Changes to legislation: There are outstanding changes not yet made to Commission Regulation (EC) No 333/2007. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the control of the levels of trace elements and processing contaminants in foodstuffs (Text with EEA relevance)

Changes to legislation: There are outstanding changes not yet made to Commission Regulation (EC) No 333/2007. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

### **ANNEX**

## PART C

## SAMPLE PREPARATION AND ANALYSIS

# C.3. METHODS OF ANALYSIS

## C.3.1. Definitions

The following definitions shall apply:

single test results obtained under repeatability conditions (i.e., same sample, same operator, same apparatus, same laboratory, and short interval of time) may be expected to lie within a specific probability (typically 95 %) and hence $r = 2.8 \times s_r$ .  '\$\s^{\circ}\$ = Standard deviation calculated from results generated under repeatability conditions.  'RSDr' = Relative standard deviation calculated from results generated under repeatability conditions [(\$\s_r/x\) × 100].  'R' = Reproducibility the value below which the absolute difference between single test results obtained under reproducibility conditions (i.e., on identical material obtained by operators in different laboratories, using the standardised test method), may be expected to lie within a certain probability (typically 95 %); R = 2.8 \times s_R.  '\$\s_R'\$ = Standard deviation, calculated from results under reproducibility conditions.  '\$\text{RSD}_R'\$ = Standard deviation calculated from results generated under reproducibility conditions [(\$\s_R/x\) × 100].  '\$\text{I}^{\text{P1}}LOD'\$ = Limit of detection, smallest measured content, from which it is possible to deduce the presence of the analyte with reasonable statistical certainty.  '\$\text{LOQ'}\$ = Limit of quantification, lowest content of the analyte which can be measured with reasonable statistical certainty.]  '\$\text{I}^{\text{P2}}HORRAT^{(1)}_r'\$ = The observed RSD_r divided by the RSD_r value estimated from the (modified) Horwitz equation <sup>(2)</sup> (cf. point C.3.3.1 ('Notes to the performance criteria')).] = Combined standard measurement uncertainty obtained using the individual standard measurement uncertainties associated with the input quantities in a measurement uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95 % (U = 2u).	( )		
'Sr' = Standard deviation calculated from results generated under repeatability conditions.  'RSDr' = Relative standard deviation calculated from results generated under repeatability conditions [(sr'X) × 100].  'R' = Reproducibility the value below which the absolute difference between single test results obtained under reproducibility conditions (i.e., on identical material obtained by operators in different laboratories, using the standardised test method), may be expected to lie within a certain probability (typically 95 %); R = 2,8 × s <sub>R</sub> .  'SR' = Standard deviation, calculated from results under reproducibility conditions.  'RSDR' = Relative standard deviation calculated from results generated under reproducibility conditions [(s <sub>R</sub> /X) × 100].  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.]  'IP2HORRAT(0)r' = The observed RSDr divided by the RSDr value estimated from the (modified) Horwitz equation(2) (cf. point C.3.3.1 ('Notes to the performance criteria')) using the assumption r = 0,66 R.]  'IP2HORRAT(3)r' = Combined standard measurement uncertainty obtained using the individual standard measurement uncertainty obtained using the individual standard measurement uncertainties associated with the input quantities in a measurement uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95 % (U = 2u).	ʻr'	=	Repeatability the value below which the absolute difference between single test results obtained under repeatability conditions (i.e., same sample, same operator, same apparatus, same laboratory, and short interval of time) may be expected to lie within a specific probability
