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Contents

II Non-legislative acts

#### REGULATIONS

*	Commission Regulation (EU) 2018/1480 of 4 October 2018 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures and correcting Commission Regulation (EU) 2017/776 (1)	1
*	Commission Regulation (EU) 2018/1481 of 4 October 2018 amending Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards octyl gallate (E 311) and dodecyl gallate (E 312) (1)	13
*	Commission Regulation (EU) 2018/1482 of 4 October 2018 amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards caffeine and theobromine (1)	19
*	Commission Implementing Regulation (EU) 2018/1483 of 4 October 2018 amending Council Regulation (EC) No 1210/2003 concerning certain specific restrictions on economic and financial relations with Iraq	22
	Commission Implementing Regulation (EU) 2018/1484 of 4 October 2018 on the minimum selling price for skimmed milk powder for the 25th partial invitation to tender within the tendering procedure opened by Implementing Regulation (EU) 2016/2080	24
DEC	CISIONS	
*	Council Decision (EU) 2018/1485 of 28 September 2018 establishing the position to be adopted on behalf of the European Union as regards the amendments to the Annexes to the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) and to the Regulations annexed to the European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN)	25





Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

*	Council Decision (EU) 2018/1486 of 28 September 2018 on the position to be taken on behalf of the European Union within the Customs Sub-Committee established by the Association Agreement between the European Union and its Member States, of the one part, and Ukraine, of the other part, as regards the replacement of Protocol I to that Agreement, concerning the definition of the concept of 'originating products' and methods of administrative cooperation, by a new protocol which refers to the Regional Convention on pan-Euro-Mediterranean preferential rules of origin	28
*	Council Implementing Decision (EU) 2018/1487 of 2 October 2018 amending Implementing Decision 2009/1013/EU authorising the Republic of Austria to continue to apply a measure derogating from Articles 168 and 168a of Directive 2006/112/EC on the common system of value added tax	33

II

(Non-legislative acts)

#### REGULATIONS

#### **COMMISSION REGULATION (EU) 2018/1480**

#### of 4 October 2018

amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures and correcting Commission Regulation (EU) 2017/776

(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 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (1), and in particular Article 37(5) and Article 53(1) thereof.

#### Whereas:

- (1) Table 3.1 of Part 3 of Annex VI to Regulation (EC) No 1272/2008 contains the list of harmonised classification and labelling of hazardous substances based on the criteria set out in Parts 2 to 5 of Annex I to that Regulation.
- Proposals to introduce harmonised classification and labelling of certain substances and to update or delete the (2) harmonised classification and labelling of certain other substances have been submitted to the European Chemicals Agency pursuant to Article 37 of Regulation (EC) No 1272/2008. Based on the opinions on those proposals issued by the Committee for Risk Assessment of the Agency (RAC), as well as on the comments received from the parties concerned, it is appropriate to introduce, update or delete harmonised classification and labelling of certain substances.
- Council Directive 67/548/EEC (2) and Directive 1999/45/EC of the European Parliament and of the Council (3) (3) were repealed with effect from 1 June 2015. As a result, Part 3 of Annex VI to Regulation (EC) No 1272/2008 was amended by Commission Regulation (EU) 2016/1179 (4) to remove Table 3.2. That amendment took effect on 1 June 2017. Annex VI to Regulation (EC) No 1272/2008 was further amended by Commission Regulation (EU) 2017/776 (\*) to delete references to Table 3.2, to convert references to Table 3.1 into references to Table 3 and to delete references to the repealed Directives. Under Article 2(2) of Regulation (EU) 2017/776, the majority of those amendments were to apply from 1 June 2017, while the remaining amendments were stated to apply from 1 December 2018. However, due to an oversight, Article 2(2) failed to list two further amendments that

(¹) OJ L 353, 31.12.2008, p. 1. (²) Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the

classification, packaging and labelling of dangerous substances (OJ 196, 16.8.1967, p. 1).

Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous

preparations (OJ L 200, 30.7.1999, p. 1).

(\*) Commission Regulation (EU) 2016/1179 of 19 July 2016 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 195, 20.7.2016, p. 11).

Commission Regulation (EU) 2017/776 of 4 May 2017 amending, for the purposes of its adaptation to technical and scientific progress,

Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 116, 5.5.2017, p. 1).

EN

should have applied from 1 June 2017, including in particular the amendment changing the name of the Table from 'Table 3.1' to 'Table 3'. The second subparagraph of Article 2(2) of Regulation (EU) 2017/776 should therefore be corrected to include reference to those two amendments. This correction, although it has the effect of applying the two amendments retroactively, does not affect the rights and obligations of manufacturers, importers, downstream users or suppliers.

- (4) Regulation (EU) 2017/776 also amended Annex VI to Regulation (EC) No 1272/2008 to add harmonised 'Acute Toxicity Estimate' (ATE) values in Table 3.1 as part of the information relating to the classification and labelling of certain substances for the purposes of the classification of mixtures. The ATE introduced for nicotine was expressed in mg/kg. In order to clarify how mixtures containing nicotine should be classified, the ATE for the oral and the dermal routes for nicotine should instead be expressed in 'mg/kg bw' (¹). The ATEs for three other substances, namely colecalciferol, 1,2-dihydroxybenzene and pinoxaden should also be expressed in the same way. In addition, in the title of the penultimate column of Table 3.1, a footnote should be added indicating what the abbreviation 'mg/kg bw' stands for.
- (5) The Annex to Commission Regulation (EU) 2018/669 (²) provides for the translation of the names of the substances included in Table 3.1 of Annex VI to Regulation (EC) No 1272/2008. As a consequence, the title of the second column of that Table, which currently refers to 'international chemical identifications', should be amended to take account of the fact that the 'international chemical identifications' will lose their international character once the Regulation providing for their translation in Annex VI becomes applicable. For the sake of consistency, this amendment should take effect when the translation of the names in Annex VI takes effect. The new title should reflect the terminology used in Article 18 of Regulation (EC) No 1272/2008.
- (6) Compliance with the new or updated harmonised classifications should not be required immediately as a certain period of time will be necessary to allow suppliers to adapt the labelling and packaging of substances and mixtures to the new or revised classifications and to sell existing stocks. That period of time will also be necessary to allow suppliers to adapt to and comply with other legislative obligations resulting from the new or updated harmonised classifications, such as those set out in Article 22(f) or Article 23 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (³), those set out in Article 50 of Regulation (EU) No 528/2012 of the European Parliament and of the Council (⁴) or those set out in Article 44 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council (⁵).
- (7) Regulation (EC) No 1272/2008 should therefore be amended accordingly.
- (8) In line with the transitional provisions of Regulation (EC) No 1272/2008 which allow for new provisions to be applied at an earlier stage on a voluntary basis, suppliers should be allowed to apply the new and updated harmonised classifications, and to adapt the labelling and packaging accordingly, on a voluntary basis before the date of application of those new or updated classifications.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

#### Article 1

#### Amendment to Regulation (EC) No 1272/2008

Annex VI to Regulation (EC) No 1272/2008 is amended as set out in the Annex to this Regulation.

(1) Body weight

(2) Commission Regulation (EU) 2018/669 of 16 April 2018 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 115, 4.5.2018, p. 1).
 (3) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration,

(3) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

(\*) Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

(5) Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

#### Article 2

#### Correction to Regulation (EU) 2017/776

In Regulation (EU) 2017/776, the second subparagraph of Article 2(2) is replaced by the following:

'In the Annex, point (1), point (2) and points (a), (b) and (c) of point (3) shall apply from 1 June 2017.'

#### Article 3

#### Entry into force and application

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

Point (1) and point (a) of point (2) of the Annex shall apply from 1 December 2019.

Points (b), (c), (d) and (e) of point (2) of the Annex shall apply from 1 May 2020.

By way of derogation from the third paragraph of this Article, substances and mixtures may, before 1 May 2020, be classified, labelled and packaged in accordance with Regulation (EC) No 1272/2008 as amended by this Regulation.

