

Commission Regulation (EU) 2016/582 of 15 April 2016 amending Regulation (EC) No 333/2007 as regards the analysis of inorganic arsenic, lead and polycyclic aromatic hydrocarbons and certain performance criteria for analysis (Text with EEA relevance)

COMMISSION REGULATION (EU) 2016/582

of 15 April 2016

amending Regulation (EC) No 333/2007 as regards the analysis of inorganic arsenic, lead and polycyclic aromatic hydrocarbons and certain performance criteria for analysis

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules⁽¹⁾, and in particular Article 11(4) thereof,

Whereas:

- (1) Commission Regulation (EC) No 333/2007⁽²⁾ lays down the methods of sampling and analysis for the official control of levels of certain contaminants in foodstuffs.
- (2) The maximum levels for certain contaminants in food have been established by Commission Regulation (EC) No 1881/2006⁽³⁾. Commission Regulation (EU) 2015/1006⁽⁴⁾ amended Regulation (EC) No 1881/2006 to set maximum levels for inorganic arsenic, consequently it is appropriate to lay down specific procedures related to analysis for inorganic arsenic.
- (3) The EN standard 13804 related to the determination of elements and their chemical species has been updated, it is therefore appropriate to update the reference to that standard accordingly.
- (4) The maximum levels for polycyclic aromatic hydrocarbons (PAH) in cocoa beans and derived products have to be established on a fat basis. Proficiency tests performed by the European Union Reference Laboratory for PAH indicate divergences in the determination of the fat content. It is therefore appropriate to harmonise the approach for the determination of the fat content.
- (5) Following advice of the European Union Reference Laboratory for heavy metals in feed and food, it is appropriate to amend the definition of the limit of quantification and the performance criteria related to the limit of detection for the methods of analysis for lead, cadmium, mercury and inorganic tin.

Status: Point in time view as at 15/04/2016.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) 2016/582. (See end of Document for details)

- (6) It is appropriate that the provisions related to the methods of sampling and analysis also apply outside the frame of official controls.
- (7) Regulation (EC) No 333/2007 should therefore be amended accordingly.
- (8) 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) the title is replaced by the following:
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;
- (2) 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-MCPD and polycyclic aromatic hydrocarbons (“PAH”) listed in Sections 3, 4 and 6 of the Annex to Regulation (EC) No 1881/2006 shall be carried out in accordance with the Annex to this Regulation.;
- (3) the Annex is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

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

Done at Brussels, 15 April 2016.

For the Commission

The President

Jean-Claude JUNCKER

Status: Point in time view as at 15/04/2016.

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ANNEX

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

(1) point C.2.2.1 is replaced by the following:

C.2.2.1. Specific procedures for lead, cadmium, mercury, inorganic tin and inorganic arsenic

The analyst shall ensure that samples do not become contaminated during sample preparation. Wherever possible, apparatus and equipment coming into contact with the sample shall not contain those metals to be determined and be made of inert materials, e.g. plastics such as polypropylene, polytetrafluoroethylene (PTFE) etc. These should be acid cleaned to minimise the risk of contamination. High quality stainless steel may be used for cutting edges.

There are many satisfactory specific sample preparation procedures which may be used for the products under consideration. For those aspects not specifically covered by this Regulation, the CEN Standard “Foodstuffs. Determination of elements and their chemical species. General considerations and specific requirements”⁽⁵⁾ has been found to be satisfactory but other sample preparation methods may be equally valid.

In the case of inorganic tin, care shall be taken to ensure that all the material is taken into solution as losses are known to occur readily, particularly because of hydrolysis to insoluble hydrated Sn(IV) oxide species.;

(2) in point C.2.2.2 Specific procedures for polycyclic aromatic hydrocarbons, the following paragraph is added:

For the analysis of PAH in cocoa and cocoa derived products, the determination of the fat content is performed in accordance with AOAC Official method 963.15 for the determination of the fat content of cocoa beans and derived products. Equivalent fat determination procedures can be applied for which it can be demonstrated that the used fat determination procedure provides an equal (equivalent) fat content value.;

(3) in point C.3.1 Definitions, the definition of LOQ is replaced by the following definition:

“LOQ” = Limit of quantification, lowest content of the analyte which can be measured with reasonable statistical certainty. If both accuracy and precision are constant over a concentration range around the limit of detection, then the limit of quantification is numerically equal to 10 times the standard deviation of the mean of blank matrix determinations ($n \geq 20$).;

(4) in point C.3.3.1 Performance criteria, point (a) is replaced by the following:

(a) Performance criteria for methods of analysis for lead, cadmium, mercury, inorganic tin and inorganic arsenic

Table 5

Parameter	Criterion
Applicability	Foods specified in Regulation (EC) No 1881/2006

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Table 5

Specificity	Free from matrix or spectral interferences				
Repeatability (RSD _T)	HORRAT _T less than 2				
Reproducibility (RSD _R)	HORRAT _R less than 2				
Recovery	The provisions of point D.1.2 apply				
LOD	= three tenths of LOQ				
LOQ	Inorganic tin	≤ 10 mg/kg			
	Lead	ML ≤ 0,01 mg/kg	0,01 < ML ≤ 0,02 mg/kg	0,02 < ML < 0,1 mg/kg	ML ≥ 0,1 mg/kg
		≤ ML	≤ two thirds of the ML	≤ two fifths of the ML	≤ one fifth of the ML
	Cadmium, mercury, inorganic arsenic	ML is < 0,100 mg/kg		ML is ≥ 0,100 mg/kg	
≤ two fifths of the ML		≤ one fifth of the ML			

(5) point C.3.2 is replaced by the following:

C.3.2. General requirements

Methods of analysis used for food control purposes shall comply with the provisions of Annex III to Regulation (EC) No 882/2004.

Methods for analysis for total tin are appropriate for control on inorganic tin levels.

For the analysis of lead in wine, the methods and rules established by the OIV⁽⁶⁾ apply in accordance with Article 80(5) of Regulation (EU) No 1308/2013⁽⁷⁾.

Methods for analysis for total arsenic are appropriate for screening purpose for control on inorganic arsenic levels. If the total arsenic concentration is below the maximum level for inorganic arsenic, no further testing is required and the sample is considered to be compliant with the maximum level for inorganic arsenic. If the total arsenic concentration is at or above the maximum level for inorganic arsenic, follow-up testing shall be conducted to determine if the inorganic arsenic concentration is above the maximum level for inorganic arsenic..

Status: Point in time view as at 15/04/2016.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) 2016/582. (See end of Document for details)

- (1) [OJ L 165, 30.4.2004, p. 1.](#)
- (2) Commission Regulation (EC) No 333/2007 of 28 March 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 ([OJ L 88, 29.3.2007, p. 29.](#))
- (3) Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs ([OJ L 364, 20.12.2006, p. 5.](#))
- (4) Commission Regulation (EU) 2015/1006 of 25 June 2015 amending Regulation (EC) No 1881/2006 as regards maximum levels of inorganic arsenic in foodstuffs ([OJ L 161, 26.6.2015, p. 14.](#))
- (5) Standard EN 13804:2013, "Foodstuffs. Determination of elements and their chemical species. General considerations and specific requirements", CEN, Rue de Stassart 36, B-1050 Brussels.';
- (6) Organisation internationale de la vigne et du vin.
- (7) Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ([OJ L 347, 20.12.2013, p. 671.](#)).

Status:

Point in time view as at 15/04/2016.

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