conditions.  Relative standard deviation calculated from results generated under repeatability conditions [(s <sub>r</sub> /X) × 100].  Reproducibility the value below which the absolute difference between single test results obtained under reproducibility conditions (i.e., on identical material obtained by operators in different laboratories, using the standardised test method), may be expected to lie within a certain probability (typically 95 %); R = 2,8 × s <sub>R</sub> .  's <sub>R</sub> '  Standard deviation, calculated from results under reproducibility conditions.  'RSD <sub>R</sub> '  Relative standard deviation calculated from results generated under reproducibility conditions [(s <sub>R</sub> /X) × 100].  'I <sup>F1</sup> 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.]  'I <sup>F2</sup> HORRAT <sup>(1)</sup> <sub>r</sub> '  The observed RSD <sub>r</sub> divided by the RSD <sub>r</sub> value estimated from the (modified) Horwitz equation <sup>(2)</sup> (cf. point C.3.3.1 ('Notes to the performance criteria'))]  'I <sup>F2</sup> HORRAT <sup>(3)</sup> <sub>R</sub> '  Combined standard measurement uncertainty obtained using the individual standard measurement uncertainty obtained using the individual standard measurement uncertainties associated with the input quantities in a measurement modell <sup>(5)</sup> The expanded measurement uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95 % (U = 2u).			(typically 95 %) and hence $r = 2.8 \times s_r$ .
'RSD <sub>r</sub> ' = Relative standard deviation calculated from results generated under repeatability conditions [(s <sub>r</sub> /x̄) × 100].  'R' = Reproducibility the value below which the absolute difference between single test results obtained under reproducibility conditions (i.e., on identical material obtained by operators in different laboratories, using the standardised test method), may be expected to lie within a certain probability (typically 95 %); R = 2,8 × s <sub>R</sub> .  'S <sub>R</sub> ' = Standard deviation, calculated from results under reproducibility conditions.  'RSD <sub>R</sub> ' = Relative standard deviation calculated from results generated under reproducibility conditions [(s <sub>R</sub> /x̄) × 100].  '[F¹LOD' = 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.]  '[F²HORRAT(¹) <sub>r</sub> ' = The observed RSD <sub>r</sub> divided by the RSD <sub>r</sub> value estimated from the (modified) Horwitz equation(²) (cf. point C.3.3.1 ('Notes to the performance criteria')).]  '[F²u' = Combined standard measurement uncertainty obtained using the individual standard measurement uncertainty obtained using the individual standard measurement uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95 % (U = 2u).	'Sr'	=	
*R' = Reproducibility the value below which the absolute difference between single test results obtained under reproducibility conditions (i.e., on identical material obtained by operators in different laboratories, using the standardised test method), may be expected to lie within a certain probability (typically 95 %); R = 2,8 × s <sub>R</sub> .  *SR' = Standard deviation, calculated from results under reproducibility conditions.  *RSDR' = Relative standard deviation calculated from results generated under reproducibility conditions [(s <sub>R</sub> /X') × 100].  *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.]  *[F²HORRAT(1)] <sub>r</sub> ' = The observed RSD <sub>r</sub> divided by the RSD <sub>r</sub> value estimated from the (modified) Horwitz equation(2) (cf. point C.3.3.1 ('Notes to the performance criteria')) using the assumption r = 0,66 R.]  *[F²u'] = The observed RSD <sub>R</sub> divided by the RSD <sub>R</sub> value estimated from the (modified) Horwitz equation(4) (cf. point C.3.3.1 ('Notes to the performance criteria'))]  *[F²u'] = Combined standard measurement uncertainty obtained using the individual standard measurement uncertainties associated with the input quantities in a measurement uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95 % (U = 2u).	'RSD <sub>r</sub> '	=	Relative standard deviation calculated from results generated under
single test results obtained under reproducibility conditions (i.e., on identical material obtained by operators in different laboratories, using the standardised test method), may be expected to lie within a certain probability (typically 95 %); R = 2,8 × s <sub>R</sub> .  's <sub>R</sub> ' = Standard deviation, calculated from results under reproducibility conditions.  'RSD <sub>R</sub> ' = Relative standard deviation calculated from results generated under reproducibility conditions [(s <sub>R</sub> /X) × 100].  '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.]  'IF2HORRAT <sup>(1)</sup> <sub>r</sub> ' = The observed RSD <sub>r</sub> divided by the RSD <sub>r</sub> value estimated from the (modified) Horwitz equation <sup>(2)</sup> (cf. point C.3.3.1 ('Notes to the performance criteria')).]  'IF2HORRAT <sup>(3)</sup> <sub>R</sub> ' = The observed RSD <sub>R</sub> divided by the RSD <sub>R</sub> value estimated from the (modified) Horwitz equation <sup>(4)</sup> (cf. point C.3.3.1 ('Notes to the performance criteria')).]  'IF2U' = Combined standard measurement uncertainty obtained using the individual standard measurement uncertainties associated with the input quantities in a measurement model] <sup>(5)</sup> 'U' = The expanded measurement uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95 % (U = 2u).			