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

Done at Brussels, 4 October 2018.

For the Commission
The President
Jean-Claude JUNCKER

Annex VI to Regulation (EC) No 1272/2008 is amended as follows:

(1) in Part 1, the heading of point 1.1.1.4 is replaced by the following:

'Chemical name';

- (2) in Part 3, Table 3.1 is amended as follows:
  - (a) the title of the second column is replaced by the following: 'Chemical name';
  - (b) the title of the penultimate column is replaced by the following: 'Specific Conc. Limits, M-factors and ATEs (\*)
    - (\*) ATEs for oral and dermal exposure routes are expressed in mg/kg bw, which stands for milligram per kilogram bodyweight.';
  - (c) the entry corresponding to index number 607-414-00-6 is deleted;
  - (d) the entries corresponding to index numbers 006-044-00-7, 015-101-00-5, 016-096-00-2, 017-011-00-1, 025-002-00-9, 603-180-00-4, 604-014-00-3, 604-016-00-4, 604-090-00-8, 605-003-00-6, 606-047-009, 607-096-00-9, 607-103-00-5, 607-113-00-X, 607-373-00-4, 613-167-00-5, 613-205-00-0 and 614-001-00-4 are replaced by the following entries respectively:

**ANNEX** 

				Classificat	ion		Labelling			
Index No	Chemical name	EC No	CAS No	Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)	Specific Conc. Limits, M-factors and ATEs	Notes
<sup>(</sup> 006-044-00-7	isoproturon (ISO); 3-(4-isopropylphenyl)-1,1-di- methylurea	251-835-4	34123-59-6	Carc. 2 STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H351 H373 (blood) H400 H410	GHS08 GHS09 Wng	H351 H373 (blood) H410		M = 10 M = 10'	
·015-101-00-5	phosmet (ISO);  S-[(1,3-dioxo-1,3-dihydro-2H-isoindol-2-yl)methyl] O,O-dimethyl phosphorodithioate;  O,O-dimethyl-S-phthalimidomethyl phosphorodithioate	211-987-4	732-11-6	Repr. 2 Acute Tox. 4 Acute Tox. 3 STOT SE 1 Aquatic Acute 1 Aquatic Chronic 1	H361f H332 H301 H370 (nervous system) H400 H410	GHS08 GHS06 GHS09 Dgr	H361f H332 H301 H370 (nervous system) H410		M = 100 M = 100'	

				Classifica	tion		Labelling				5.10
Index No	Chemical name	EC No	CAS No	Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)	Specific Conc. Limits, M-factors and ATEs	Notes	5.10.2018
'016-096-00-2	thifensulfuron-methyl (ISO); methyl 3-(4-methoxy-6- methyl-1,3,5-triazin-2-ylcarba- moylsulfamoyl)thiophene-2- carboxylate	_	79277-27-3	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M = 100 M = 100'		EN
'017-011-00-1	sodium hypochlorite, solution % Cl active	231-668-3	7681-52-9	Skin Corr. 1B Eye Dam. 1 Aquatic Acute 1 Aquatic Chronic 1	H314 H318 H400 H410	GHS05 GHS09 Dgr	H314 H410	EUH031	M = 10 M = 1 EUH031: C ≥ 5 %	В'	Official Jour
'025-002-00-9	potassium permanganate	231-760-3	7722-64-7	Ox. Sol. 2 Repr. 2 Acute Tox. 4 * Aquatic Acute 1 Aquatic Chronic 1	H272 H361d H302 H400 H410	GHS03 GHS08 GHS07 GHS09 Dgr	H272 H361d H302 H410'				Official Journal of the European Union
'603-180-00-4	colecalciferol; cholecalciferol; vitamin D <sub>3</sub>	200-673-2	67-97-0	Acute Tox. 2 Acute Tox. 2 Acute Tox. 2 STOT RE 1	H330 H310 H300 H372	GHS06 GHS08 Dgr	H330 H310 H300 H372		inhalation: ATE = 0,05 mg/L (dusts or mists) dermal: ATE = 50 mg/kg bw oral: ATE = 35 mg/kg bw STOT RE 1; H372: $C \ge 3\%$ STOT RE 2; H373: 0,3 % $\le C < 3\%$		L 251/5

				Classificat	ion		Labelling			_
Index No	Chemical name	EC No	CAS No	Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)	Specific Conc. Limits, M-factors and ATEs	Notes
604-014-00-3	chlorocresol; 4-chloro-m-cresol; 4-chloro-3-methylphenol	200-431-6	59-50-7	Acute Tox. 4 Skin Corr. 1C Eye Dam. 1 STOT SE 3 Skin Sens. 1B Aquatic Acute 1 Aquatic Chronic 3	H302 H314 H318 H335 H317 H400 H412	GHS07 GHS05 GHS09 Dgr	H302 H314 H335 H317 H410		M = 1'	
'604-016-00-4	1,2-dihydroxybenzene; pyrocatechol	204-427-5	120-80-9	Carc. 1B Muta. 2 Acute Tox. 3 Acute Tox. 3 Skin Irrit. 2 Eye Irrit. 2	H350 H341 H311 H301 H315 H319	GHS08 GHS06 Dgr	H350 H341 H311 H301 H315 H319		oral: ATE = 300 mg/kg bw dermal: ATE = 600 mg/kg bw'	
·604-090-00-8	4-tert-butylphenol	202-679-0	98-54-4	Repr. 2 Skin Irrit. 2 Eye Dam. 1 Aquatic Chronic 1	H361f H315 H318 H410	GHS08 GHS05 GHS09 Dgr	H361f H315 H318 H410		M = 1'	
·605-003-00-6	acetaldehyde; ethanal	200-836-8	75-07-0	Flam. Liq. 1 Carc. 1B Muta. 2 STOT SE 3 Eye Irrit. 2	H224 H350 H341 H335 H319	GHS02 GHS08 GHS07 Dgr	H224 H350 H341 H335 H319'			
·606-047-00-9	2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone	404-360-3	119313-12-1	Repr. 1B Aquatic Acute 1 Aquatic Chronic 1	H360D H400 H410	GHS08 GHS09 Dgr	H360D H410'			

L 251/6

EN

Official Journal of the European Union

5.10.2018

				Classifica	tion		Labelling			
Index No	Chemical name	EC No	CAS No	Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)	Specific Conc. Limits, M-factors and ATEs	Notes
607-096-00-9	maleic anhydride	203-571-6	108-31-6	Acute Tox. 4 STOT RE 1 Skin Corr. 1B Eye Dam. 1 Resp. Sens. 1 Skin Sens. 1A	H302 H372 (respiratory system) (inhalation) H314 H318 H334 H317	GHS07 GHS08 GHS05 Dgr	H302 H372 (respiratory system) (inhalation) H314 H334 H317	EUH071	Skin Sens. 1A; H317: C ≥ 0,001 %'	
607-103-00-5	succinic anhydride	203-570-0	108-30-5	Acute Tox. 4 Skin Corr. 1 Eye Dam. 1 Resp. Sens. 1 Skin Sens. 1	H302 H314 H318 H334 H317	GHS07 GHS05 GHS08 Dgr	H302 H314 H334 H317	EUH071'		
'607-113-00-X	isobutyl methacrylate	202-613-0	97-86-9	Flam. Liq. 3 STOT SE 3 Skin Irrit. 2 Skin Sens. 1B	H226 H335 H315 H317	GHS02 GHS07 Wng	H226 H335 H315 H317			D'
·607-373-00-4	quizalofop-P-tefuryl (ISO); (+/-) tetrahydrofurfuryl (R)-2-[4-(6-chloroquinoxalin-2-yloxy)phenyloxy]propionate	414-200-4	200509-41-7	Carc. 2 Repr. 2 Acute Tox. 4 STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H351 H361fd H302 H373 H400 H410	GHS08 GHS07 GHS09 Wng	H351 H361fd H302 H373 H410		M = 1 M = 1'	

