

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

DRAFT

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 the substance with FCM substance No 856, is replaced by the following:

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; - or, 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"	
-----	-------	--	---	-----	----	----	--	--	--	--

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

"1061		80512-44-3	2,4,4,0-trifluorobenzophenone	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 FCM, and when the low molecular weight 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 , $n = 2.72-2.9$	(26)
1065		85711-28-0	mixture of methyl-branched and linear $C_{14}-C_{18}$ alkanamides, derived from fatty acids	yes	no	no	0,05		Only to be used in the manufacture of articles made of polyolefins, and which do not come into contact with foods for which	(27)"

										simulant D2 is assigned in table 2 of Annex III.	
--	--	--	--	--	--	--	--	--	--	--	--

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

“(25)	Simulant E shall be used for verification of compliance without the use of any correction factors
(26)	When used reheat agent in PET verification of the migration limit is not required; in all other cases compliance to the migration limit shall be verified in accordance with Article 18; the migration limit is expressed as mg tungsten / kg food”;
(27)	Migration of n-stearamide shall be excluded for verification of the compliance of the migration of the mixture to the migration limit laid down for the mixture”