

Commission Regulation (EU) No 1282/2011 of 28 November 2011 amending and correcting Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance)

COMMISSION REGULATION (EU) No 1282/2011

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amending and correcting Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food

(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 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC⁽¹⁾, and in particular points (a) and (e) of Article 5(1), Article 11(3) and Article 12(6) thereof,

Whereas:

- (1) Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food⁽²⁾ establishes a Union list of monomers, other starting substances and additives which may be used in the manufacture of plastic materials and articles. Recently the European Food Safety Authority (the Authority) issued a favourable scientific evaluation for additional substances which should now be added to the current list.
- (2) For certain other substances, the restrictions and/or specifications already established at the EU level should be amended on the basis of a new favourable scientific evaluation by the Authority.
- (3) The restrictions and specifications for the use of the substance with FCM substance number 239 with the name 2,4,6-triamino-1,3,5-triazine (Melamine) should be amended following the scientific opinion published on 13 April 2010 by the Authority. That opinion laid down a tolerable daily intake (TDI) of 0,2 mg/kg body weight (b.w.) for this substance. In its opinion the Authority also concluded that exposure in children due to migration from food contact materials would be in the range of the TDI. Taking into account the TDI and the exposure from all other sources the migration limit for the substance 239 should be reduced. The proposed migration limit of 2,5 mg/kg food is in line with the maximum level of melamine contamination allowed in food laid down in the Commission Regulation (EC) No 1135/2009 of 25 November 2009 imposing special conditions governing the import of products originating in or consigned from China, and repealing Commission Decision 2008/798/EC⁽³⁾.
- (4) Annex I to Regulation (EU) No 10/2011 should therefore be amended accordingly.

- (5) The substance with FCM substance number 438 and the name bis(2,6-diisopropylphenyl) carbodiimide is authorised to be used as an additive in plastics according to Table 1 of Annex I to Regulation (EU) No 10/2011. The Authority reassessed the safety of the authorised substance. The Opinion delivered by the Authority⁽⁴⁾ clarified that the substance is to be used as a monomer instead of an additive in plastics. For this reason it is appropriate to correct the use and to update the reference number accordingly in the Annex I.
- (6) The substance with FCM substance number 376 and the name N-methylpyrrolidone is authorised to be used as an additive in plastics in Table 1 of Annex I to Regulation (EU) No 10/2011 without a specific migration limit. The Opinion delivered by the Authority⁽⁵⁾ established a TDI of 1 mg/kg b.w. resulting in an SML of 60 mg/kg food. This limit coincides with the generic specific migration limit established in Article 11(2) of Regulation (EU) No 10/2011, however if the SML of 60 mg/kg is derived from a toxicological threshold such as the TDI the SML should be specifically mentioned in the Annex I.
- (7) The substance with FCM substance number 797 and the name polyester of adipic acid with 1,3-butanediol, 1,2-propanediol and 2-ethyl-1-hexanol is authorised to be used as an additive in plastics in Table 1 of Annex I to Regulation (EU) No 10/2011 and listed with the CAS No 0007328-26-5. According to the Opinion delivered by the Authority⁽⁶⁾ this CAS No should read 0073018-26-5. Therefore the CAS No for this substance needs to be corrected in the Annex I.
- (8) In order to limit the administrative burden to business operators, plastic materials and articles which have been lawfully placed on the market based on the requirements set out in Regulation (EU) No 10/2011 and which do not comply with this Regulation should be able to be placed on the market until 1 January 2013. They should be able to remain on the market until exhaustion of stocks.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health, and neither the European Parliament nor the Council has opposed them,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EU) No 10/2011 is amended in accordance with the Annex to this Regulation.

Article 2

Plastic materials and articles which have been lawfully placed on the market before 1 January 2012 and which do not comply with this Regulation may continue to be placed on the market until 1 January 2013. Those plastic materials and articles may remain on the market until the exhaustion of stocks.

Article 3

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

This Regulation shall be binding in its entirety and directly applicable in the Member States in accordance with the Treaties.

Done at Brussels, 28 November 2011.

For the Commission

The President

José Manuel BARROSO

ANNEX

Annex I to Regulation (EU) No 10/2011 is amended as follows:

- (1) in Table 1 the following lines are inserted in numerical order of the FCM substance numbers:

