EUROPEAN
COMMISSION

Brussels, XXX
PLAN/2026/1373
[…](2026) XXX draft

COMMISSION REGULATION (EU) …/…

of XXX

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

(Text with EEA relevance)

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(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 foodstuff 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 underdeveloped immune systems, 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 gastrointestinal symptoms after consuming products later included in the recalls. Furthermore, the deaths of two infants, potentially linked to the consumption of recalled products, were under judicial investigation in one Member State.

(4) On 2 February 2026, at the urgent request of the Commission, the European Food Safety Authority (EFSA) published a rapid risk assessment[3] establishing an acute reference dose (ARfD) for cereulide in infants and providing data on acute consumption levels of

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

infant formulae. The assessment determined cereulide concentrations in infant formulae, follow-on formulae, and dietary foods for special medical purposes intended for infants that could exceed 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) EFSA'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 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 dried infant formulae, dried follow-on formulae and dried dietary foods for special medical purposes intended for infants. Given that cereulide contamination can be fully prevented through rigorous manufacturing practices and hygiene controls and that chronic toxic effects may arise from repeated low-dose exposure in infants, the safety criterion should be based on the absence of detectable toxin. The reference method should be ISO 18465 with a limit of quantification (LOQ) of 0.1 µg/kg which is a threshold achievable by most laboratories and sufficiently sensitive to ensure infant safety. Additionally, the criterion should require prior sample hydration before acetonitrile extraction when analysing dried matrices as this step is essential to ensure reliable results under ISO 18465.

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

(8) 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