purposes intended for infants. Given that cereulide contamination can be ~~fully~~ substantially mitigated~~prevented~~ through rigorous manufacturing practices and hygiene controls and that chronic toxic effects in infants following repeated low-dose exposure cannot be ruled out, the safety criterion should be based on the absence of quantifiable toxin when applying the reference method ISO 18465 to products placed on the market.

(7) For dried products, which constitute the most common forms of such foods on the market, the maximum limit should be set at 0.1 µg/kg, corresponding to the limit of quantification (LOQ) routinely achievable by laboratories while ensuring a high level of infant protection. To ensure reliability, the analysis of dried products should require sample hydration prior to acetonitrile extraction, using either the water-to-sample ratio specified in the manufacturer's instructions for use, or any other validated ratio that does not adversely affect the toxin extraction efficiency. Furthermore, the limit should be expressed on a dry matter basis.

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~~(6)~~(8) For ready-to-use liquid products, the maximum ~~permissible~~ limit ~~for these products should be~~would be set at 0,0125 µg/L~~kg~~ which corresponds to the limit of 0.1 µg/kg for dried products based on standard reconstitution factor of 1:8.~~given the dilution factor. Compliance of these liquid products should be verified using this lowest achievable LOQ.~~ However, regular testing against this limit should not be required for ready-to-use liquid products obtained from dried products that comply with the 0.1 µg/kg limit.~~ Additionally, to ensure reliable results when analysing dried products, the criterion should require prior sample hydration before acetonitrile extraction using the water-to-sample ratio specified in the manufacturer's instructions for use, or any other validated ratio not affecting the toxin extraction efficiency compared to the manufacturer's specified ratio~~

~~(7)~~(9) Regulation (EC) No 2073/2005 should therefore be amended accordingly.

[3] https://doi.org/10.2903/j.efsa.2026.9941

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~~(8)~~(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EC) No 2073/2005 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union.*

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN

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