

REGULATIONS

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)

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

⁽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.

⁽¹⁾ OJ L 338, 13.11.2004, p. 4.

⁽²⁾ OJ L 12, 15.1.2011, p. 1.

No 0007328-26-5. According to the Opinion delivered by the Authority ⁽¹⁾ 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

⁽¹⁾ 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.

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 macro-molecule obtained from microbial fermentation (yes/no)	FRF applicable (yes/no)	SML [mg/kg]	SML(T) [mg/kg] (Group restriction No)	Restrictions and specifications	Notes on verification of 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 or 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.	
857	66765	0037953-21-2	(methyl methacrylate, butyl acrylate, styrene, glycidyl methacrylate) copolymer	yes	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	0000646-25-3	1,10-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 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	0016545-54-3	thiodipropionic acid, ditetradecyl ester	yes	no	no		(14)		
895	47060	0171090-93-0	3-(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.	

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
896	71958	0958445-44-8	3H-perfluoro-3-[(3-methoxy-propoxy) propanoic acid], ammonium salt	yes	no	no			Only to be used in the polymerisation of fluoropolymers when: <ul style="list-style-type: none"> — 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 polyoxy-methylene polymers and intended for repeated use articles. 	
923	39150	0000120-40-1	N,N-bis(2-hydroxyethyl)dodecanamide	yes	no	no	5		The residual amount of diethanolamine in plastics, as an impurity and decomposition product of the substance, should not result in a migration of diethanolamine higher than 0,3 mg/kg food.	(18)
924	94987		trimethylolpropane, mixed triesters and diesters with n-octanoic and n-decanoic acids	yes	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	0908020-52-0	perfluoro[(2-ethyloxy-ethoxy)acetic acid], ammonium salt	yes	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	0002459-10-1	trimethyl trimellitate	no	yes	no			Only to be used as a co-monomer up to 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.	(17)
972	45197	0012158-74-6	copper hydroxide phosphate	yes	no	no				
973	22931	0019430-93-4	(perfluorobutyl)ethylene	no	yes	no			Only to be used as a co-monomer up to 0,1 % w/w in the polymerisation of fluoropolymers, sintered at high temperatures.	

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
974	74050	939402-02-5	phosphorous acid, mixed 2,4-bis(1,1-dimethylpropyl)phenyl and 4-(1,1-dimethylpropyl)phenyl triesters	yes	no	yes	5		SML expressed as the sum of phosphite and phosphate form of the substance and the hydrolysis product 4-t-amyphenol. The migration of the hydrolysis product 2,4-di-t-amyphenol should not exceed 0,05 mg/kg.	

(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 other starting substance or macro-molecule obtained from microbial fermentation (yes/no)	FRF applicable (yes/no)	SML [mg/kg]	SML(T) [mg/kg] (Group restriction No)	Restrictions and specifications	Notes on verification of compliance
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
438	13303	0002162-74-5	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	

(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 other starting substance or macro-molecule obtained from microbial fermentation (yes/no)	FRF applicable (yes/no)	SML [mg/kg]	SML(T) [mg/kg] (Group restriction No)	Restrictions and specifications	Notes on verification of compliance
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
797	76807	0073018-26-5	polyester 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 other starting substance or macro-molecule obtained from microbial fermentation (yes/no)	FRF applicable (yes/no)	SML [mg/kg]	SML(T) [mg/kg] (Group restriction No)	Restrictions and specifications	Notes on verification of compliance
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
239	19975	0000108-78-1	2,4,6-triamino-1,3,5-triazine	yes	yes	no	2,5			
	25420									
	93720									
376	66905	0000872-50-4	N-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 other starting substance or macro-molecule obtained from microbial fermentation (yes/no)	FRF applicable (yes/no)	SML [mg/kg]	SML(T) [mg/kg] (Group restriction No)	Restrictions and specifications	Notes on verification of compliance
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
452	38885	0002725-22-6	2,4-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 other starting substance or macro-molecule obtained from microbial fermentation (yes/no)	FRF applicable (yes/no)	SML [mg/kg]	SML(T) [mg/kg] (Group restriction No)	Restrictions and specifications	Notes on verification of compliance
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
794	18117	0000079-14-1	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	0124578-12-7	poly(12-hydroxystearic acid)-polyethyleneimine copolymer	yes	no	no			Only to be used in plastics up to 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 other starting substance or macro-molecule obtained from microbial fermentation (yes/no)	FRF applicable (yes/no)	SML [mg/kg]	SML(T) [mg/kg] (Group restriction No)	Restrictions and specifications	Notes on verification of compliance
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
862	15180	0018085-02-4	3,4-diacetoxy-1-butene	no	yes	no	0,05		SML 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	294 368 894	5	Expressed as the sum of the substances and their oxidation products

(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