conditions.  Relative standard deviation calculated from results generated under reproducibility conditions $[(s_R/X) \times 100]$ .  Limit of detection, smallest measured content, from which it is possible to deduce the presence of the analyte with reasonable statistical certainty.  Limit of quantification, lowest content of the analyte which can be measured with reasonable statistical certainty.  The observed RSD <sub>r</sub> divided by the RSD <sub>r</sub> value estimated from the (modified) Horwitz equation <sup>(2)</sup> (cf. point C.3.3.1 ('Notes to the performance criteria')) using the assumption $r = 0.66 R.$ ]  The observed RSD <sub>R</sub> divided by the RSD <sub>R</sub> value estimated from the (modified) Horwitz equation <sup>(4)</sup> (cf. point C.3.3.1 ('Notes to the performance criteria')).]  The observed RSD <sub>R</sub> divided by the RSD <sub>R</sub> value estimated from the (modified) Horwitz equation <sup>(4)</sup> (cf. point C.3.3.1 ('Notes to the performance criteria')).]  Combined standard measurement uncertainty obtained using the individual standard measurement uncertainties associated with the input quantities in a measurement model] <sup>(5)</sup> The expanded measurement uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95 % (U = 2u).	'R'	=	single test results obtained under reproducibility conditions (i.e., on identical material obtained by operators in different laboratories, using the standardised test method), may be expected to lie within a certain
'RSD <sub>R</sub> ' = Relative standard deviation calculated from results generated under reproducibility conditions $[(s_R/X) \times 100]$ .  '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.]  'IF2HORRAT(1)', = The observed RSD <sub>r</sub> divided by the RSD <sub>r</sub> value estimated from the (modified) Horwitz equation(2) (cf. point C.3.3.1 ('Notes to the performance criteria')) using the assumption $r = 0.66 \text{ R.}$ ]  'IF2HORRAT(3) <sub>R</sub> ' = The observed RSD <sub>R</sub> divided by the RSD <sub>R</sub> value estimated from the (modified) Horwitz equation(4) (cf. point C.3.3.1 ('Notes to the performance criteria')).]  'IF2u' = Combined standard measurement uncertainty obtained using the individual standard measurement uncertainties associated with the input quantities in a measurement model](5)  'U' = The expanded measurement uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95 % (U = 2u).	's <sub>R</sub> '	=	
Limit of detection, smallest measured content, from which it is possible to deduce the presence of the analyte with reasonable statistical certainty.  Limit of quantification, lowest content of the analyte which can be measured with reasonable statistical certainty.  The observed RSD <sub>r</sub> divided by the RSD <sub>r</sub> value estimated from the (modified) Horwitz equation <sup>(2)</sup> (cf. point C.3.3.1 ('Notes to the performance criteria')) using the assumption r = 0,66 R.]  The observed RSD <sub>R</sub> divided by the RSD <sub>R</sub> value estimated from the (modified) Horwitz equation <sup>(4)</sup> (cf. point C.3.3.1 ('Notes to the performance criteria')).]  Combined standard measurement uncertainty obtained using the individual standard measurement uncertainties associated with the input quantities in a measurement model] <sup>(5)</sup> The expanded measurement uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95 % (U = 2u).	'RSD <sub>R</sub> '	=	
