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ANNEX 1

ANNEX

to the

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

**amending Regulation (EC) No 333/2007 as regards the analysis of 3-
monochloropropane diol (3-MCPD) fatty acid esters, glycidyl fatty acid esters,
acrylamide and perchlorate**

ANNEX

The Annex to Regulation (EC) No 333/2007 is amended as follows:

- (1) in point C.3.1., Definitions, the definitions of 'LOD' and 'LOQ' are replaced by the following:

“LOD” = Limit of detection, smallest measured content, from which it is possible to deduce the presence of the analyte with reasonable statistical certainty.

”LOQ” = Limit of quantification, lowest content of the analyte which can be measured with reasonable statistical certainty.’

- (2) in point C.3.3.1., Performance criteria, point (b) is replaced by the following:

‘(b) Performance criteria for methods of analysis for 3-monochloropropane diol (3-MCPD), 3-MCPD fatty acid esters and glycidyl fatty acid esters:

- Performance criteria for methods of analysis for 3-MCPD in foods specified in point 4.1 of the Annex to Regulation (EC) No 1881/2006

Table 6a

Parameter	Criterion
Applicability	Foods specified in point 4.1 of the Annex to Regulation (EC) No 1881/2006
Specificity	Free from matrix or spectral interferences
Field blanks	Less than LOD
Repeatability (RSDr)	0,66 times RSDr as derived from (modified) Horwitz equation
Reproducibility (RSDR)	as derived from (modified) Horwitz equation
Recovery	75-110 %
Limit of Detection (LOD)	≤ 5 µg/kg (on dry matter basis)
Limit of Quantification (LOQ)	≤ 10 µg/kg (on dry matter basis)

- Performance criteria for methods of analysis for 3-MCPD in foods specified in point 4.3 of the Annex to Regulation (EC) No 1881/2006

Table 6b

Parameter	Criterion
Applicability	Foods specified in point 4.3. of the Annex to Regulation (EC) No 1881/2006
Specificity	Free from matrix or spectral interferences
Field blanks	Less than LOD
Repeatability (RSDr)	0,66 times RSDr as derived from (modified) Horwitz equation
Reproducibility (RSDR)	as derived from (modified) Horwitz equation
Recovery	75-110 %
Limit of Detection (LOD)	≤ 7 µg/kg
Limit of Quantification (LOQ)	≤ 14 µg/kg

- Performance criteria for methods of analysis for 3-MCPD fatty acid esters in foods specified in point 4.3 of the Annex to Regulation (EC) No 1881/2006

Table 6c

Parameter	Criterion
Applicability	Foods specified in point 4.3. of the Annex to Regulation (EC) No 1881/2006
Specificity	Free from matrix or spectral interferences
Repeatability (RSDr)	0,66 times RSDR as derived from (modified) Horwitz equation
Reproducibility (RSDR)	as derived from (modified) Horwitz equation
Recovery	70-125 %
Limit of Detection (LOD)	Three tenths of LOQ
Limit of Quantification (LOQ) for foods specified in 4.3.1 and 4.3.2	$\leq 100 \mu\text{g/kg}$ in oils and fats
Limit of Quantification (LOQ) for foods specified in 4.3.3 and in 4.3.4 with a fat content < 40%	\leq two fifths of the ML
Limit of Quantification (LOQ) for foods specified in 4.3.4 with a fat content $\geq 40\%$	$\leq 15 \mu\text{g/kg}$ fat

- Performance criteria for methods of analysis for glycidyl fatty acid esters in foods specified in point 4.2 of the Annex to Regulation (EC) No 1881/2006

Table 6d

Parameter	Criterion
Applicability	Foods specified in point 4.2 of the Annex to Regulation (EC) No 1881/2006
Specificity	Free from matrix or spectral interferences
Repeatability (RSDr)	0,66 times RSDR as derived from (modified) Horwitz equation
Reproducibility (RSDR)	as derived from (modified) Horwitz equation
Recovery	70-125 %
Limit of Detection (LOD)	Three tenths of LOQ
Limit of Quantification (LOQ) for foods specified in 4.2.1 and 4.2.2	$\leq 100 \mu\text{g/kg}$ in oils and fats
Limit of Quantification (LOQ) for foods specified in 4.2.3 with a fat content < 65% and in 4.2.4 with a fat content < 8%	\leq two fifths of the ML
Limit of Quantification (LOQ) for foods specified in 4.2.3 with a fat content $\geq 65\%$ and in 4.2.4 with a fat content $\geq 8\%$	$\leq 31 \mu\text{g/kg}$ fat

- (3) in point C.3.3.1, Performance criteria, point (d), ‘Notes to the performance criteria’ is replaced by the following:

‘(d) Performance criteria for methods of analysis for acrylamide:

Table 8

Parameter	Criterion
Applicability	All foods
Specificity	Free from matrix or spectral interferences
Field blanks	Less than Limit of Detection (LOD)
Repeatability (RSD _r)	0.66 times RSD _R as derived from (modified) Horwitz equation
Reproducibility (RSD _R)	as derived from (modified) Horwitz equation
Recovery	75-110 %
Limit of Detection (LOD)	Three tenths of LOQ
Limit of Quantification (LOQ)	For foods with benchmark levels < 125 µg/kg: ≤ two fifths of the benchmark level, however not required to be lower than 20 µg/kg For foods with benchmark level ≥ 125 µg/kg: ≤ 50 µg/kg’

- (4) in point C.3.3.1, Performance criteria, the following points (e) and (f) are added:

‘(e) Performance criteria for methods of analysis for perchlorate:

Table 9

Parameter	Criterion
Applicability	All foods
Specificity	Free from matrix or spectral interferences
Repeatability (RSD _r)	0,66 times RSD _R as derived from (modified) Horwitz equation
Reproducibility (RSD _R)	as derived from (modified) Horwitz equation
Recovery	70-110 %
Limit of Detection (LOD)	Three tenths of LOQ
Limit of Quantification (LOQ)	≤ two fifths of the ML

- (f) Notes to the performance criteria:

The Horwitz equation (*) (for concentrations $1.2 \times 10^{-7} \leq C \leq 0.138$) and the modified Horwitz equation (**) (for concentrations $C < 1.2 \times 10^{-7}$) are generalised precision equations which are independent of analyte and matrix but solely dependent on concentration for most routine methods of analysis.

Modified Horwitz equation for concentrations $C < 1.2 \times 10^{-7}$:

$$RSD_R = 22 \%$$

where:

- RSD_R is the relative standard deviation calculated from results generated under reproducibility conditions $[(s_R / \bar{x}) \times 100]$

- C is the concentration ratio (i.e. 1 = 100g/100g, 0.001 = 1000 mg/kg). The modified Horwitz equation applies to concentrations $C < 1.2 \times 10^{-7}$.

Horwitz equation for concentrations $1.2 \times 10^{-7} \leq C \leq 0.138$:

$$RSD_R = 2C^{(-0.15)}$$

where:

- RSD_R is the relative standard deviation calculated from results generated under reproducibility conditions $[(sR / \bar{x}) \times 100]$
- C is the concentration ratio (i.e. 1 = 100g/100g, 0.001 = 1000 mg/kg). The Horwitz equation applies to concentrations $1.2 \times 10^{-7} \leq C \leq 0.138$.
- (*) W. Horwitz, L.R. Kamps, K.W. Boyer, J.Assoc.Off.Analy.Chem.,1980, 63, 1344.
- (**) M. Thompson, Analyst, 2000, p. 125 and 385-386.'

- (5) in point C.3.3.2., 'Fitness-for-purpose' approach, the words "Table 8" are replaced by the words "Table 10".