

## 2024/1045

## COMMISSION IMPLEMENTING REGULATION (EU) 2024/1045

## of 9 April 2024

# amending Regulation (EC) No 333/2007 as regards the methods of sampling and analysis for the control of levels of nickel in foodstuffs and amending certain references

(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 89/662/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) (<sup>1</sup>), and in particular Article 34(6) thereof,

Whereas:

- (1) Commission Regulation (EC) No 333/2007 (<sup>2</sup>) 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) In order to ensure the reliability and consistency of official controls on the maximum levels for nickel in certain foods, specific requirements should be set in Regulation (EC) No 333/2007 for the methods used for sampling and for laboratory analyses as regards that contaminant and for the determination of the dry matter content of foods.
- (3) Commission Regulation (EU) 2023/915 (<sup>3</sup>) set out maximum levels for nickel in certain foods and repealed Commission Regulation (EC) No 1881/2006 (<sup>4</sup>). Article 9 of Regulation (EU) 2023/915 provides that the references to the repealed Regulation (EC) No 1881/2006 are to be construed as references to Regulation (EU) 2023/915 and to be read in accordance with the correlation table in Annex II to that Regulation. However, the correlation table in Annex II does not provide details on the correlation of specific entries in Annex I to Regulation (EU) 2023/915 and the Annex to Regulation (EC) No 1881/2006 and this makes difficult to construe the references that Regulation (EC) No 333/2007 makes to the Annex to Regulation (EC) No 1881/2006. Therefore, it is appropriate to replace the references contained in Regulation (EC) No 333/2007 to specific entries in the Annex to Regulation (EC) No 1881/2006 with references to the corresponding entries of Annex I to Regulation (EU) 2023/915. For the sake of consistency, all other references to Regulation (EC) No 1881/2006 in Regulation (EC) No 333/2007 should also be replaced by references to Regulation (EU) 2023/915.

<sup>(&</sup>lt;sup>1</sup>) OJ L 95, 7.4.2017, p. 1, ELI: http://data.europa.eu/eli/reg/2017/625/oj.

<sup>(2)</sup> 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, ELI: http://data.europa.eu/eli/reg/ 2007/333/oj).

<sup>(3)</sup> Commission Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006 (OJ L 119, 5.5.2023, p. 103, ELI: http://data.europa.eu/eli/reg/2023/915/oj).

<sup>(\*)</sup> 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, ELI: http://data.europa.eu/eli/reg/2006/1881/oj).

- (4) Regulation (EU) 2017/625 on official controls repealed and replaced, on 14 December 2019, Regulation (EC) No 882/2004 of the European Parliament and of the Council (<sup>5</sup>). Since the references to Regulation (EC) No 1881/2006 are being replaced, it is appropriate to also replace the reference to Regulation (EC) No 882/2004.
- (5) Regulation (EC) No 333/2007 should therefore be amended accordingly.
- (6) 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) Article 1 is replaced by the following:

'Article 1

1. Sampling and analysis for the control of the levels of lead, cadmium, mercury, inorganic tin, inorganic arsenic, nickel, 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, 5 and 6 of Annex I to Commission Regulation (EU) 2023/915 (\*) and for the control of the levels of acrylamide in accordance with Commission Regulation (EU) 2017/2158 (\*\*) shall be carried out in accordance with the Annex to this Regulation.

2. Paragraph 1 shall apply without prejudice to the provisions of Regulation (EU) 2017/625 of the European Parliament and of the Council (\*\*\*).

<sup>\*</sup> Commission Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006 (OJ L 119, 5.5.2023, p. 103).

<sup>\*\*</sup> Commission Regulation (EU) 2017/2158 of 20 November 2017 establishing mitigation measures and benchmark levels for the reduction of the presence of acrylamide in food (OJ L 304, 21.11.2017, p. 24).

<sup>\*\*\*</sup> 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) (OJ L 95, 7.4.2017, p. 1).';

<sup>(2)</sup> the Annex is amended in accordance with the Annex to this Regulation.

<sup>(&</sup>lt;sup>5</sup>) Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on officials controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p. 1, ELI: http://data.europa.eu/eli/reg/2004/882/oj).

## 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, 9 April 2024.

For the Commission The President Ursula VON DER LEYEN

## ANNEX

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

## (1) point C.2.1. is replaced by the following:

### 'C.2.1. Precautions and general considerations

The basic requirement is to obtain a representative and homogeneous laboratory sample without introducing secondary contamination.

The whole part to which the maximum level is applicable shall be used for homogenisation of the sample.

For products other than fish all of the sample material received by the laboratory shall be used for the preparation of the laboratory sample.

For fish, all of the sample material received by the laboratory shall be homogenised. From the homogenised aggregate sample, a representative part/quantity shall be used for the preparation of the laboratory sample.