FCM substance No	Ref. No	CAS No	Substance name	Use as additive or polymer production aid (yes/no)	Use as monomer or other starting substance or macromolecule obtained from microbial fermentation (yes/no)	FRF applicable (yes/no)	SML (mg/kg) (yes/no)	SML (Group restriction No)	Restrictions and specifications	Notes on compliance
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
855	40560		(butadiene, styrene, methyl methacrylate) copolymer cross-linked with 1,3-butanediol dimethacrylate	yes	no	no			Only to be used in rigid poly(vinyl chloride) (PVC) at a maximum level of 12 % at room temperature or below.	
856	40563		(butadiene, styrene, methyl methacrylate, butyl acrylate) copolymer cross-linked with divinylbenzene	yes	no	no			Only to be used in rigid poly(vinyl chloride) (PVC) at a maximum level	

			or 1,3- butanediol dimethacrylate					of 12 % at room temperature or below.
857	66765	003795	vinyl methacrylate, butyl acrylate, styrene, glycidyl methacrylate) copolymer	no	no			Only to be used in rigid poly(vinyl chloride) (PVC) at a maximum level of 2 % at room temperature or below.
863	15260	000064	1,6- decanediamine	no	yes	no	0,05	Only to be used as a co- monomer for manufacturing polyamide articles for repeated use in contact with aqueous, acidic and dairy foodstuffs at room temperature or for short term contact

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									up to 150 °C.
873	93460		titanium dioxide reacted with octyltriethoxysilane	yes	no	no			Reaction product of titanium dioxide with up to 2 % w/w surface treatment substance octyltriethoxysilane, processed at high temperatures.
894	93360	001654	5-14-11 propionic acid, ditetradecyl ester	no	no		(14)		
895	47060	017109	0-93-0 (3,5- di- tert- butyl-4- hydroxyphenyl) propanoic acid, esters with C13- C15 branched and linear alcohols	yes	no	no	0,05		Only to be used in polyolefins in contact with foods other than fatty/ high- alcoholic and dairy products.
896	71958	095844	3-14-8 perfluoro-3- [(3- methoxy- propoxy)propanoic acid], ammonium salt	yes	no	no			Only to be used in the polymerisation of fluoropolymers when: — processed at temperatures

										higher than 280 °C for at least 10 minutes, processed at temperatures higher than 190 °C up to 30 % w/w for use in blends with polyoxymethylene polymers and intended for repeated use articles.
923	39150	000012040	N,N-bis(2-hydroxyethyl)dodecanamide	yes	no	no	5			(18) The residual amount of diethanolamine in plastics, as an impurity and decomposition product of the substance, should not result in a migration of

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								diethanolamine higher than 0,3 mg/ kg food.
924	94987		trimethylpropane, mixed triesters and diesters with n- octanoic and n- decanoic acids	no	no	0,05		Only for use in PET in contact with all types of foods other than fatty, high- alcoholic and dairy products.
926	71955	0908020-5710	perfluoro(2- ethoxy- ethoxy)acetic acid], ammonium salt	no	no			Only to be used in the polymerisation of fluoropolymers that are processed at temperatures higher than 300 °C for at least 10 minutes.
971	25885	0002459-116	trimellitic anhydride	yes	no			Only to be used as a co- monomer up to (17)

									0,35 % w/w to produce modified polyesters intended to be used in contact with aqueous and dry foodstuffs containing no free fat at the surface.
972	45197	0012158	746	sopper hydroxide phosphate	yes	no	no		
973	22931	0019430	0314	perfluorobutylacrylate	no	no	no		Only to be used as a co-monomer up to 0,1 % w/w in the polymerisation of fluoropolymers, sintered at high temperatures.
974	74050	939402	025	phosphoric acid, mixed 2,4-bis(1,1-dimethylpropyl)phenyl and 4-(1,1-	yes	no	yes	5	SML expressed as the sum of phosphite and phosphate form

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			dimethylpropyl)phenyl triesters							of the substance and the hydrolysis product 4-t- amylphenol. The migration of the hydrolysis product 2,4- di-t- amylphenol should not exceed 0,05 mg/ kg.
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- (2) in Table 1 for the following substance, the content of the columns (2), (5), (6) and (10) is replaced by the following:

FCM substance No	Ref. No	CAS No	Substance name	Use as additive or polymer production aid (yes/ no)	Use as monomer or starting substance or macro- molecule obtained from microbial fermentation (yes/ no)	FRF applicable (no)	SML [mg/kg] (yes/ no)	SML [mg/kg] (Group restriction No)	Restrictions and specific compliance	Notes on compliance
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
438	13303	00021623	bis(2,6- diisopropylphenyl) carbodiimide	no	yes	no	0,05		Expressed as the sum of bis(2,6- diisopropylphenyl)carbodiimide and its hydrolysis product	

										2,6-diisopropylaniline
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(3) in Table 1 for the following substance, the content of the column (3) is replaced by the following:

FCM substance No	Ref. No	CAS No	Substance name	Use as additive or polymer production aid (yes/no)	Use as monomer or starting substance or macro-molecule obtained from microbial fermentation (yes/no)	FRF applicable (yes/no)	SML (mg/kg) (yes/no)	SML (mg/kg) (Group restriction No)	Restrictions and specifications	Notes on compliance
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
797	76807	007301	polyesters of adipic acid with 1,3-butanediol, 1,2-propanediol and 2-ethyl-1-hexanol	yes	no	yes		(31) (32)		

