

Brussels, XXX SANTE/10814/2017 ANNEX CIS Rev. 3 (POOL/E2/2017/10814/10814R3-EN ANNEX CIS.doc) [...](2017) XXX draft

ANNEX 1

ANNEX

to the

COMMISSION REGULATION (EU) .../...

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

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ANNEX

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

- (1) in point 1, Table 1 is amended as follows:
 - (a) the entry concerning FCM substance No 856 is replaced by the following:

	1						
856	40563	25101-	(butadiene,	yes	no	no	Only to be used
		28-4	styrene,				in:
			methyl				- rigid
			methacrylate,				poly(vinyl
			butyl acrylate)				chloride)
			copolymer				(PVC) at a
			cross-linked				maximum
			with				level of 12%
			divinylbenzene				at room
			or 1,3-				temperature
			butanediol				or below; or
			dimethacrylate				- at up to 40%
							w/w in blends
							of styrene
							acrylonitrile
							copolymer
							(SAN) /
							poly(methyl
							methacrylate)
							(PMMA)
							repeat-use
							articles at
							room
							temperature
							or below, and
							when either
							in contact
							only with
							aqueous,
							acidic and/or
							low alcoholic
							(< 20%)
							foodstuffs for
							less than 1
							day, or when
							in contact
							only with dry
							foodstuffs for
							any duration
							of time.";
L	l	l					or allie, ,

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

1061	80512- 44-3	2,4,4- trifluorobenzophen one	no	yes	no		Only to be used as a co-monomer in the manufacture of polyether ether ketone plastics up to 0.3% w/w of the final material.	
1063	1547-26- 8	2,3,3,4,4,5,5- heptafluoro-1- pentene	no	yes	no		Only to be used together with tetrafluoroethylene and/or ethylene comonomers to manufacture fluorocopolymers for application as polymer processing aid at up to 0.2% w/w of the food contact material, and when the low-molecular mass fraction below 1,500 Da in the fluorocopolymer does not exceed 30 mg/kg.	
1064	39318- 18-8	tungsten oxide	yes	no	no	0,05	Stoichiometry: WO_n , $n = 2.72-2.90$	(25)
1065	85711- 28-0	mixture of methylbranched and linear C ₁₄ -C ₁₈ alkanamides, derived from fatty acids	yes	no	no	5	Only to be used in the manufacture of articles made of polyolefins, and which do not come into contact with foods for which food simulant D2 is assigned in Table 2 of Annex III.	(26)

(2) in point 3, in Table 3, the following entries are added:

, ,	When used as reheat agent in polyethylene terephthalate (PET) verification of compliance with the specific migration limit is not required; in all other cases compliance with the specific migration limit shall be verified in accordance with Article 18; the specific migration limit is expressed as mg tungsten / kg food.
	Migration of stearamide, listed in Table 1 under FCM substance No 306 to which no specific migration limit applies, shall be excluded from verification of the compliance of the migration of the mixture with the specific migration limit laid down for the mixture."