				Classifica	tion		Labelling			
Index No	Chemical name	EC No	CAS No	Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)	Specific Conc. Limits, M-factors and ATEs	Notes
613-167-00-5	reaction mass of 5-chloro-2-methyl-2 <i>H</i> -isothiazol-3-one and 2-methyl-2 <i>H</i> -isothiazol-3-one (3:1)		55965-84-9	Acute Tox. 2 Acute Tox. 2 Acute Tox. 3 Skin Corr. 1C Eye Dam. 1 Skin Sens. 1A Aquatic Acute 1 Aquatic Chronic 1	H330 H310 H301 H314 H318 H317 H400 H410	GHS06 GHS05 GHS09 Dgr	H330 H310 H301 H314 H317 H410	EUH071	Skin Corr. 1C; H314: C ≥ 0,6 % Skin Irrit. 2; H315: 0,06 % ≤ C < 0,6 % Eye Dam. 1; H318: C ≥ 0,6 % Eye Irrit. 2; H319: 0,06 % ≤ C < 0,6 % Skin Sens. 1A; H317: C ≥ 0,0015 % M = 100 M = 100	B,
613-205-00-0	propiconazole (ISO); (2RS,4RS;2RS,4SR)-1-{[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl}-1H-1,2,4-triazole	262-104-4	60207-90-1	Repr. 1B Acute Tox. 4 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H360D H302 H317 H400 H410	GHS08 GHS07 GHS09 Dgr	H360D H302 H317 H410		M = 1 M = 1'	
614-001-00-4	nicotine (ISO); 3-[(2S)-1-methylpyrrolidin-2-yl]pyridine	200-193-3	54-11-5	Acute Tox. 2 Acute Tox. 2 Acute Tox. 2 Aquatic Chronic 2	H330 H310 H300 H411	GHS06 GHS09 Dgr	H330 H310 H300 H411		inhalation:  ATE = 0,19 mg/L (dusts or mists) dermal:  ATE = 70 mg/kg bw oral:  ATE = 5 mg/kg bw'	

	Chemical name			Classifica	tion		Labelling			
Index No		EC No	CAS No	Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		Notes
604-094-00-X	isoeugenol; [1] (E)-2-methoxy-4-(prop-1-enyl) phenol; [2] (Z)-2-methoxy-4-(prop-1-enyl) phenol [3]	202-590-7 [1] 227-678-2 [2] 227-633-7 [3]	97-54-1 [1] 5932-68-3 [2] 5912-86-7 [3]	Skin Sens. 1A	H317	GHS07 Wng	H317		Skin Sens. 1A; H317: C ≥ 0,01 %'	
607-724-00-1	2,3,5,6-tetrafluoro-4-(methoxy-methyl)benzyl (1R,3R)-2,2-di-methyl-3-[(1Z)-prop-1-en-1-yl] cyclopropanecarboxylate; epsilon-metofluthrin	_	240494-71-7	Acute Tox. 4 Acute Tox. 3 STOT SE 1 STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H332 H301 H370 (nervous system) H373 H400 H410	GHS06 GHS08 GHS09 Dgr	H332 H301 H370 (nervous system) H373 H410		M = 100 M = 100'	
607-725-00-7	isopropyl (2E,4E,7S)-11-meth- oxy-3,7,11-trimethyldodeca- 2,4-dienoate; S-methoprene	_	65733-16-6	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M = 1 M = 1'	
607-726-00-2	pinoxaden (ISO); 8-(2,6-diethyl-4-methylphenyl)-7-oxo-1,2,4,5-tetrahydro-7H-pyrazolo[1,2-d][1,4,5]oxadia-zepin-9-yl 2,2-dimethylpropanoate		243973-20-8	Repr. 2 Acute Tox. 4 Acute Tox. 4 Eye Irrit. 2 STOT SE 3 Skin Sens. 1A Aquatic Acute 1 Aquatic Chronic 3	H361d H332 H302 H319 H335 H317 H400	GHS08 GHS07 GHS09 Wng	H361d H332 H302 H319 H335 H317		inhalation:  ATE = 4,63 mg/L (dusts or mists)  oral:  ATE = 500 mg/kg bw  M = 1'	

				Classifica	tion		Labelling			
Index No	Chemical name	EC No	CAS No	Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)	Specific Conc. Limits, M-factors and ATEs	Notes
607-727-00-8	tetramethrin (ISO); (1,3-dioxo-1,3,4,5,6,7-hexahy-dro-2 <i>H</i> -isoindol-2-yl)methyl 2,2-dimethyl-3-(2-methylprop-1-en-1-yl)cyclopropanecarboxylate	231-711-6	7696-12-0	Carc. 2 Acute Tox. 4 STOT SE 2 Aquatic Acute 1 Aquatic Chronic 1	H351 H302 H371 (nervous system) (inhalation) H400 H410	GHS08 GHS07 GHS09 Wng	H351 H302 H371 (nervous system) (inhalation) H410		M = 100 M = 100'	
'607-728-00-3	(1,3,4,5,6,7-hexahydro-1,3-di- oxo-2 <i>H</i> -isoindol-2-yl)methyl (1 <i>R-trans</i> )-2,2-dimethyl-3-(2- methylprop-1-enyl)cyclopropa- necarboxylate	214-619-0	1166-46-7	Carc. 2 Acute Tox. 4 STOT SE 2 Aquatic Acute 1 Aquatic Chronic 1	H351 H302 H371 (nervous system) (inhalation) H400 H410	GHS08 GHS07 GHS09 Wng	H351 H302 H371 (nervous system) (inhalation) H410		M = 100 M = 100'	
·607-729-00-9	mesosulfuron-methyl (ISO); methyl 2-[(4,6-dimethoxypyri- midin-2-ylcarbamoyl)sulfa- moyl]-α-(methanesulfona- mido)-p-toluate;	_	208465-21-8	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M = 100 M = 100'	
607-730-00-4	spirodiclofen (ISO); 3-(2,4-dichlorophenyl)-2-oxo- 1-oxaspiro[4.5]dec-3-en-4-yl 2,2-dimethylbutyrate	_	148477-71-8	Carc. 1B Repr. 2 STOT RE 2 Skin Sens. 1B Aquatic Chronic 1	H350 H361f H373 H317 H410	GHS08 GHS07 GHS09 Dgr	H350 H361f H373 H317 H410		M = 10'	

				Classifica	tion		Labelling				
Index No	Chemical name	EC No	CAS No	Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)	Specific Conc. Limits, M-factors and ATEs	Notes	
'607-731-00-X	sodium methyl [(4-aminophenyl)sulphonyl]carbamate; sodium methyl ( <i>EZ</i> )-sulfanilylcarbonimidate; asulam-sodium	218-953-8	2302-17-2	Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H317 H400 H410	GHS07 GHS09 Wng	H317 H410		M = 1 M = 1'		
'607-732-00-5	salicylic acid	200-712-3	69-72-7	Repr. 2 Acute Tox. 4 Eye Dam. 1	H361d H302 H318	GHS08 GHS07 GHS05 Dgr	H361d H302 H318'				
'608-068-00-9	flutianil (ISO); (2Z)-{[2-fluoro-5-(trifluoro-methyl)phenyl]thio}[3-(2-methoxyphenyl)-1,3-thiazolidin-2-ylidene]acetonitrile	_	958647-10-4	Aquatic Chronic 1	H410	GHS09 Wng	H410		M = 100'		
·612-293-00-8	reaction mass of 1-[2-(2-ami- nobutoxy)ethoxy]but-2-yla- mine and 1-({[2-(2-aminobu- toxy)ethoxy]methyl}propoxy) but-2-ylamine	447-920-2	-	Repr. 2 Acute Tox. 4 Skin Corr. 1B Eye Dam. 1	H361f H302 H314 H318	GHS08 GHS07 GHS05 Dgr	H361f H302 H314	EUH071'			
·613-326-00-9	2-methylisothiazol-3(2H)-one	220-239-6	2682-20-4	Acute Tox. 2 Acute Tox. 3 Acute Tox. 3 Skin Corr. 1B Eye Dam. 1 Skin Sens. 1A Aquatic Acute 1 Aquatic Chronic 1	H330 H311 H301 H314 H318 H317 H400 H410	GHS05 GHS06 GHS09 Dgr	H330 H311 H301 H314 H317 H410	EUH071	Skin Sens. 1A; H317: C ≥ 0,0015 % M = 10 M = 1'		

