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Delegations will find attached document D040232/03 ANNEX I.

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ANNEX 1

ANNEX

to the

COMMISSION REGULATION (EU) …/…

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

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'(*) 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.

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(*) 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.'

(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				
Specificity	Free from matrix or spectral interferences				
Repeatability (RSD_r)	$HORRAT_r$ 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(*) apply in accordance with Article 80 (5) of Regulation (EU) No 1308/2013(**).

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.

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(*) Organisation internationale de la vigne et du vin.

(**) 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).'