

Brussels, XXX SANTE/10028/2018 ANNEX (POOL/E2/2018/10028/10028-EN ANNEX.doc) D055333/02 [...](2018) XXX draft

ANNEX

ANNEX

to the

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

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

EN EN

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 entries concerning FCM substances No 822 and No 974 are replaced by the following:

"

'822	71938		Perchloric acid, salts	yes	no	no	0,002		(4)'
'974	74050	939402-02- 5	phosphorous acid, mixed 2,4-bis(1,1- dimethylpropyl)phenyl and 4-(1,1-dimethylpropyl)phenyl triesters	yes	no	yes	10	SML expressed as the sum of the phosphite and phosphate forms of the substance, 4-tert-amylphenol and 2,4-di-tert-amylphenol. The migration of 2,4-di-tert-amylphenol shall not exceed 1 mg/kg food.'	

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

'1066	23985-75-3	1,2,3,4-tetrahydronaphtalene- 2,6-dicarboxylic acid, dimethyl ester	no	yes	no	0,05	Only to be used as a co-monomer in the manufacture of a polyester non-food contact layer in a plastic multilayer material, which is to be used only in contact with foods for which food simulants A, B, C and/or D1 are assigned in Table 2 of Annex III. The specific migration limit in column 8 refers to the sum of the substance and of its dimers (cyclic and open chain)'.
'1068	2530-83-8	[3-(2,3- epoxypropoxy)propyl]trimetho xy silane	yes	no	no		Only to be used as a component of a sizing agent to treat glass fibres to be embedded in glass-fibre-reinforced low diffusivity plastics (polyethylene terephthalate (PET), polycarbonate (PC), polybutylene terephthalate (PBT), thermoset polyesters and epoxy bisphenol vinylester) in contact with all foodstuffs. In treated glass fibres, residues of the substance must not be
							detectable at 0,01 mg/kg for the substance and 0,06 mg/kg for each of the reaction products (hydrolysed monomers and epoxy-containing cyclic dimer, trimer and tetramer).'

•