				Classificati	.on		Labelling			
Index No	Chemical name	EC No	CAS No	Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)	Specific Conc. Limits, M-factors and ATEs	Notes
613-327-00-4	pyroxsulam (ISO);	_	422556-08-9	Skin Sens. 1	H317	GHS07	H317		M = 100	
	N-(5,7-dimethoxy[1,2,4]tria-			Aquatic Acute 1	H400	GHS09	H410		M = 100'	
	zolo[1,5-a]pyrimidin-2-yl)-2- methoxy-4-(trifluoromethyl) pyridine-3-sulfonamide			Aquatic Chronic 1	H410	Wng				
'613-328-00-X	1-vinylimidazole	214-012-0	1072-63-5	Repr. 1B	H360D	GHS08 Dgr	H360D		Repr. 1B; H360D: C ≥ 0,03 %'	
·616-224-00-2	amisulbrom (ISO);		348635-87-0	Carc. 2	H351	GHS08	H351		M = 10	
	3-(3-bromo-6-fluoro-2-methy-			Eye Irrit. 2	H319	GHS07	H319		M = 10'	
	lindol-1-ylsulfonyl)-N,N-di- methyl-1H-1,2,4-triazole-1-sul- fonamide			Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410			

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#### **COMMISSION REGULATION (EU) 2018/1481**

#### of 4 October 2018

amending Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards octyl gallate (E 311) and dodecyl gallate (E 312)

(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 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (1), and in particular Article 10(3) and Article 14 thereof,

#### Whereas:

- (1) Annex II to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in foods and their conditions of use.
- (2) Annex III to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in food additives, food enzymes, food flavourings, nutrients and their conditions of use.
- (3) Commission Regulation (EU) No 231/2012 (²) lays down specifications for food additives that are listed in Annexes II and III to Regulation (EC) No 1333/2008.
- (4) Octyl gallate (E 311) and dodecyl gallate (E 312) are substances authorised as antioxidants in a variety of foods, as well as in food flavourings, in accordance with Annexes II and III to Regulation (EC) No 1333/2008.
- (5) Article 32(1) of Regulation (EC) No 1333/2008 provides that all food additives that were already permitted in the Union before 20 January 2009 are subject to a new risk assessment by the European Food Safety Authority ('the Authority').
- (6) For that purpose, a program for the re-evaluation of food additives is laid down in Commission Regulation (EU) No 257/2010 (3). Pursuant to Regulation (EU) No 257/2010 the re-evaluation of antioxidants had to be completed by 31 December 2015.
- (7) On 5 May 2015 the Authority delivered a Scientific Opinion on the re-evaluation of dodecyl gallate (E 312) as a food additive (4). The opinion stated that there was a lack of adequate toxicological data on dodecyl gallate. Consequently the Authority was not able to confirm the safety of dodecyl gallate as a food additive and concluded that the present group Acceptable Daily Intake (ADI) for propyl gallate (E 310), octyl gallate (E 311) and dodecyl gallate (E 312) should no longer be valid. The opinion stated that a sufficient toxicological database would be required for an adequate assessment of the safety of dodecyl gallate as a food additive.
- (8) On 1 October 2015 the Authority delivered a Scientific Opinion on the re-evaluation of octyl gallate (E 311) as a food additive (5). The opinion stated that there was a lack of adequate toxicological data on octyl gallate. Consequently the Authority was not able to confirm the safety of octyl gallate as a food additive and concluded that the present group ADI for propyl gallate (E 310), octyl gallate (E 311) and dodecyl gallate (E 312) should no longer be valid. The opinion stated that a sufficient toxicological database would be required for an adequate assessment of the safety of octyl gallate as a food additive.

<sup>(1)</sup> OJ L 354, 31.12.2008, p. 16.

<sup>(\*)</sup> Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).

<sup>(2)</sup> Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up the program for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives (OJ L 80, 26.3.2010, p. 19).

<sup>(4)</sup> EFSA Journal 2015;13(5):4086.

<sup>(5)</sup> EFSA Journal 2015;13(10):4248.

- (9) On 30 May 2017 the Commission launched a public call for scientific and technological data on propyl gallate (E 310), octyl gallate (E 311) and dodecyl gallate (E 312) (¹), targeting the data needs identified in the Scientific Opinions on the re-evaluation of those substances as food additives. However, no business operator committed to providing the requested toxicological data for octyl gallate (E 311) and dodecyl gallate (E 312). Without those data the Authority cannot complete the re-evaluation of the safety of octyl gallate and dodecyl gallate as food additives and consequently it cannot be determined whether those substances still fulfil the conditions pursuant to Article 6(1) of Regulation (EC) No 1333/2008 for inclusion in the Union list of approved food additives.
- (10) It is therefore appropriate to remove octyl gallate (E 311) and dodecyl gallate (E 312) from the Union list of approved food additives.
- (11) Pursuant to Article 10(3) of Regulation (EC) No 1333/2008, the Union list of approved food additives shall be amended in accordance with the procedure referred to in Regulation (EC) No 1331/2008 of the European Parliament and of the Council (2).
- (12) Article 3(1) of Regulation (EC) No 1331/2008 provides that the Union list of food additives may be updated either on the initiative of the Commission or following an application.
- (13) Therefore, Annexes II and III to Regulation (EC) No 1333/2008 and the Annex to Regulation (EU) No 231/2012 should be amended by deleting octyl gallate (E 311) and dodecyl gallate (E 312) from the Union list of authorised food additives since due to the absence of appropriate toxicological data their inclusion in the list can no longer be justified.
- (14) It is appropriate to provide for a transitional period during which foods containing octyl gallate (E 311) and/or dodecyl gallate (E 312) that have been lawfully placed on the market before the entry in force of this Regulation may continue to be marketed.
- (15) 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

Annexes II and III to Regulation (EC) No 1333/2008 are amended in accordance with the Annex to this Regulation.

#### Article 2

In the Annex to Regulation (EU) No 231/2012, the entries for food additives octyl gallate (E 311) and dodecyl gallate (E 312) are deleted.

#### Article 3

Foods containing octyl gallate (E 311) and/or dodecyl gallate (E 312) that have been lawfully placed on the market before the entry into force of this Regulation may continue to be marketed until 25 April 2019.

#### Article 4

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

(¹) http://ec.europa.eu/food/safety/food\_improvement\_agents/additives/re-evaluation\_en.

<sup>(\*)</sup> Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1).

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

Done at Brussels, 4 October 2018.