Limit of detection, smallest measured content, from which it is possible to deduce the presence of the analyte with reasonable statistical certainty.  Limit of quantification, lowest content of the analyte which can be measured with reasonable statistical certainty.  The observed RSD <sub>r</sub> divided by the RSD <sub>r</sub> value estimated from the (modified) Horwitz equation <sup>(2)</sup> (cf. point C.3.3.1 ('Notes to the performance criteria')) using the assumption r = 0,66 R.]  The observed RSD <sub>R</sub> divided by the RSD <sub>R</sub> value estimated from the (modified) Horwitz equation <sup>(4)</sup> (cf. point C.3.3.1 ('Notes to the performance criteria')).]  Combined standard measurement uncertainty obtained using the individual standard measurement uncertainties associated with the input quantities in a measurement model] <sup>(5)</sup> The expanded measurement uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95 % (U = 2u).			reproducibility conditions $[(s_R/X) \times 100]$ .
'LOQ'  = Limit of quantification, lowest content of the analyte which can be measured with reasonable statistical certainty.]  '[F2HORRAT(I)]'  = The observed RSD <sub>r</sub> divided by the RSD <sub>r</sub> value estimated from the (modified) Horwitz equation(2) (cf. point C.3.3.1 ('Notes to the performance criteria')) using the assumption r = 0,66 R.]  '[F2HORRAT(3)] <sub>R</sub> '  = The observed RSD <sub>R</sub> divided by the RSD <sub>R</sub> value estimated from the (modified) Horwitz equation(4) (cf. point C.3.3.1 ('Notes to the performance criteria')).]  - ([F2u]'  = Combined standard measurement uncertainty obtained using the individual standard measurement uncertainties associated with the input quantities in a measurement uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95 % (U = 2u).	'[ <sup>F1</sup> LOD'	=	Limit of detection, smallest measured content, from which it is possible to deduce the presence of the analyte with reasonable statistical
"[F2HORRAT(1)]" = The observed RSD <sub>r</sub> divided by the RSD <sub>r</sub> value estimated from the (modified) Horwitz equation(2) (cf. point C.3.3.1 ('Notes to the performance criteria')) using the assumption r = 0,66 R.]  "[F2HORRAT(3)] <sub>R</sub> " = The observed RSD <sub>R</sub> divided by the RSD <sub>R</sub> value estimated from the (modified) Horwitz equation(4) (cf. point C.3.3.1 ('Notes to the performance criteria')).]  "[F2u" = Combined standard measurement uncertainty obtained using the individual standard measurement uncertainties associated with the input quantities in a measurement uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95 % (U = 2u).	'LOQ'	=	Limit of quantification, lowest content of the analyte which can be
performance criteria')) using the assumption $r = 0,66 \text{ R.}]$ "[F2HORRAT(3)] <sub>R</sub> ' = The observed RSD <sub>R</sub> divided by the RSD <sub>R</sub> value estimated from the (modified) Horwitz equation (cf. point C.3.3.1 ('Notes to the performance criteria')).]  "[F2u' = Combined standard measurement uncertainty obtained using the individual standard measurement uncertainties associated with the input quantities in a measurement uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95 % (U = 2u).	'[F2HORRAT(1)]'	=	The observed RSD <sub>r</sub> divided by the RSD <sub>r</sub> value estimated from
'[F2HORRAT(3)]R' = The observed RSD <sub>R</sub> divided by the RSD <sub>R</sub> value estimated from the (modified) Horwitz equation(4) (cf. point C.3.3.1 ('Notes to the performance criteria')).]  '[F2u' = Combined standard measurement uncertainty obtained using the individual standard measurement uncertainties associated with the input quantities in a measurement uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95 % (U = 2u).			
performance criteria')).]  [F <sup>2</sup> u' = Combined standard measurement uncertainty obtained using the individual standard measurement uncertainties associated with the input quantities in a measurement model] (5)  [U' = The expanded measurement uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95 % (U = 2u).	'[F2HORRAT(3)R'	=	The observed RSD <sub>R</sub> divided by the RSD <sub>R</sub> value estimated from
"IF2u" = Combined standard measurement uncertainty obtained using the individual standard measurement uncertainties associated with the input quantities in a measurement model] (5)  "U" = The expanded measurement uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95 % (U = 2u).			
quantities in a measurement model (5)  'U' = The expanded measurement uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95 % (U = 2u).	'[ <sup>F2</sup> u'	=	Combined standard measurement uncertainty obtained using the
which gives a level of confidence of approximately 95 % ( $U = 2u$ ).	(T.I.)		quantities in a measurement model] <sup>(5)</sup>
	·U′	=	
	'Uf'	=	Maximum standard measurement uncertainty.

