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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

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

(1) The following rows 1.31 and 1.32 are~~is~~ added:

‘

Food category	Micro-organisms/their toxins, metabolites	Sampling plan		Limits		Analytical reference method	Stage where the criterion applies
		n	c	m	M		
1.31 Dried ~~I~~infant formulae, follow-on formulae and foods for special medical purposes intended for infants	Cereulide toxin	3	0	0,1 µg/kg (*)		ISO 18465 (**)	Products placed on the market during their shelf-life
1.32 Ready-to-use liquid infant formulae, follow-on formulae and foods for special medical purposes intended for infants (***)	Cereulide toxin	3	0	0,0125 µg/L		ISO 18465	Products placed on the market during their shelf-life

(*) The limit is expressed on a dry matter basis.~~Analysis of ready-to-use liquid products is restricted to laboratories capable of achieving a limit of quantification (LOQ) significantly below 0,1 µg/kg. The applicable limit for these products is this lowest achievable LOQ and it shall not be lower than 0,0125 µg/kg.~~

(**) ~~Dried s~~Samples ~~of the target matrix~~ shall be reconstituted using the manufacturer’s specified water-to-sample ratio before proceeding with acetonitrile extraction. Laboratories may use a lower ratio if validated data demonstrate an equivalent toxin extraction efficiency.’

(***) Regular testing against this criterion is not required for ready-to-use liquid products obtained from dried products complying with criterion 1.31.

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

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

– satisfactory, if all the values observed are ≤ the limit,

– unsatisfactory, if any of the values observed are > the limit.’

(3) Footnote 2 is replaced by the following:

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‘([2]) For points 1.1-1.24, 1.27a and 1.28-1.32~~1~~, m = M’

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