For the Commission The President Jean-Claude JUNCKER

#### **ANNEX**

- (1) Annex II to Regulation (EC) No 1333/2008 is amended as follows:
  - (a) in Part B, in Table 3: Additives other than colours and sweeteners, the entries for the food additives E 311 octyl gallate and E 312 dodecyl gallate are deleted;
  - (b) in Part C, in Table 5: Other additives that may be regulated combined, point (k) 'E 310-320: Gallates, TBHQ and BHA' is replaced by the following:
    - '(k) E 310-320: Propyl gallate, TBHQ and BHA

E-number	Name
E 310	Propyl gallate
E 319	Tertiary-butyl hydroquinone (TBHQ)
E 320	Butylated hydroxyanisole (BHA)'

- (c) Part E is amended as follows:
  - 1. In category 01.5 (Dehydrated milk as defined by Directive 2001/114/EC), the entry concerning food additives E 310-320 (Gallates, TBHQ and BHA) is replaced by the following:

	'Е 310-320	Propyl gallate, TBHQ and BHA	200	(1)	only milk powder for vending machines'
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2. In category 02.1 (Fats and oils essentially free from water (excluding anhydrous milkfat)), the entry concerning food additives E 310-320 (Gallates, TBHQ and BHA, individually or in combination) is replaced by the following:

'Е 310-320	Propyl gallate, TBHQ and BHA	200	(1) (41)	only fats and oils for the professional manufacture of heat-treated foods; frying oil and frying fat (excluding olive pomace oil) and lard, fish oil, beef, poultry and sheep fat'
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3. In category 02.2.2 (Other fat and oil emulsions including spreads as defined by Council Regulation (EC) No 1234/2007 and liquid emulsions), the entry concerning food additives E 310-320 (Gallates, TBHQ and BHA, individually or in combination) is replaced by the following:

'E 310-32	Propyl gall	ate, TBHQ and BHA	200	(1) (2)	only frying fat'
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4. In category 04.2.5.4 (Nut butters and nut spreads), the entry concerning food additives E 310-320 (Gallates, TBHQ and BHA) is replaced by the following:

	Έ 310-320	Propyl gallate, TBHQ and BHA	200	(1) (41)	only processed nuts'
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5. In category 04.2.6 (Processed potato products), the entry concerning food additives E 310-320 (Gallates, TBHQ and BHA) is replaced by the following:

	'Е 310-320	Propyl gallate, TBHQ and BHA	25	(1)	only dehydrated potatoes'
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6. In category 05.3 (Chewing gum), the entry concerning food additives E 310-321 (Gallates, TBHQ, BHA and BHT) is replaced by the following:

BHT
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	 <u>,                                     </u>		r		
7.	category 06.3 (Br A) is replaced by t		ing foo	od additives	s E 310-320 (Gallates, TBHQ and
	'Е 310-320	Propyl gallate, TBHQ and BHA	200	(1) (13)	only precooked cereals'
8.		e-cooked or processed cereals), the eplaced by the following:	entry c	oncerning f	Good additives E 310-320 (Gallates,
	'Е 310-320	Propyl gallate, TBHQ and BHA	200	(1)	only pre-cooked cereals'
9.	category 07.2 (Fir A) is replaced by t		ning fo	od additive	es E 310-320 (Gallates, TBHQ and
	'Е 310-320	Propyl gallate, TBHQ and BHA	200	(1)	only cake mixes'
10.		(Non-heat–treated meat products) BHA) is replaced by the following:	, the o	entry conce	erning food additives E 310-320
	'E 310-320	Propyl gallate, TBHQ and BHA	200	(1) (13)	only dehydrated meat'
11.		Heat–treated meat products), the entire deplaced by the following:	ntry co	ncerning fo	ood additives E 310-320 (Gallates,
	'Е 310-320	Propyl gallate, TBHQ and BHA	200	(1) (13)	only dehydrated meat'
12.		Seasonings and condiments), the entry is replaced by the following:	ntry co	ncerning fo	ood additives E 310-321 (Gallates,
	'Е 310-321	Propyl gallate, TBHQ, BHA and BHT	200	(1) (13)'	
13.	category 12.5 (So A) is replaced by t		ning fo	od additive	s E 310-320 (Gallates, TBHQ and
	'E 310-320	Propyl gallate, TBHQ and BHA	200	(1) (13)	only dehydrated soups and broths'
14.	category 12.6 (Sa laced by the follow		additiv	res E 310-3	320 (Gallates, TBHQ and BHA) is
	 'E 310-320	Propyl gallate, TBHQ and BHA	200	(1) (13)'	
15.		ato-, cereal-, flour- or starch-based and BHA) is replaced by the follow		s), the entry	concerning food additives E 310-
	'Е 310-320	Propyl gallate, TBHQ and BHA	200	(1)	only cereal-based snack foods'
16.	category 15.2 (Pro eplaced by the fol		food a	dditives E 3	10-320 (Gallates, TBHQ and BHA)
	'E 310-320	Propyl gallate, TBHQ and BHA	200	(1) (13)'	
		•			

17. In category 17.1 (Food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable forms), the entry concerning food additives E 310-321 (Gallates, TBHQ, BHA and BHT) is replaced by the following:

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18. In category 17.2 (Food supplements supplied in a liquid form), the entry concerning food additives E 310-321 (Gallates, TBHQ, BHA and BHT) is replaced by the following:

	'Е 310-321	Propyl gallate, TBHQ, BHA and BHT	400	(1)'	
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19. In category 17.3 (Food supplements supplied in a syrup-type or chewable form), the entry concerning food additives E 310-321 (Gallates, TBHQ, BHA and BHT) is replaced by the following:

'E 310-321 Propyl gallate, TBHQ, BHA and BHT 40	400	(1)	
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- (2) Annex III to Regulation (EC) No 1333/2008 is amended as follows:
  - (a) in Part 4 (Food additives including carriers in food flavourings), the entries concerning food additives E 310, E 311, E 312, E 319 and E 320 are replaced by the following:

E 310	Propyl gallate Tertiary-butyl hydroquinone (TBHQ)	Essential oils	1 000 mg/kg (propyl gallate, TBHQ and BHA, individually or in combination) in the essential oils
E 320	Butylated hydroxyanisole (BHA)	Flavourings other than essential oils	100 mg/kg (¹) (propyl gallate) 200 mg/kg (¹) (TBHQ and BHA, individually or in combination) in flavourings'

- (b) in Part 4 (Food additives including carriers in food flavourings), the footnote (1) is replaced by the following:
  - '(1) Proportionality rule: when combinations of propyl gallate, TBHQ, and BHA are used, the individual levels must be reduced proportionally.'

#### **COMMISSION REGULATION (EU) 2018/1482**

#### of 4 October 2018

#### amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards caffeine and theobromine

(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 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (1), and in particular Article 11(3) thereof,

Having regard to Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (2), and in particular Article 7(5) thereof,

#### Whereas:

- Annex I to Regulation (EC) No 1334/2008 lays down a Union list of flavourings and source materials approved (1) for use in and on foods and their conditions of use.
- Commission Implementing Regulation (EU) No 872/2012 (3) adopted the list of flavouring substances and (2) introduced that list in Part A of Annex I to Regulation (EC) No 1334/2008.
- That list may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) (3)No 1331/2008, either on the initiative of the Commission or following an application submitted by the Member State or by an interested party.
- (4)Part A of the Union list contains both evaluated flavouring substances, for which no footnotes are assigned, and flavouring substances under evaluation, which are identified by footnote references 1 to 4.
- The substances caffeine (FL No 16.016) and theobromine (FL No 16.032) were listed with footnote 1 according (5) to which the evaluation for those substances had to be completed by the European Food Safety Authority ('the Authority').
- On 31 January 2017, the Authority completed the evaluation of the safety of caffeine (FL No 16.016) and (6)theobromine (FL No 16.032) when used as flavouring substances (4) and concluded that their use as flavoring substances does not give rise to safety concerns based on their estimated levels of intake in certain food categories. The conditions of use already laid down in the Union list may therefore be maintained.
- Therefore, caffeine (FL No 16.016) and theobromine (FL No 16.032) should be listed as evaluated substances in (7) the Union list of flavouring substances without the footnote reference contained in their current entries of the Union list.
- (8) Part A of Annex I to Regulation (EC) No 1334/2008 should therefore be amended accordingly.
- The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

<sup>(</sup>¹) OJ L 354, 31.12.2008, p. 34. (²) OJ L 354, 31.12.2008, p. 1.

Commission Implementing Regulation (EU) No 872/2012 of 1 October 2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council, introducing it in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council and repealing Commission Regulation (EC) No 1565/2000 and Commission Decision 1999/217/ÊC (OJ L 267, 2.10.2012, p. 1).

<sup>(4)</sup> EFSA Journal 2017;15(4):4729.

#### HAS ADOPTED THIS REGULATION:

#### Article 1

Part A of Annex I to Regulation (EC) No 1334/2008 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.

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

Done at Brussels, 4 October 2018.

