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Subject: Draft COMMISSION REGULATION amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food

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Delegations will find attached Commission document D022886/02.

Encl.: D022886/02



EUROPEAN COMMISSION

Brussels, **XXX**  
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**COMMISSION REGULATION (EU) No .../..**

**of **XXX****

**amending and correcting 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 .../..**

**of XXX**

**amending and correcting 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<sup>1</sup>, 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<sup>2</sup> 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 favourable scientific evaluations 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) Annex I to Regulation (EU) No 10/2011 should therefore be amended accordingly.
- (4) The substance with FCM Substance Number 257 and the name dipropyleneglycol 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 0000110-98-5. In Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs<sup>3</sup> this substance was referred to by CAS No 0025265-71-8. That reference was deleted upon the entry into force of Regulation (EU) No 10/2011, replacing Directive 2002/72/EC, because it was considered superfluous. However, taking into account that CAS No 0025265-71-8 refers to the

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<sup>1</sup> OJ L 338, 13.11.2004, p. 4.

<sup>2</sup> OJ L 12, 15.1.2011, p. 1.

<sup>3</sup> OJ L 220, 15.8.2002, p. 18.

commercially used mixture of isomers rather than to the pure substance, it should be reinserted in Regulation (EU) No 10/2011. CAS No 0000110-98-5 should remain in Table 1.

- (5) Compliance Note No (4) in Table 3 of Annex I to Regulation (EU) No 10/2011 gives an ambiguous reference to simulant D, where a reference to simulant D2 is intended. Therefore, the Note No (4) should refer to simulant D2.
- (6) Annex I to Regulation (EU) No 10/2011 should therefore be corrected accordingly.
- (7) 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 one year after entry into force of this Regulation. They should be able to remain on the market until exhaustion of stocks.
- (8) 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 2013 and which do not comply with this Regulation may continue to be placed on the market until 1 January 2014. 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 twentieth day following 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,

*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 for the following substance, the content of the column (3) is replaced by the following:

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
257	13550 16660 51760	0000110-98-5  0025265-71-8	dipropylene glycol	yes	yes	no				

- (2) In Table 1 for the following substance, the content of the column (8) is replaced by the following:

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
449	49840	0002500-88-1	dioctadecyl disulphide	yes	no	yes	0.05			

- (3) In Table 1 for the following substance, the content of the columns (8) and (9) is replaced by the following:

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
180	17160	0000097-53-0	eugenol	no	yes	no		(33)		

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

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
807	93485	—	titanium nitride, nanoparticles	yes	no	no			<p>No migration of titanium nitride nanoparticles</p> <p>Only to be used in polyethylene terephthalate (PET) up to 20 mg/kg</p> <p>In the PET, the agglomerates have a diameter of 100 – 500 nm consisting of primary titanium nitride nanoparticles; primary particles have a diameter of approximately 20 nm.</p>	

865	40619	0025322-99-0	(butyl acrylate, methyl methacrylate, butyl methacrylate) copolymer	yes	no	no			Only to be used in:  (a) rigid poly(vinyl chloride) (PVC) at a maximum level of 1% w/w;  (b) polylactic acid (PLA) at a maximum level of 5 % w/w.
868	53245	0009010-88-2	(ethyl acrylate, methyl methacrylate) copolymer	yes	no	no			Only to be used in:  (a) rigid poly(vinyl chloride) (PVC) at a maximum level of 2% w/w;  (b) polylactic acid (PLA) at a maximum level of 5 % w/w;  (c) polyethylene terephthalate (PET) at a maximum level of 5 % w/w.

(5) In Table 1 the following lines are inserted in numerical order of the FCM Substance numbers:

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
858	38565	0090498-90-1	3,9-bis[2-(3-(3-tert-butyl-4-hydroxy-5-methylphenyl)propionyloxy)-1,1-dimethylethyl]-2,4,8,10-tetraoxaspiro[5,5]undecane	yes	no	yes	0.05		SML expressed as the sum of the substance and its oxidation product 3-[(3-(3-tert-butyl-4-hydroxy-5-methylphenyl)prop-2-enoyloxy)-1,1-dimethylethyl]-9-[(3-(3-tert-butyl-4-hydroxy-5-methylphenyl)propionyloxy)-1,1-dimethylethyl]-2,4,8,10-tetraoxaspiro[5,5]-undecane in equilibrium with its para quinone methid tautomer	(2)
874	16265	0156065-00-8	$\alpha$ -dimethyl-3-(4'-hydroxy-3'-methoxyphenyl)propylsilyloxy, $\omega$ -3-dimethyl-3-(4'-hydroxy-3'-methoxyphenyl)propylsilyl polydimethylsiloxane	no	yes	no	0.05	(33)	Only to be used as comonomer in siloxane modified polycarbonate  The oligomeric mixture shall be characterized by the formula $C_{24}H_{38}Si_2O_5(SiOC_2H_6)_n$ ( $50 > n \geq 26$ )	

902		0000128-44-9	1,2-benzisothiazol-3(2H)-one 1,1-dioxide, sodium salt	yes	no	no			The substance shall comply with the specific purity criteria as set out in Commission Regulation (EU) No 231/2012 <sup>4</sup>
979	79987	-	(polyethylene terephthalate, hydroxylated polybutadiene, pyromellitic anhydride) copolymer	yes	no	no			Only to be used in polyethylene terephthalate (PET) at a maximum level of 5% w/w

(6) in Table 2 the following line is inserted in numerical order of the group restriction numbers:

(1)	(2)	(3)	(4)
Group Restriction No	FCM substance No	SML (T) [mg/kg]	Group restriction specification
33	180 874	ND	expressed as eugenol

(7) In Table 3 on verification of compliance the content of note (4) is replaced by the following:

(1)	(2)
Note No.	Note on verification of compliance
(4)	Compliance testing when there is a fat contact should be performed using saturated fatty food simulants as simulant D2.

<sup>4</sup> OJ L 83, 22.3.2012, p. 1.