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)

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)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation)[(1)], and in particular Article 34(6) thereof,

Whereas:

(1) Commission Regulation (EC) No 333/2007[(2)] lays down the methods of sampling and analysis to be used for the official control of the levels of certain contaminants in foodstuffs.

(2) The maximum allowed levels for 3-monochloropropane-1,2-diol (3-MCPD) fatty acid esters, glycidyl fatty acid esters and perchlorate in foodstuffs have been established by Commission Regulation (EC) No 1881/2006[(3)]. Commission Regulation (EU) 2017/2158[(4)] establishes mitigation measures and benchmark levels for the reduction of the presence of acrylamide in certain categories of foodstuffs.

(3) Regulation (EC) No 333/2007 establishes specific performance criteria to be met by the validated methods of analysis for contaminants in food, applied by the relevant European laboratories. Consequently, it is appropriate to lay down specific performance criteria in Regulation (EC) No 333/2007, with which the method of analysis for controlling the maximum levels of 3-MCPD fatty acid esters, glycidyl fatty acid esters, perchlorate and acrylamide in foodstuffs has to comply.

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

(4) The European Union Reference Laboratories in the field of Contaminants in Feed and Food have elaborated a guidance document on the estimation of the Limit of Detection (LOD) and Limit of Quantification (LOQ) for measurements in the field of contaminants in feed and food[(5)]. Consequently, it is appropriate to adapt the definitions contained in Regulation (EC) No 333/2007 and related to the limit of detection and the limit of quantification.

(5) Regulation (EC) No 333/2007 should therefore be amended accordingly.

(6) Regulation (EU) 2017/625 applies with effect from 14 December 2019. Therefore this Regulation should start to apply from the same date.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

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

(1) in Article 1, paragraph 1 is replaced by the following:

1. Sampling and analysis for the control of the levels of lead, cadmium, mercury, inorganic tin, inorganic arsenic, 3-monochloropropane-1,2-diol (3-MCPD), 3-MCPD fatty acid esters, glycidyl fatty acid esters, polycyclic aromatic hydrocarbons (PAH) and perchlorate listed in Sections 3, 4, 6 and 9 of the Annex to Regulation (EC) No 1881/2006 and for the control of the levels of acrylamide in accordance with Commission Regulation (EU) 2017/2158[(6)] shall be carried out in accordance with the Annex to this Regulation.;

(2) the Annex is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 14 December 2019.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 29 November 2019.

For the Commission

The President

Jean-Claude JUNCKER

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**

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