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.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) No 1282/2011. (See end of Document for details)*

(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

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) No 1282/2011. (See end of Document for details)*

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 (yes/no)	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	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	0037953-21-2	(methyl 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	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