



EUROPEAN
COMMISSION

Brussels, XXX
[...] (2025) XXX draft

ANNEX

ANNEX

to the

COMMISSION REGULATION

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

ANNEX

(1) Annex I is amended as follows:

(a) the following entries are inserted at the end of Table 1 in numerical order:

FCM substance No	Ref. No	CAS No	Substance name	Use as additive or polymer production aid (yes/no)	Use as monomer or other starting substance or macromolecule obtained from microbial fermentation (yes/no)	FRF applicable (yes/no)	SML [mg/kg]	SML(T) [mg/kg] (Group restriction No)	Restrictions and specifications	Notes on verification of compliance
“1086			chopped carbon fibres, from carbonised polyacrylonitrile	yes	no	no			Only to be used as a filler at up to 40% w/w for polyether ether ketone (PEEK) polymer. Minimum carbon content of 95% (at sizes not at the nanoscale).	
1087		471-34-1	nano precipitated calcium carbonate	yes	no	no			Not to be used in the manufacture of articles intended for contact with infant formula ⁽¹⁾ and human milk.	(32)
1088			poly(2-hydroxypropionic acid), n-octyl/n-decyl esters	yes	no	no	0,05		Only to be used as an additive up to 15% w/w in materials and articles made from polylactic acid (PLA) that does not contain starch (FCM No 564) or other additives with similar function as starch and could increase migration and are intended to be in contact for up to 10 days at 40°C with foods for which Table 2 of	(33)

¹ Infant formula and follow-on formula as defined in Article 2(2) of Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).

									Annex III assigns food stimulant B, and for which simulants D, D2 or E are not assigned in Annex III.	
1090		646-24-2 and 148 528-05-6	mixture of 1,9-nonanediamine ('NMDA') and 2-methyl-1,8-octanediamine ('MODA')	no	yes	no	0,05		<p>Only to be used as a co-monomer with terephthalic acid to manufacture polyamide materials and articles intended for contact with food.</p> <p>Not to be used in the manufacture of materials and articles intended for contact with infant formula ⁽²⁾ and human milk.</p> <p>The migration of the fraction with molecular weight below 1000 Da that contains NMDA/MODA-related species shall not exceed 5 mg/kg food.</p>	
)”

(b) in point 3, table 3, the following entries are added:

“(32)	There is a risk that the overall migration limit could be exceeded in contact with acidic foods.”.
(33)	There is a risk that the specific migration limit could be exceeded in contact with the use of food simulants for non-acidic foods.”.

² Infant formula and follow-on formula as defined in Article 2(2) of Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).