For the Commission
The President
Jean-Claude JUNCKER

#### ANNEX

Annex I to Regulation (EC) No 1334/2008 is amended as follows:

1. In Section 2 of Part A, the entry concerning FL No 16.016 is replaced by the following:

Caffeine	58-08-2	11741	Restrictions for use as a flavouring substance:	EFSA'
			In category 1 — not more than 70 mg/kg	
			In category 3 — not more than 70 mg/kg	
			In category 5 — not more than 100 mg/kg	
			In category 14.1 — not more than 150 mg/kg	

'16.032	Theo-	83-67-0			Restrictions for use as a flavouring substance:	EFSA'
	bromine			In category 1 — not more than 70 mg/kg		
					In category 14.1 — not more than 100 mg/kg	

#### COMMISSION IMPLEMENTING REGULATION (EU) 2018/1483

#### of 4 October 2018

### amending Council Regulation (EC) No 1210/2003 concerning certain specific restrictions on economic and financial relations with Iraq

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1210/2003 of 7 July 2003 concerning certain specific restrictions on economic and financial relations with Iraq and repealing Regulation (EC) No 2465/96 (¹), and in particular Article 11(b) thereof,

#### Whereas:

- (1) Annex III to Regulation (EC) No 1210/2003 lists public bodies, corporations and agencies and natural and legal persons, bodies and entities of the previous government of Iraq covered by the freezing of funds and economic resources that were located outside Iraq on the date of 22 May 2003 under that Regulation.
- (2) On 1 October 2018, the Sanctions Committee of the United Nations Security Council decided to remove one entry from the list of persons or entities to whom the freezing of funds and economic resources should apply.
- (3) Annex III to Regulation (EC) No 1210/2003 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

#### Article 1

Annex III to Regulation (EC) No 1210/2003 is amended as set out in the Annex to this Regulation.

#### Article 2

This Regulation shall enter into force on the 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, 4 October 2018.

For the Commission,
On behalf of the President,
Head of the Service for Foreign Policy Instruments

<sup>(1)</sup> OJ L 169, 8.7.2003, p. 6.

#### ANNEX

In Annex III to Council Regulation (EC) No 1210/2003, the following entry is deleted:

'177. STATE ORGANISATION FOR CONSTRUCTION INDUSTRIES. Address: P.O. Box 2101, Masbeh Square, Baghdad, Iraq.'

#### COMMISSION IMPLEMENTING REGULATION (EU) 2018/1484

#### of 4 October 2018

on the minimum selling price for skimmed milk powder for the 25th partial invitation to tender within the tendering procedure opened by Implementing Regulation (EU) 2016/2080

THE EUROPEAN COMMISSION,

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

Having regard to 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 (1),

Having regard to Commission Implementing Regulation (EU) 2016/1240 of 18 May 2016 laying down rules for the application of Regulation (EU) No 1308/2013 of the European Parliament and of the Council with regard to public intervention and aid for private storage (2), and in particular Article 32 thereof,

#### Whereas:

- Commission Implementing Regulation (EU) 2016/2080 (3) has opened the sale of skimmed milk powder by a tendering procedure.
- (2) In the light of the tenders received for the 25th partial invitation to tender, a minimum selling price should be
- The measures provided for in this Regulation are in accordance with the opinion of the Committee for the (3)Common Organisation of the Agricultural Markets,

HAS ADOPTED THIS REGULATION:

#### Article 1

For the 25th partial invitation to tender for the selling of skimmed milk powder within the tendering procedure opened by Implementing Regulation (EU) 2016/2080, in respect of which the period during which tenders were to be submitted ended on 2 October 2018, the minimum selling price shall be 123 EUR/100 kg.

#### Article 2

This Regulation shall enter into force on the day 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, 4 October 2018.

For the Commission, On behalf of the President, Jerzy PLEWA Director-General Directorate-General for Agriculture and Rural Development

 <sup>(</sup>¹) OJ L 347, 20.12.2013, p. 671.
 (²) OJ L 206, 30.7.2016, p. 71.
 (³) Commission Implementing Regulation (EU) 2016/2080 of 25 November 2016 opening the sale of skimmed milk powder by a tendering procedure (OJ L 321, 29.11.2016, p. 45).

#### **DECISIONS**

#### COUNCIL DECISION (EU) 2018/1485

#### of 28 September 2018

establishing the position to be adopted on behalf of the European Union as regards the amendments to the Annexes to the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) and to the Regulations annexed to the European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 91, in conjunction with the Article 218(9) thereof,

Having regard to the proposal from the European Commission,

#### Whereas:

- (1) The European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) entered into force on 29 January 1968. The European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN) entered into force on 29 February 2008.
- (2) The Union is not a Contracting Party to the ADR or to the ADN. All Member States are Contracting Parties to the ADR, and 13 Member States are Contracting Parties to the ADN.
- (3) Pursuant to Article 14 of the ADR, any Contracting Party can propose one or more amendments to the Annexes to the ADR. The Working Party on Transport of Dangerous Goods (WP.15) can adopt draft amendments to those Annexes. Pursuant to Article 20 of the ADN, the ADN Administrative Committee can adopt draft amendments to the Regulations annexed to the ADN. Such proposed amendments are to be deemed to have been accepted unless, within three months from the date on which the Secretary-General of the United Nations circulates them, at least one-third of the Contracting Parties, or five of them if one-third exceeds this figure, have given the Secretary-General written notification of their objection to the proposed amendments.
- (4) The proposed amendments adopted during the 2016–2018 biennium by WP.15 and the ADN Administrative Committee were circulated to the ADR and ADN Contracting Parties on 1 July 2018.
- (5) The proposed amendments are capable of decisively influencing the content of Union law, namely Directive 2008/68/EC of the European Parliament and of the Council (¹). That Directive lays down requirements for the transport of dangerous goods by road, rail or inland waterways within or between Member States by referring to the ADR, to the Regulation concerning the International Carriage of Dangerous Goods by Rail (RID) in Appendix C to the Convention concerning International Carriage by Rail (COTIF) and to the ADN. Article 4 of Directive 2008/68/EC provides that the transport of dangerous goods between Member States and third countries is to be authorised in so far as it complies with the requirements of the ADR, RID or ADN, unless otherwise indicated in the Annexes to that Directive. Under Article 8 of Directive 2008/68/EC, the Commission is empowered to adapt the Annexes to that Directive according to scientific and technical progress, in particular to take account of amendments to the ADR, the RID and the ADN.
- (6) The proposed amendments concern technical standards or uniform technical prescriptions, with the objective of ensuring the safe and efficient transport of dangerous goods whilst taking into account scientific and technical progress in the sector and the developments of new substances and articles that pose a danger during their transport. The development of the transport of dangerous goods by road and inland waterways, both within the Union and between the Union and its neighbouring countries, is a key component of the common transport policy and ensures the proper functioning of all industrial branches that produce or make use of goods classified as dangerous under the ADR and the ADN.

<sup>(1)</sup> Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods (OJ L 260, 30.9.2008, p. 13).

(7) All the proposed amendments are justified and beneficial, and should therefore be supported by the Union. The position to be adopted on behalf of the Union as regards the proposed amendments to the Annexes to the ADR and to the Regulations annexed to the ADN should therefore be based on the attachment to this Decision,

HAS ADOPTED THIS DECISION:

#### Article 1

The position to be adopted on behalf of the Union as regards the proposed amendments to the Annexes to the ADR and to the Regulations annexed to the ADN shall be based on the attachment to this Decision.

Minor changes to the proposed amendments to the Annexes to the ADR and to the Regulations annexed to the ADN may be agreed without a further decision of the Council, in accordance with Article 2.

#### Article 2

The position to be adopted on behalf of the Union as regards the proposed amendments to the Annexes to the ADR, as set out in Article 1, shall be expressed by those Member States which are Contracting Parties to the ADR, acting jointly in the interest of the Union.

