COMMISSION IMPLEMENTING REGULATION (EU) 2021/705

of 28 April 2021

amending Regulation (EC) No 333/2007 as regards the required number of incremental samples and the performance criteria for some methods of analysis

(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 trace elements and processing contaminants in foodstuffs.

(2) The sampling methods currently provided for in Regulation (EC) No 333/2007 provide that an aggregate sample of at least 1 kg is to be taken. For food supplements, dried spices or herbs, dried fungi, algae or lichen, which have high cost per unit weight, this results in a disproportionately high sample cost. Therefore, specific sampling methods should be provided for with regard to these commodities.

(3) On the basis of the best available scientific information, 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 ([3]). As this Guidance Document contains the best up to date technological knowledge, its conclusions should be reflected in the requirements for LOQs for analytical methods for trace elements set out in Regulation (EC) No 333/2007.

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

(5) 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

The Annex to Regulation (EC) No 333/2007 is amended in accordance with the Annex to this Regulation.

([1]) OJ L 95, 7.4.2017, p. 1.

([2]) 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 (OJ L 88, 29.3.2007, p. 29).

([3]) Wenzl, T., Haedrich, J., Schaechtele, A., Robouch, P., Stroka, J., *Guidance Document on the Estimation of LOD and LOQ for Measurements in the Field of Contaminants in Feed and Food*; EUR 28099, Publications Office of the European Union, Luxembourg, 2016, ISBN 978-92-79-61768-3; doi:10.2787/8931

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*.

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

Done at Brussels, 28 April 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

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

(1) point B.2.2. is replaced by the following:

'B.2.2. **Number of incremental samples**

For food, other than food supplements, dried spices or herbs, dried fungi, algae or lichen, the aggregate sample shall be at least 1 kilogram or 1 litre, except where it is not possible, e.g. when the sample consists of 1 package or unit.

For food supplements, dried spices or herbs, dried fungi, algae or lichen the aggregate sample shall be at least 100 grams or 100 millilitres.

For food, other than food supplements, the minimum number of incremental samples to be taken from the lot or sublot shall be in accordance with Table 3.

In the case of bulk liquid products, the lot or sublot shall be thoroughly mixed in so far as possible and in so far it does not affect the quality of the product, by either manual or mechanical means immediately prior to sampling. In this case, a homogeneous distribution of contaminants shall be assumed within a given lot or sublot. Therefore the number of incremental samples from a lot or sublot to form the aggregate sample shall be three.

Where the lot or sublot consists of individual packages or units, for food, other than food supplements, the number of packages or units (incremental samples) to be taken to form the aggregate sample shall be in accordance with Table 4a.

The incremental samples shall be of similar weight/volume. For food, other than food supplements, dried spices or herbs, dried fungi, algae or lichen, the weight/volume of an incremental sample shall be at least 100 grams or 100 millilitres, resulting in an aggregate sample of at least about 1 kilogram or 1 litre.

For dried spices or herbs, dried fungi, algae or lichen, the weight/volume of an incremental sample shall be at least 35 grams or 35 millilitres, resulting in an aggregate sample of at least 100 grams or 100 millilitres.

The maximum levels for inorganic tin apply to the contents of each can, but for practical reasons an aggregate sampling approach may be used. If the result of the test for an aggregate sample of cans is less than but close to the maximum level of inorganic tin and if it is suspected that individual cans might exceed the maximum level, then further investigations shall be conducted.

For food supplements the minimum number and size of the incremental samples shall be in accordance with Table 4b.

Where it is not possible to carry out the method of sampling set out in this point B.2. because of the unacceptable commercial consequences (e.g. because of packaging forms, damage to the lot) or where it is practically impossible to apply the method of sampling provided for in this point B.2., an alternative method of sampling may be applied provided that it is sufficiently representative for the sampled lot or sublot and is fully documented. This shall be recorded in the record provided for in point B.1.8.

Table 1

Subdivision of lots into sublots for products traded in bulk consignments

Lot weight (ton)	Weight or number of sublots
≥ 1 500	500 tonnes
> 300 and < 1 500	3 sublots
≥ 100 and ≤ 300	100 tonnes
< 100	—

Table 2

Subdivision of lots into sublots for products not traded in bulk consignments

Lot weight (ton)	Weight or number of sublots
≥ 15	15-30 tonnes
< 15	—

Table 3

Minimum number of incremental samples to be taken from the lot or sublot of food, other than food supplements

Weight or volume of lot/sublot (in kilogram or litre)	Minimum number of incremental samples to be taken
< 50	3
≥ 50 and ≤ 500	5
> 500	10

Table 4a

Number of packages or units (incremental samples) to be taken to form the aggregate sample where the lot or sublot consists of individual packages or units of food, other than food supplements

Number of packages or units in the lot/sublot	Number of packages or units to be taken
≤ 25	at least 1 package or unit
26-100	about 5 %, at least 2 packages or units
> 100	about 5 %, at maximum 10 packages or units

Table 4b

The minimum number and size of the incremental samples for food supplements

Lot size (number of packages)	Number of packages (incremental samples) to be taken for sample	Size of the incremental sample
1-50	1	Entire content of the package
51-250	2	Entire content of the package
251-1 000	4	From each retail package taken for sample, half of the content of the package

> 1 000	4 + 1 packages per 1 000 retail packages with a maximum of 25 retail packages	≤ 10 packages: from each retail package, half of the content of the package > 10 packages: from each package, an equal amount is taken to result in a sample with the equivalent of the content of 5 packages
Unknown (only applicable for e-commerce)	1	Entire content of the package'

(2) in point C.3.3.1., 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 ≤ 0,02 mg/kg	0,02 < ML < 0,1 mg/kg	ML ≥ 0,1 mg/kg
		≤ ML	≤ two thirds of the ML	≤ one fifth of the ML
	Cadmium, mercury, inorganic arsenic	ML ≤ 0,02 mg/kg	0,02 < ML < 0,1 mg/kg	ML is ≥ 0,1 mg/kg
		≤ two fifths of the ML	≤ two fifths of the ML	≤ one fifth of the ML'