In case the maximum level applies to the dry matter, the dry matter content of the product shall be determined on a part of the homogenised sample, using a method that has been demonstrated to determine accurately the dry matter content.

Compliance with maximum levels laid down in Regulation (EU) 2023/915 shall be established on the basis of the levels determined in the laboratory samples.';

- (2) point C.2.2.1. is replaced by the following:
  - 'C.2.2.1. Specific procedures for lead, cadmium, mercury, inorganic tin, inorganic and total arsenic and nickel

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 shall 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.

In the case of nickel, contamination problems may arise when stainless steel or iron equipment is used for sampling or analysis. Special equipment shall be used in such cases in materials such as titanium, ceramics or agate.

(\*) Standard EN 13804:2013, "Foodstuffs. Determination of elements and their chemical species. General considerations and specific requirements", CEN, Rue de Stassart/Stassartstraat 36, B-1050 Bruxelles/Brussel, BELGIQUE/BELGIË.';

- (3) 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, inorganic and total arsenic and nickel

Parameter	Criterion			
Applicability	Foods specified in Regulation (EU) 2023/915			
Specificity	Free from matrix or spectral interferences			
Repeatability (RSD <sub>r</sub> )	HORRAT <sub>r</sub> less than 2			
Reproducibility (RSD <sub>R</sub> )	HORRAT <sub>R</sub> less than 2			
Recovery	The provisions of point D.1.2 apply			
LOD	= three tenths of LOQ			
LOQ	Inorganic tin	$\leq 10 \text{ mg/kg}$		
	Lead	$ML \le 0.02 \text{ mg/kg}$	0,02 < ML < 0,1 mg/kg	$ML \ge 0.1 mg/kg$
		≤ ML	≤ two thirds of the ML	≤ one fifth of the ML
	Cadmium, mercury	$ML \le 0.02 \text{ mg/kg}$	0,02 < ML < 0,1 mg/kg	$ML \ge 0.1 mg/kg$
		≤ two fifths of the ML	≤ two fifths of the ML	≤ one fifth of the ML
	Inorganic arsenic and total arsenic	ML ≤ 0,03 mg/kg	0,03 < ML < 0,1 mg/kg	$ML \ge 0.1 \text{ mg/kg}$
		≤ ML	≤ two thirds of the ML	≤ two thirds of the ML
	Nickel	ML ≤ 0,3 mg/kg	0,3 < ML < 0,6 mg/ kg	$ML \ge 0.6 \text{ mg/kg}$
		≤ ML	≤ two thirds of the ML	$\leq$ one third of the ML'

### Table 5

- (4) in point C.3.3.1, point (b), first indent, the references to 'point 4.1 of the Annex to Regulation (EC) No 1881/2006' in the title of Table 6a and in Table 6a are replaced by 'point 5.2 of Annex I to Regulation (EU) 2023/915';
- (5) in point C.3.3.1, point (b), second indent, the references to 'point 4.3 of the Annex to Regulation (EC) No 1881/2006' in the title of Table 6b and in Table 6b is replaced by 'point 5.3 of Annex I to Regulation (EU) 2023/915';
- (6) in point C.3.3.1, point (b), third indent:
  - (a) the reference to 'point 4.3 of the Annex to Regulation (EC) No 1881/2006' in the title of Table 6c and in Table 6c is replaced by 'point 5.3 of Annex I to Regulation (EU) 2023/915';
  - (b) in the column 'Parameter' of Table 6c, the reference to entry '4.3.1' is replaced by '5.3.1', '4.3.2' by '5.3.2', '4.3.3' by '5.3.3.1' and '4.3.4' by '5.3.3.2';

- (7) in point C.3.3.1, point (b), fourth indent:
  - (a) the reference to 'point 4.2 of the Annex to Regulation (EC) No 1881/2006' in the title of Table 6d and in Table 6d is replaced by 'point 5.4 of Annex I to Regulation (EU) 2023/915';
  - (b) in the column 'Parameter' of Table 6d, the reference to entry '4.2.1' is replaced by '5.4.1', '4.2.2' by '5.4.2', '4.2.3' by '5.4.3.1' and '4.2.4' by '5.4.3.2';
- (8) in point C.3.3.1, point (c), in Table 7 the reference to 'Regulation (EC) No 1881/2006' is replaced by 'Regulation (EU) 2023/915';
- (9) in point D.1.1. the reference to 'Regulation (EC) No 1881/2006' is replaced by 'Regulation (EU) 2023/915';
- (10) in point D.2.1. the reference to 'Regulation (EC) No 1881/2006' is replaced by 'Regulation (EU) 2023/915';
- (11) in point D.2.2. the reference to 'Regulation (EC) No 1881/2006' is replaced by 'Regulation (EU) 2023/915'.