The position to be adopted on behalf of the Union as regards the proposed amendments to the Regulations annexed to the ADN, as set out in Article 1, shall be expressed by those Member States which are Contracting Parties to the ADN, acting jointly in the interest of the Union.

#### Article 3

A reference to the accepted amendments to the Annexes to the ADR and to the Regulations annexed to the ADN, including the date(s) of their entry into force, shall be published in the Official Journal of the European Union.

Article 4

This Decision shall enter into force on the date of its adoption.

Done at Brussels, 28 September 2018.

For the Council The President M. SCHRAMBÖCK

#### ATTACHMENT

Proposal	Reference Document	Notification	Issue	Comments	EU Position
1	ECE/TRANS/ WP.15/240	C.N.304.2018. TREATIES-XI.B.14	Draft amendments to annexes A and B of ADR	Technical consensus at the Working Party on the Transport of Dangerous Goods – WP.15.	Agree with the amendments.
2	ECE/TRANS/ WP.15/240/Add.1	C.N.304.2018. TREATIES-XI.B.14	Draft amendments to annexes A and B of ADR - Addendum (Reissued 8 June 2018)	Technical consensus at the Working Party on the Transport of Dangerous Goods – WP.15.	Agree with the amendments.
3	ECE/TRANS/ WP.15/240/Corr.1	C.N.304.2018. TREATIES-XI.B.14	Draft amendments to annexes A and B of ADR - Corrigendum (Reissued 8 June 2018)	Technical consensus at the Working Party on the Transport of Dangerous Goods – WP.15.	Agree with the amendments.
4	ECE/ADN/45	C.N.297.2018. TREATIES-XI.D.6	Draft amendments to the Regulations annexed to ADN	Technical consensus at the ADN Administrative Committee.	Agree with the amendments.

#### COUNCIL DECISION (EU) 2018/1486

#### of 28 September 2018

on the position to be taken on behalf of the European Union within the Customs Sub-Committee established by the Association Agreement between the European Union and its Member States, of the one part, and Ukraine, of the other part, as regards the replacement of Protocol I to that Agreement, concerning the definition of the concept of 'originating products' and methods of administrative cooperation, by a new protocol which refers to the Regional Convention on pan-Euro-Mediterranean preferential rules of origin

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 207, in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

#### Whereas:

- (1) The Association Agreement between the European Union and its Member States, of the one part, and Ukraine, of the other part (¹) ('the Agreement') was signed by the Union in accordance with Council Decision 2014/668/EU (²) and entered into force on 1 September 2017.
- (2) Pursuant to paragraph 1 of Article 39 of Protocol I to the Agreement ('Protocol I'), the Customs Sub-Committee established under Article 83 of Chapter 5 of Title IV of the Agreement ('the Customs Sub-Committee') may adopt amendments to the provisions of that Protocol.
- (3) Pursuant to paragraph 2 of Article 39 of Protocol I, the Customs Sub-Committee may also decide, following the accession of Ukraine to the Regional Convention on pan-Euro-Mediterranean preferential rules of origin (3) (the Convention), to replace the rules of origin set out in that Protocol by those appended to the Convention.
- (4) The Convention lays down provisions on the origin of goods traded under relevant agreements concluded between the Contracting Parties and entered into force in relation to the Union on 1 May 2012 and in relation to Ukraine on 1 February 2018.
- (5) The Customs Sub-Committee is to adopt a Decision on the replacement of Protocol I, concerning the definition of the concept of 'originating products' and methods of administrative cooperation, by a new protocol which refers to the Convention.
- (6) It is appropriate to establish the position to be taken on the Union's behalf in the Customs Sub-Committee as the Decision of the Customs Sub-Committee will be binding on the Union.
- (7) Article 6 of the Convention provides that each Contracting Party is to take appropriate measures to ensure that the Convention is effectively applied. To that effect, Protocol I should be replaced by a new protocol which, with regard to the rules of origin, refers to the Convention.
- (8) The position to be taken on the Union's behalf within the Customs Sub-Committee should therefore be based on the draft Decision attached to this Decision.
- (9) As the Decision of the Customs Sub-Committee is to amend Protocol I, it should be published in the Official Journal of the European Union.
- (10) Within the Customs Sub-Committee, the Union is to be represented by the Commission in accordance with paragraph 1 of Article 17 of the Treaty on European Union,

<sup>(1)</sup> OJ L 161, 29.5.2014, p. 3.

<sup>(\*)</sup> Council Decision 2014/668/EU of 23 June 2014 on the signing, on behalf of the European Union, and provisional application of the Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and Ukraine, of the other part, as regards Title III (with the exception of the provisions relating to the treatment of third-country nationals legally employed as workers in the territory of the other Party) and Titles IV, V, VI and VII thereof, as well as the related Annexes and Protocols (OJ L 278, 20.9.2014, p. 1).

<sup>(3)</sup> OJ L 54, 26.2.2013, p. 4.

EN

#### HAS ADOPTED THIS DECISION:

#### Article 1

The position to be taken on the Union's behalf within the Customs Sub-Committee established under Article 83 of the Association Agreement between the European Union and its Member States, of the one part, and Ukraine, of the other part ('the Customs Sub-Committee') shall be based on the draft Decision attached to this Decision.

#### Article 2

Minor technical corrections to the draft Decision referred to in Article 1 may be agreed to by the representatives of the Union in the Customs Sub-Committee without a further decision of the Council.

Article 3

This Decision is addressed to the Commission.

Done at Brussels, 28 September 2018.

For the Council The President M. SCHRAMBÖCK

#### DRAFT

#### DECISION No $\dots$ /2018 OF THE EU-UKRAINE CUSTOMS SUB-COMMITTEE

#### of ...

replacing Protocol I to the EU-Ukraine Association Agreement, concerning the definition of the concept of 'originating products' and methods of administrative cooperation

THE EU-UKRAINE CUSTOMS SUB-COMMITTEE,

Having regard to the Association Agreement between the European Union and its Member States, of the one part, and Ukraine, of the other part (1), and in particular Article 26(2) thereof,

Having regard to Protocol I to the Association Agreement between the European Union and its Member States, of the one part, and Ukraine, of the other part, concerning the definition of the concept of 'originating products' and methods of administrative cooperation,

#### Whereas:

- Article 26(2) of the Association Agreement between the European Union and its Member States, of the one part, (1) and Ukraine, of the other part ('the Agreement') refers to Protocol I to the Agreement ('Protocol I') for the rules of origin.
- (2) The Agreement entered into force on 1 September 2017.
- Article 39 of Protocol I provides that the Customs Sub-Committee established under Article 83 of Chapter 5 of (3) Title IV of the Agreement may decide to amend the provisions of that Protocol and replace the rules of origin set out in that Protocol.
- The Regional Convention on pan-Euro-Mediterranean preferential rules of origin (2) (the Convention) aims to replace the protocols on rules of origin currently in force in the countries of the pan-Euro-Mediterranean area with a single legal act.
- The European Union signed the Convention on 15 June 2011. On 16 May 2017, the Joint Committee (5) established under Article 3(1) of the Convention decided that Ukraine should be invited to accede to the Convention (3).
- The European Union deposited its instrument of acceptance with the depositary of the Convention on 26 March (6)2012. Ukraine deposited its instrument of acceptance with the depositary of the Convention on 19 December 2017. As a consequence, in application of Article 10(2) and (3) thereof, the Convention entered into force in relation to the Union on 1 May 2012 and in relation to Ukraine on 1 February 2018.
- (7) Protocol I should therefore be replaced by a new protocol which refers to the Convention,

HAS ADOPTED THIS DECISION:

#### Article 1

Protocol I to the Association Agreement between the European Union and its Member States, of the one part, and Ukraine, of the other part, concerning the definition of the concept of 'originating products' and methods of administrative cooperation shall be replaced by the text set out in the Annex to this Decision.

#### Article 2

This Decision shall be published in the Official Journal of the European Union.

<sup>(1)</sup> OJ L 161, 29.5.2014, p. 3.