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### **Textual Amendments**

- **F1** Substituted by 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).
- **F2** Substituted by Commission Regulation (EU) No 836/2011 of 19 August 2011 amending Regulation (EC) No 333/2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs (Text with EEA relevance).

Changes to legislation: There are outstanding changes not yet made to Commission Regulation (EC) No 333/2007. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

- **(1)** [F2Horwitz W. and Albert, R., 2006, The Horwitz Ratio (HorRat): A useful Index of Method Performance with respect to Precision, Journal of AOAC International, Vol. 89, 1095-1109.
- **(2)** [F2M. Thompson, Analyst, 2000, p. 125 and 385-386.]
- **(3)** [F2Horwitz W. and Albert, R., 2006, The Horwitz Ratio (HorRat): A useful Index of Method Performance with respect to Precision, Journal of AOAC International, Vol. 89, 1095-1109.]
- **(4)** [F2M. Thompson, Analyst, 2000, p. 125 and 385-386.]
- **(5)** [F2International vocabulary of metrology – Basic and general concepts and associated terms (VIM), JCGM 200:2008.1

# **Textual Amendments**

Substituted by Commission Regulation (EU) No 836/2011 of 19 August 2011 amending Regulation (EC) No 333/2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs (Text with EEA relevance).

### **Changes to legislation:**

There are outstanding changes not yet made to Commission Regulation (EC) No 333/2007. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.

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# Changes and effects yet to be applied to the whole legislation item and associated provisions

- Signature words omitted by S.I. 2019/639 reg. 29
- Annex para. B.1.1 words omitted by S.I. 2019/639 reg. 30(a) (This amendment not applied to legislation.gov.uk. Reg. 30 substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 8(10))
- Annex para. C.3.3.1 words omitted by S.I. 2019/639 reg. 30(e) (This amendment not applied to legislation.gov.uk. Reg. 30 substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 8(10))
- Annex para. B words omitted by virtue of S.I. 2019/639, reg. 30(a) (as substituted) by S.I. 2020/1504 reg. 8(10)
- Annex para. C words omitted by virtue of S.I. 2019/639, reg. 30(e) (as substituted) by S.I. 2020/1504 reg. 8(10)
- Annex para. B.1.6 words substituted by S.I. 2019/639 reg. 30(b) (This amendment not applied to legislation.gov.uk. Reg. 30 substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 8(10))
- Annex para. B.1.8 words substituted by S.I. 2019/639 reg. 30(c) (This amendment not applied to legislation.gov.uk. Reg. 30 substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 8(10))
- Annex para. C.2.4 words substituted by S.I. 2019/639 reg. 30(d) (This amendment not applied to legislation.gov.uk. Reg. 30 substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 8(10))
- Annex para. B words substituted by S.I. 2019/639, reg. 30(b) (as substituted) by S.I. 2020/1504 reg. 8(10)
- Annex para. B words substituted by S.I. 2019/639, reg. 30(c) (as substituted) by S.I. 2020/1504 reg. 8(10)
- Annex para. C words substituted by S.I. 2019/639, reg. 30(d) (as substituted) by S.I. 2020/1504 reg. 8(10)