
Status: Point in time view as at 31/01/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2019/2093. (See end of Document for details)

Commission Implementing Regulation (EU) 2019/2093 of 29 November 2019 amending Regulation (EC) No 333/2007 as regards the analysis of 3-monochloropropane-1,2-diol (3-MCPD) fatty acid esters, glycidyl fatty acid esters, perchlorate and acrylamide (Text with EEA relevance)

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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-1,2-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 (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)	≤ 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
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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 (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)	≤ 7 µg/kg
Limit of Quantification (LOQ)	≤ 14 µg/kg

— Performance criteria for methods of analysis for 3-MCPD fatty acid esters, expressed as 3-MCPD, 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 (RSD _r)	0,66 times RSD _R as derived from (modified) Horwitz equation
Reproducibility (RSD _R)	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	≤ 100 µg/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 %	≤ two fifths of the ML
Limit of Quantification (LOQ) for foods specified in 4.3.4 with a fat content ≥ 40 %	≤ 15 µg/kg fat

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- Performance criteria for methods of analysis for glycidyl fatty acid esters, expressed as glycidol, 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 (RSD _r)	0,66 times RSD _R as derived from (modified) Horwitz equation
Reproducibility (RSD _R)	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	≤ 100 µg/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 %	≤ two fifths of the ML
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 %	≤ 31 µg/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)

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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⁽¹⁾ (for concentrations $1,2 \times 10^{-7} \leq C \leq 0,138$) and the modified Horwitz equation⁽²⁾ (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:

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- RSD_R is the relative standard deviation calculated from results generated under reproducibility conditions

$$[(s_R/x) \times 100]$$

- C is the concentration ratio (i.e. 1 = 100g/100g, 0,001 = 1 000 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

$$[(s_R/x) \times 100]$$

- C is the concentration ratio (i.e. 1 = 100g/100g, 0,001 = 1 000 mg/kg). The Horwitz equation applies to concentrations $1,2 \times 10^{-7} \leq C \leq 0,138$.

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

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- (1) W. Horwitz, L.R. Kamps, K.W. Boyer, J.Assoc.Off.Analy.Chem.,63, 1980, 1344-1354.
- (2) M. Thompson, Analyst, 125, 2000, 385-386.'

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