<sup>(</sup>²) OJ L 54, 26.2.2013, p. 4. (²) Decision No 1/2017 of the Joint Committee of the Regional Convention on pan-Euro-Mediterranean preferential rules of origin of 16 May 2017 as regards the request of Ukraine to become a Contracting Party to the Regional Convention on pan-Euro-Mediterranean preferential rules of origin [2017/1367] (OJ L 191, 22.7.2017, p. 11).

#### Article 3

This Decision	shall ente	er into fo	orce on	the date	of its adoption	•
It shall apply f	from					

Done at ...,

For the EU-Ukraine Customs Sub-Committee
The Chairman

#### **ANNEX**

#### Protocol I

concerning the definition of the concept of 'originating products' and methods of administrative cooperation

#### Article 1

#### Applicable rules of origin

- 1. For the purpose of implementing this Agreement, Appendix I and the relevant provisions of Appendix II to the Regional Convention on pan-Euro-Mediterranean preferential rules of origin (1) (the Convention') shall apply.
- 2. All references to the 'relevant Agreement' in Appendix I and in the relevant provisions of Appendix II to the Convention shall be construed as referring to this Agreement.

#### Article 2

#### Dispute settlement

- 1. Where disputes arise in relation to the verification procedures of Article 32 of Appendix I to the Convention that cannot be settled between the customs authorities requesting the verification and the customs authorities responsible for carrying out that verification, they shall be submitted to the Customs Sub-Committee. The provisions on the dispute settlement mechanism in Chapter 14 (Dispute Settlement) of Title IV (Trade and Trade-related Matters) of this Agreement shall not apply.
- 2. In all cases the settlement of disputes between the importer and the customs authorities of the importing country shall take place under the legislation of that country.

#### Article 3

#### Amendments to the Protocol

The Customs Sub-Committee may decide to amend the provisions of this Protocol.

#### Article 4

#### Withdrawal from the Convention

- 1. Should either the European Union or Ukraine give notice in writing to the depositary of the Convention of their intention to withdraw from the Convention in accordance with Article 9 thereof, the European Union and Ukraine shall immediately enter into negotiations on rules of origin for the purpose of implementing this Agreement.
- 2. Until the entry into force of such newly negotiated rules of origin, the rules of origin contained in Appendix I and, where appropriate, the relevant provisions of Appendix II to the Convention, applicable at the moment of withdrawal, shall continue to apply to this Agreement. However, as of the moment of withdrawal, the rules of origin contained in Appendix I and, where appropriate, the relevant provisions of Appendix II to the Convention shall be construed as allowing bilateral cumulation between the European Union and Ukraine only.

#### Article 5

#### Transitional provisions - cumulation

Notwithstanding Articles 16(5) and 21(3) of Appendix I to the Convention, where cumulation involves only EFTA States, the Faroe Islands, the European Union, Turkey, the participants in the Stabilisation and Association Process, the Republic of Moldova, Georgia and Ukraine, the proof of origin may be a movement certificate EUR.1 or an origin declaration.

#### **COUNCIL IMPLEMENTING DECISION (EU) 2018/1487**

#### of 2 October 2018

amending Implementing Decision 2009/1013/EU authorising the Republic of Austria to continue to apply a measure derogating from Articles 168 and 168a of Directive 2006/112/EC on the common system of value added tax

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to Council Directive 2006/112/EC of 28 November 2006 on the common system of value added tax (1), and in particular the first subparagraph of Article 395(1) thereof,

Having regard to the proposal from the European Commission,

#### Whereas:

- (1) By virtue of Council Implementing Decision 2009/1013/EU (²), the Republic of Austria (Austria) was authorised to apply a special measure derogating from Directive 2006/112/EC ('special measure'). The application of the special measure was subsequently extended by Council Implementing Decision 2012/705/EU (³) until 31 December 2015 and by Council Implementing Decision (EU) 2015/2428 (⁴) until 31 December 2018.
- (2) The special measure derogates from Articles 168 and 168a of Directive 2006/112/EC which govern taxable persons' right to deduct value added tax (VAT) charged on goods and services supplied to them for the purposes of their taxed transactions. The special measure is intended to exclude VAT borne on goods and services from the right of deduction where those goods and services are used by taxable persons for more than 90 % for their private purposes or for the purposes of their employees, or in general for non-business purposes or non-economic activities.
- (3) The objective of the special measure is to simplify the procedure for charging and collecting VAT.
- (4) By letter registered with the Commission on 23 March 2018, Austria requested authorisation to continue to apply the special measure, in accordance with Article 395(2) of Directive 2006/112/EC.
- (5) By letter registered with the Commission on 4 April 2018, Austria sent a report on the application of the special measure including a review of the apportionment rate applied on the right to deduct VAT as required by Article 2 of Implementing Decision 2009/1013/EU.
- (6) The Commission transmitted the request made by Austria to the other Member States by letter dated 11 April 2018, in accordance with the second subparagraph of Article 395(2) of Directive 2006/112/EC. By letter dated 12 April 2018, the Commission notified Austria that it had all the information necessary to consider the request.
- (7) According to the information provided by Austria, the legal and factual situation which justified the current application of the special measure has not changed, but continues to exist. Austria should therefore be authorised to continue to apply the special measure for a further period of time, but that period should be limited in time until 31 December 2021 in order to allow for a review of the necessity and effectiveness of the special measure and of the apportionment rate between the business and non-business use that it is based upon.
- (8) Where Austria considers that a further extension of the authorisation beyond 2021 is necessary, a report on the application of the measure, which includes a review of the apportionment rate applied, should be submitted to the Commission together with the extension request by no later than 31 March 2021 in order to allow sufficient time for the Commission to examine the request.

<sup>(</sup>¹) OJ L 347, 11.12.2006, p. 1.

<sup>(2)</sup> Council Implementing Decision 2009/1013/EU of 22 December 2009 authorising the Republic of Austria to continue to apply a measure derogating from Article 168 of Directive 2006/112/EC on the common system of value added tax (OJ L 348, 29.12.2009, p. 21)

<sup>(3)</sup> Council Implementing Decision 2012/705/EU of 13 November 2012 amending Decision 2009/791/EC and Implementing Decision 2009/1013/EU authorising Germany and Austria respectively to continue to apply a measure derogating from Articles 168 and 168a of Directive 2006/112/EC on the common system of value added tax (OJ L 319, 16.11.2012, p. 8).

<sup>(\*)</sup> Council Implementing Decision (EU) 2015/2428 of 10 December 2015 amending Decision 2009/791/EC and Implementing Decision 2009/1013/EU authorising Germany and Austria respectively to continue to apply a measure derogating from Articles 168 and 168a of Directive 2006/112/EC on the common system of value added tax (OJ L 334, 22.12.2015, p. 12).

- (9) The special measure will only have a negligible effect on the overall amount of tax revenue collected at the stage of final consumption and will not have adverse effects on the Union's own resources accruing from VAT.
- (10) Implementing Decision 2009/1013/EU should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

#### Article 1

Articles 1 and 2 of Implementing Decision 2009/1013/EU are replaced by the following:

'Article 1

By way of derogation from Article 168 and Article 168a of Directive 2006/112/EC, Austria is authorised to completely exclude value added tax (VAT) borne on goods and services from the right to deduct VAT when the goods and services in question are used for more than 90 % for the private purposes of a taxable person or of his employees, or, more generally, for non-business purposes or non-economic activities.

Article 2

This Decision shall expire on 31 December 2021.

Any request for the extension of the derogating measure provided for in this Decision shall be submitted to the Commission by 31 March 2021 at the latest.

Such a request shall be accompanied by a report on the application of this measure which includes a review of the apportionment rate applied on the right to deduct VAT on the basis of this Decision.'.

Article 2

This Decision shall take effect on the date of its notification.

This Decision shall apply from 1 January 2019.

Article 3

This Decision is addressed to the Republic of Austria.

Done at Luxembourg, 2 October 2018

For the Council The President H. LÖGER



