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Subject:	ANNEX to the COMMISSION REGULATION (EU) .../... of XXX 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 D048354/02 ANNEX 1.

Encl.: D048354/02 ANNEX 1



EUROPEAN
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Brussels, **XXX**
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ANNEX 1

ANNEX

to the

COMMISSION REGULATION

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

ANNEX

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

(1) Annex I is amended as follows:

(a) in point 1, Table 1 is amended as follows:

(i) in column 11 as regards the entries for the substances with FCM substance numbers 142, 168, 202, 387, 462, 467, 481, 502, 662 and 779, the reference to note "(1)" is deleted;

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

"1007		976-56-7	diethyl[[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]methyl]phosphonate	no	yes	no			Only to be used up to 0.2% w/w based on the final polymer weight in the polymerisation process to manufacture poly(ethylene terephthalate) (PET).
"1016			(methacrylic acid, ethyl acrylate, n-butyl acrylate, methyl methacrylate and butadiene) copolymer in nanoform	yes	no	no			Only to be used up to: (a) 10% w/w in non-plasticised PVC; (b) 15% w/w in non-plasticised PLA. The final material shall be used at room temperature or below".
"1030			montmorillonite clay modified by dimethyldialkyl(C16-C18)ammonium chloride	yes	no	no			Only to be used up to 12% (w/w) in polyolefins in contact with dry foods to which simulant E is assigned in table 2 of Annex III at room temperature or below. The sum of the specific migration of 1-chlorohexadecane and 1-chlorooctadecane shall not exceed 0.05 mg/kg food. Can contain platelets in the nanoform that are only in one dimension thinner than 100 nm. Such

									platelets shall be oriented parallel to the polymer surface and shall be fully embedded in the polymer".	
"1055		7695-91-2 58-95-7	α -tocopherol acetate	yes	no	no			Only to be used as antioxidant in polyolefins.	(24)
1060			ground sunflower seed hulls	yes	no	no			Only to be used at room temperature or below in contact with foods for which Table 2 of Annex III assigns food simulant E. The seed hulls shall be obtained from sunflower seeds that are fit for human consumption. The processing temperature of the plastic containing the additive shall not exceed 240°C.	
1062			mixture composed of 97% tetraethyl orthosilicate (TEOS) with CAS No 78-10-4 and 3% hexamethyldisilazane (HMDS) with CAS No 999-97-3	no	yes	no			Only to be used for the production of recycled PET and at up to 0.12% (w/w)".	

(b) in point 3, in Table 3, the following entry is added:

"(24)	The substance or its hydrolysis products are authorised food additives and compliance with Article 11(3) shall be verified";
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(2) In point 1 of Annex II, the following line is inserted after Manganese:

"Nickel = 0,02 mg/kg food or food simulant.";

(3) In Annex III, point 4 is replaced by the following:

"4. Food simulant assignment for testing overall migration

For tests to demonstrate compliance with the overall migration limit food simulants shall be chosen as set out in Table 3:

Table 3

Food simulant assignment for demonstrating compliance with the overall migration limit

Foods covered	Food simulants in which testing shall be performed
all types of food	1) distilled water or water of equivalent quality or food simulant A; 2) food simulant B; and 3) food simulant D2.
all types of food except for acidic foods	1) distilled water or water of equivalent quality or food simulant A; and 2) food simulant D2.
all aqueous and alcoholic foods and milk products	food simulant D1
all aqueous, acidic and alcoholic foods and milk products	1) food simulant D1; and 2) food simulant B.
all aqueous foods and alcoholic foods up to an alcohol content of 20 %	food simulant C
all aqueous and acidic foods and alcoholic foods up to an alcohol content of 20%	1) food simulant C; and 2) food simulant B.

(4) In Annex IV, point 8(iii) is replaced by the following:

"(iii) the highest food contact surface area to volume ratio for which compliance has been verified in accordance with Article 17 and 18 or equivalent information;".