(4) in Table 1 for the following substances, the content of the column (8) is replaced by the following:

FCM substance No	Ref. No	CAS No	Substance name	Use as additive or polymer production aid (yes/no)	Use as monomer or starting substance or macro-molecule obtained from microbial fermentation (yes/no)	FRF applicable (yes/no)	SML (mg/kg) (yes/no)	SML (mg/kg) (Group restriction No)	Restrictions and specifications	Notes on compliance
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(1)	(2)	(3)	(4)	(5)	fermentation (yes/ no)	(7)	(8)	(9)	(10)	(11)
239	19975	0000102-48-1	2,4,6-triamino-1,3,5-triazine	yes	yes	no	2,5			
	25420									
	93720									
376	66905	0000872-50-4	2-methylpyrrolidone	yes	no	no	60			

- (5) in Table 1 for the following substance, the content of the columns (8) and (10) is replaced by the following:

FCM substance No	Ref. No	CAS No	Substance name	Use as additive or polymer production aid (yes/ no)	Use as monomer or polymer starting aid (yes/ no)	FRF applicable (yes/ no)	SML [mg/kg] (yes/ no)	SML [mg/kg] (Group restriction No)	Restrictions and specific conditions	Notes on compliance
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
452	38885	0002722-42-6	bis(2,4-dimethylphenyl)-6-(2-hydroxy-4-n-octyloxyphenyl)-1,3,5-triazine	yes	no	no	5			

- (6) in Table 1 for the following substances, the content of the column (10) is replaced by the following:

FCM substance No	Ref. No	CAS No	Substance name	Use as additive or polymer production aid (yes/ no)	Use as monomer or polymer starting aid (yes/ no)	FRF applicable (yes/ no)	SML [mg/kg] (yes/ no)	SML [mg/kg] (Group restriction No)	Restrictions and specific conditions	Notes on compliance
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(1)	(2)	(3)	(4)	(5)	obtained from microbial fermentation (yes/no)		(8)	(9)	(10)	(11)
794	18117	000007914	glycolic acid	no	yes	no			Only to be used for manufacture of polyglycolic acid (PGA) for (i) indirect food contact behind polyesters such as polyethylene terephthalate (PET) or polylactic acid (PLA); and (ii) direct food contact of a blend of PGA up to 3 % w/w in PET or PLA.	
812	80350	0124578	poly(12-hydroxystearic acid)-polyethyleneimine copolymer	yes	no	no			Only to be used in plastics up to	

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0,1 %
w/w.
Prepared
by the
reaction
of
poly(12-
hydroxystearic
acid)
with
polyethyleneimine.

- (7) in Table 1 for the following substance, the content of the columns (10) and (11) is replaced by the following:

FCM substance No	Ref. No	CAS No	Substance name	Use as additive or polymer production aid (yes/ no)	Use as monomer or starting substance or macro- molecule obtained from microbial fermentation (yes/ no)	FRF applicable (yes/ no)	SML (mg/ kg) (Group restriction No)	SML (mg/ kg) (Group restriction No)	Restrictions and specific restrictions	Notes on compliance of
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
862	15180	001808	3,4-diacetoxy-1-butene	no	yes	no	0,05		SML (17) including the hydrolysis product 3,4-dihydroxy-1-butene. Only to be used as a co-monomer for ethylvinylalcohol (EVOH) and polyvinylalcohol (PVOH) copolymers.	(17) (19)

- (8) in Table 2 for the following group restriction, the content of the columns (2) and (4) is replaced by the following:

Group restriction No	FCM substance No	SML (T)[mg/kg]	Group restriction specification
(1)	(2)	(3)	(4)
14	294	5	Expressed as the sum of the substances and their oxidation products
	368		
	894		

- (9) in Table 3 the following notes on verification of compliance are inserted in numerical order:

Note No	Notes on verification of compliance
(1)	(2)
(18)	There is a risk that the SML could be exceeded from low-density polyethylene (LDPE)
(19)	There is a risk that the OML could be exceeded in direct contact with aqueous foods from ethylvinylalcohol (EVOH) and polyvinylalcohol (PVOH) copolymers

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- (1) OJ L 338, 13.11.2004, p. 4.
- (2) OJ L 12, 15.1.2011, p. 1.
- (3) OJ L 311, 26.11.2009, p. 3.
- (4) Scientific Opinion on the safety evaluation of the substance bis (2,6-diisopropylphenyl)carbodiimide for use in food contact materials. *EFSA Journal* 2010; 8(12):1928.
- (5) Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request from the Commission related to a seventh list of substances for food contact materials. *EFSA Journal* (2005) 201, 1-28.
- (6) Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request related to a 18th list of substances for food contact materials. *EFSA Journal* (2008) 628-633, 1-19.