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From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	9 October 2025
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	D(2025) 109239 annex
Subject:	ANNEX to the COMMISSION REGULATION (EU) .../... of XXX amending Annex I to Regulation (EU) No 10/2011 as regards the authorisation or the conditions of use of several substances

Delegations will find attached document D(2025) 109239 annex.

Encl.: D(2025) 109239 annex



EUROPEAN
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Luxembourg, **XXX**
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ANNEX

ANNEX

to the

COMMISSION REGULATION

**amending Annex I to Regulation (EU) No 10/2011 as regards the authorisation or the
conditions of use of several substances**

ANNEX

Annex I is amended as follows:

(1) Table 1 is amended as follows:

(a) entry 768 is replaced by the following:

'768	34850	014392 5-92-2	amines, di-C14- C20-alkyl, oxidised, from hydrogena ted tallow	yes	no	no			Only to be used in contact with non-fatty foods: (a) at 0,1% w/w in polyolefins (b) at 0,25% w/w in PET';	
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(b) the following entries are added:

'1084		182121 7-71-3	phosphor ous acid, triphenyl ester, polymer with 1,4- cyclohexa nedimetha nol and polypropy lene glycol, C10-16 alkyl esters	yes	n o	yes	5		Only to be used as an additive at up to 0,15% w/w in polyolefins intended for contact with food at room temperature and below, including hot-fill and/or heating up to 100 °C for up to 2 hours. Not to be used in the manufacture of articles intended for contact with infant formula ⁽⁷⁾ , and human milk. The fraction with a molecular weight below 1000 Da shall not exceed 13% w/w of the substance. The SML applies to the total of phosphite and phosphate species.	(2)
1089		81607- 35-4	calcium <i>tert</i> - butylphos phonate	yes	n o	no			Only to be used as a nucleating agent at up to 0,15% w/w in polyolefins intended for contact with food at	

								room temperature and below, including temperatures up to 100 °C for maximum 2 hours and up to 130 °C for less than 15 minutes. Not to be used in materials and articles intended for contact with infant formula ⁽⁷⁾ , and human milk.	
1092		180186 3-42-2	amines, di-C14-C20-alkyl, oxidised, from hydrogenated vegetable oil	yes	no			Only to be used as an additive at up to 0,1% w/w in polyolefins, which are to be used only in contact with non-fatty foods at room temperature and below, including hot-fill and/or heating up to 100 °C for up to 2 hours. Not to be used in the manufacture of materials and articles intended for contact with infant formula ⁽⁷⁾ , and human milk.	
1093		188358 3-80-9	wax, rice bran, oxidised	yes	no			Only to be used as an additive at up to 0,3% w/w in polyethylene terephthalate, polylactic acid and rigid poly(vinyl chloride) materials and articles intended for contact with non-fatty foods, at room temperature and below, including hot-fill and/or heating up to 100°C for up to 2 hours.	
1094		2752- 17-2	2,2'-oxydiethylamine	no	yes	no	0,05	Only to be used as a comonomer at up to 14% w/w with adipic acid and caprolactam, or with authorised	(31)

								<p>homologues of these two substances with a longer C chain, to manufacture polyamide films with a thickness of up to 25 µm.</p> <p>The migration of oligomers containing the substance with a molecular weight below 1000 Da shall not exceed 5 mg/kg food.</p> <p>Not to be used in the manufacture of materials and articles intended for contact with infant formula⁽⁷⁾, and human milk.</p>	
1096		185035 7-57-1	wax, rice bran, oxidised, calcium salt	yes	no	no		<p>Only to be used as an additive at up to 0,3% w/w in polyethylene terephthalate, polylactic acid and rigid poly(vinyl chloride) materials and articles intended for contact with non-fatty foods, at room temperature and below, including hot-fill and/or heating up to 100 °C for up to 2 hours.</p>	

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

‘(31)	Water shall be used for verification of compliance instead of food simulants listed in Table 1 of Annex III.’
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