EUROPEAN
COMMISSION

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SANTE/1373/2026 ANNEX
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ANNEX

ANNEX

to the

COMMISSION REGULATION (EU) .../...

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

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.

ANNEX

In Annex I to Regulation (EC) No 2073/2005, Chapter 1 (Food safety criteria) is amended as follows:

(1) The following ~~entry~~ row 1.3~~0~~ is added:

‘

Food category	Micro-organisms/their toxins, metabolites	Sampling plan		Limits		Analytical reference method	Stage where the criterion applies
		n	c	m	M		
1.3~~0~~ ~~Dried i~~Infant formulae, ~~dried~~ follow-on formulae and ~~dried dietary~~ foods for special medical purposes intended for infants	Cereulide toxin	~~5~~3	0	Below the limit of quantification (LOQ) of 0,1 µg/kg~~Not detected in 25 g~~		ISO 18465*	Products placed on the market during their shelf-life

~~*~~* Dried samples of the target matrix shall be reconstituted using the water-to-sample ratio specified in the manufacturer’s instructions for use before proceeding with acetonitrile extraction.~~The preliminary addition of water is required prior to acetonitrile extraction when analysing dried samples.~~

Formateret: Normal

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(2) In the notes on the interpretation of the test results, the following entry is added:

‘Cereulide toxin in ~~dried~~ infant formulae, ~~dried~~ follow-on formulae and ~~dried dietary~~ foods for special medical purposes intended for infants:

– satisfactory, if all observed values are below the limit of quantification (LOQ) of 0,1 µg/kg,

– unsatisfactory, if any observed value is equal to or exceeds the LOQ of 0,1 µg/kg.’