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Subject:	ANNEX to the COMMISSION REGULATION (EU) .../... 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 D058297/02.

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ANNEX

ANNEX

to the

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

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

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	3724-65-0	crotonic acid	yes	yes	no		(35) ”		
	45600									
“744	18888	080181-31-3	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		23985-75-3	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, 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]trimethoxy silane	no	yes	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 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 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		147398-31-0	poly((R)-3-hydroxybutyrate-co-(R)-3-hydroxyhexanoate)	no	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		616-38-6	dimethyl carbonate	no	yes	no			Only to be used: 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'-methylenediphenyldii socyanate 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 at room temperature) with food for which simulants A and/or B are assigned in Table 2 of Annex III; or b) for the production of other polycarbonates and/or under other conditions provided that the migration of dimethyl carbonate does not exceed 0,05 mg/kg food and that the migration of all polycarbonate oligomers with a molecular weight below 1 000 Da together does not	(27)”

									exceed 0,05 mg/kg food.”
“1069		75-28-5	isobutane	yes	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”