

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) 2019/37, ANNEX. (See end of Document for details)

ANNEX

Annexes I and III to Regulation (EU) No 10/2011 are amended as follows:

(1) in Annex I, Table 1 is amended as follows:

(a) the entries concerning FCM substances No 467, 744, 1066, and 1068 are replaced by the following:

467	14800 45600	3724-6501	crotonic acid	yes	yes	no		(35)		
744	18888	08018	3-3-hydroxybutanoic acid-3-hydroxypentanoic acid, copolymer	no	yes	no		(35)	The substance is used as product obtained by bacterial fermentation. In compliance with the specifications mentioned in the Table 4 of Annex I.	
1066		23985	1,2,3,4-tetrahydronaphthalene-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,	

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								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	2530-83-8 (2,3-epoxypropoxy)propyl]trimethoxy silane	no	yes	no			Only to be used as a component of a

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								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 vinyl ester) 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
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									and 0,06 mg/kg for each of the reaction products (hydrolysed monomers and epoxy-containing cyclic dimer, trimer and tetramer).’
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(b) the following entries are inserted in numerical order of the FCM substance numbers:

1059	147398	poly((R)-3-hydroxybutyrate-co-(R)-3-hydroxyhexanoate)	yes	no		(35)	Only to be used alone or blended with other polymers in contact with foods for which food simulant E is assigned in Table 2 of Annex III.
‘1067	616-386	dimethyl carbonate	yes	no			Only to be used: (27)’

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									a)	with 1,6-hexanediol in the manufacture of polycarbonate pre-polymers that are used at up to 30 % to manufacture thermoplastic polyurethanes with 4,4'-methylenediphenyldiisocyanate and diols, such as polypropylene glycol and 1,4-butanediol. The resulting material shall only be applied in repeated use articles intended to come into short-term contact (≤ 30 min)
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									oligomers with a molecular weight below 1 000 Da together does not exceed 0,05 mg/kg food.
'1069		75-28-5	isobutylene	no	no			Only to be used as a blowing agent.	

(2) in Table 2 of Annex I, the following entry is added:

35	467 744 1059	0,05	expressed as crotonic acid
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(3) in Table 3 of Annex I, the following entry is added:

(27)	When a final material or article containing this substance and produced under conditions other than those described in point (a) column 10 of Table 1 is placed on the market, a well described method to determine whether the oligomer migration complies with the restrictions specified in point (b) column 10 of Table 1 shall form part of the supporting documentation referred to in Article 16. This method shall be suitable for use by a competent authority to verify compliance. If an adequate method is publicly available, reference shall be made to that method. If the method requires a calibration sample, a sufficient sample shall be supplied to the competent authority on its request.
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- (4) in Table 4 of Annex I, the row concerning restriction of the entry concerning substance FCM No 744 is replaced by the following:

Restriction	Specific migration limit for crotonic acid is 0,05 mg/kg food
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- (5) in table 3 of point 4 of Annex III, the third and fourth rows are replaced by the following:

all aqueous and alcoholic foods and milk products with a pH \geq 4,5	food simulant D1
all aqueous and alcoholic foods and milk products with a pH $<$ 4,5	food simulant D1 and food simulant B

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