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

Delegations will find attached document D034272/03 - Annex I.

Encl.: D034272/03 - Annex I



EUROPEAN
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Brussels, **XXX**
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ANNEX 1

ANNEX

to the

COMMISSION REGULATION (EU) No .../..

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

ANNEX

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

(1) Table 1 is amended as follows:

(a) the entries concerning FCM substances Nos. 161, 241, 344, 364, 410, 713, 784, 799, 880 and 881 are replaced by the following:

'161	92160	000087-69-4	L-(+)-tartaric acid	yes	no	no				
241	22960	0000108-95-2	phenol	no	yes	no	3			
344	13810	0000505-65-7	1,4-butanediol formal	no	yes	no	0,05	15 30		(21)
	21821									
364	15404	0000652-67-5	1,4:3,6-dianhydrosorbitol	no	yes	no	5		Only to be used as: (a) a co-monomer in poly(ethylene-co-isosorbide terephthalate); (b) a co-monomer	

									at levels of up to 40 mole % of the diol component in combination with ethylene glycol and/or 1,4-bis(hydroxymethyl)cyclohexane, for the production of polyesters. Polyesters made using dianhydrosorbitol together with 1,4-bis(hydroxymethyl)cyclohexane shall not be used in contact with foods containing more than 15% alcohol.	
410	62720	0001332-58-7	kaolin	yes	no	no			Particles can be thinner than 100 nm only if incorporated at a quantity of less than 12 % w/w in an ethylene vinyl alcohol copolymer (EVOH) inner layer of a multi-layer structure, in which the layer in direct contact with the food provides a functional barrier preventing migration of particles into the food.	
713	43480	0064365-11-3	charcoal, activated	yes	no	no			Only for use in PET at maximum 10 mg/kg of polymer. Same purity requirements as for Vegetable Carbon (E 153) set out by Commission Regulation (EU)	

		0007440-44-0							No 231/2012* with exception of ash content which can be up to 10 % (w/w).	
784	95420	0745070-61-5	1,3,5-tris (2,2-di-methylpropanamido) benzene	yes	no	no	5			
799	77708		polyethyleneglycol (EO= 1-50) ethers of linear and branched primary (C ₈ -C ₂₂) alcohols	yes	no	no	1,8		In compliance with the maximum ethylene oxide content as laid down in the purity criteria for food additives in Commission Regulation (EU) No 231/2012.	
880	31348		acids, fatty (C ₈ -C ₂₂), esters with pentaerythritol'	yes	no	no				
881	25187	0003010-96-6	2,2,4,4-tetramethylcyclobutane-1,3-diol	no	yes	no	5		Only for: (a) repeated use articles for long term storage at room temperature or below and hotfill; (b) single use materials and articles as a co-monomer at a maximum use level of 35 mole % of the diol component of polyesters, and if such materials and articles are for long term storage at room temperature or below of food types which have an alcohol	

									content of up to 10 % and for which Table 2 of Annex III does not assign simulant D2. Hot fill conditions are allowed for such single use materials and articles.	
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* Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of 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).'

(b) the following entries are inserted in numerical order of the FCM substance numbers:

'859			(butadiene, ethyl acrylate, methyl methacrylate, styrene) copolymer crosslinked with divinylbenzene, in nanoform	yes	no	no			Only to be used as particles in non-plasticised PVC up to 10 % w/w in contact with all food types at room temperature or below including long-term storage. When used together with the substance with FCM No 998 and/or the substance with FCM No 1043, the restriction of 10 % w/w applies to the sum of those substances. The diameter of particles shall be > 20 nm, and for at least 95 % by number it shall be > 40 nm.	
903		37486-69-4	2H-perfluoro-[(5,8,11,14-tetramethyl)-tetraethyleneglycol ethyl propyl ether]	yes	no	no			Only to be used as a polymer production aid in the polymerisation of fluoropolymers intended for: (a) repeated and	

									single use materials and articles when sintered or processed (non-sintered) at temperatures at or above 360°C for at least 10 minutes or at higher temperatures for equivalent shorter times; (b) repeated use materials and articles when processed (non-sintered) at temperatures from 300°C and up to 360°C for at least 10 minutes.	
969		24937-78-8	ethylene-vinyl acetate copolymer wax	yes	no	no			Only to be used as a polymeric additive up to 2 % w/w in polyolefins. The migration of low molecular weight oligomeric fraction below 1000 Da shall not exceed 5 mg/kg food.	
998			(butadiene, ethyl acrylate, methyl methacrylate, styrene) copolymer not cross-linked, in nanoform	yes	no	no			Only to be used as particles in non-plasticised PVC up to 10 % w/w in contact with all food types at room temperature or below including long-term storage. When used together with the substance with FCM No 859 and/or the substance with FCM No 1043, the restriction of	

									10 % w/w applies to the sum of those substances. The diameter of particles shall be > 20 nm, and for at least 95 % by number it shall be > 40 nm.	
1017		25618-55-7	polyglycerol	yes	no	no			To be processed under conditions preventing the decomposition of the substance and up to a maximum temperature of 275°C.	
1043			(butadiene, ethyl acrylate, methyl methacrylate, styrene) copolymer crosslinked with 1,3-butanediol dimethacrylate, in nanoform	yes	no	no			Only to be used as particles in non-plasticised PVC up to 10 % w/w in contact with all food types at room temperature or below including long-term storage. When used together with the substance with FCM No 859 and/or the substance with FCM No 998, the restriction of 10 % w/w applies to the sum of those substances. The diameter of particles shall be > 20 nm, and for at least 95 % by number it shall be > 40 nm.'	

(c) The entry concerning FCM substance No 725 is deleted.

(2) In Table 2, the entries concerning group restrictions Nos. 15 and 30 are replaced by the following:

'15	98 196 344	15	expressed as formaldehyde
30	254 344 672	5	expressed as 1,4-butanediol'

(3) In Table 3, the following entry is added:

(21)	In case of reaction with foods or simulants verification of compliance shall include verification that the migration limits of the hydrolysis products, formaldehyde and 1,4-butanediol, are not exceeded.'
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