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[...] (2022) **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 as regards changes to substance authorisations and the addition of new substances

ANNEX

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

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

(a) entry 96 on wood flour and fibers, untreated, and entry 121 on salicylic acid are deleted;

(b) entry 157 on phthalic acid, dibutyl ester is replaced by the following:

“157	74880	000008 4-74-2	phthalic acid, dibutyl ester (‘DBP’)	yes	no	no	0,12	(32) (36)	Only to be used as: (a) plasticiser in repeated use materials and articles contacting non-fatty foods; (b) technical support agent in polyolefins in concentrations up to 0,05 % (w/w) in the final product.	(7)”
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(c) entry 159 on phthalic acid, benzyl butyl ester is replaced by the following:

“159	74560	000008 5-68-7	phthalic acid, benzyl butyl ester (‘BBP’)	yes	no	no	6	(32) (36)	Only to be used as: (a) plasticiser in repeated use materials and articles; (b) plasticiser in single-use materials and articles contacting non-fatty foods except for infant formula and follow-on formula (*); (c) technical support agent in concentrations up to 0,1 % (w/w) in the final product.	(7)”
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(d) entry 283 on phthalic acid, bis(2-ethylhexyl) ester is replaced by the following:

“283	74640	000011 7-81-7	phthalic acid, bis(2- ethylhexyl) ester (‘DEHP’)	yes	no	no	0,6	(32) (36)	Only to be used as: (a) plasticiser in repeated use materials and articles contacting non-fatty foods; (b) technical support agent in concentrations up to 0,1 % (w/w) in the final product.	(7)”
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- (e) entry 728 on phthalic acid, diesters with primary, saturated C₈-C₁₀ branched alcohols, more than 60 % C₉ is replaced by the following:

“728	75100	006851 5-48-0 002855 3-12-0	phthalic acid, diesters with primary, saturated C 8- C 10 branched alcohols, more than 60 % C 9 (‘DINP’)	yes	no	no		(26) (32)	Only to be used as: (a) plasticiser in repeated use materials and articles; (b) plasticiser in single-use materials and articles contacting non-fatty foods except for infant formula and follow-on formula (*) (c) technical support agent in concentrations up to 0,1 % (w/w) in the final product. Not to be used in combination with FCM substances 157, 159, 283, or 1085.	(7)”
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- (f) entry 793 on triethanolamine is replaced by the following:

“793	94000	000010 2-71-6	triethanolamine	yes	no	no		(37) ”		
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- (g) entry 822 on perchloric acid, salts (perchlorate) is replaced by the following:

“822	71983	14797- 73-0	Perchloric acid, salts (perchlorate)	yes	no	no		(38) ”		
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- (h) entry 1007 on diethyl[[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]methyl]phosphonate is replaced by the following:

“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) and poly(ethylene 2,5-furandicarboxylate) (PEF)	”
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- (i) entry 1059 on poly((R)-3-hydroxybutyrate-co-(R)-3-hydroxyhexanoate) is replaced by the following:

“1059	147398 -31-0	Poly((R)-3-hydroxybutyrate	no	yes	no			(35)	The substance is a macromolecule obtained	(23)”
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		e-co-(R)-3-hydroxyhexanoate) ('PHBH')							from microbial fermentation. Only to be used at temperature conditions not exceeding the conditions defined in point 2.1.4(d) of Annex V. The migration of all oligomers with a molecular weight below 1 000 Da shall not exceed 5,0 mg/kg food.
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(j) entry 1076 on Phosphorous acid, triphenyl ester, polymer with alpha-hydro-omega-hydroxypoly[oxy(methyl-1,2-ethanediyl)], C10-16 alkyl ester is replaced by the following :

"1076	122793 7-46-3	Phosphorous acid, triphenyl ester, polymer with alpha-hydro-omega-hydroxypoly[oxy(methyl-1,2-ethanediyl)], C10-16 alkyl esters	yes	no	no	0,05			To be used only: a) as an additive at up to 0,2 % w/w in high impact polystyrene materials and articles 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. It shall not be used in contact with foods for which simulant C and/or D1 is assigned in Annex III. b) as an additive at up to 0.025% w/w in acrylonitrile-butadiene-styrene (ABS) materials for use at room temperature and below"
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(k) the following entries are inserted at the end of Table 1 in numerical order:

"1078	3319- 31-1	tris(2-ethylhexyl) benzene-1,2,4-tricarboxylate	yes	no	no	1	(32)		Only to be used as plasticiser to manufacture soft poly(vinyl chloride) Not to be used in contact with foods intended for infants (*)
1080	156157 -97-0	(triethanolamin e-perchlorate,	yes	no	no		(37) (38)		Only to be used in rigid poly(vinyl chloride) in

			sodium salt) dimer						contact with foods included in the food category with reference number 01.01.A in table 2 of Annex III	
1081		-	N, N-bis(2- hydroxyethyl)st earylamine partially esterified with saturated C16/C18 fatty acids	yes	no	no		(7)	Only to be used at up to 2% (w/w) in plastic materials and articles intended for the packaging by food business operators of dry foods for which simulant E is assigned in table 2 of Annex III.	(30)
1082		52628- 03-2	Phosphoric acid, mixed esters with 2- hydroxyethyl methacrylate	no	ye s	no	0.05		Only to be used at up to 0,35% (w/w) to manufacture polymethylmethacrylate. SML expressed as the sum of the mono-, di- and triesters of phosphoric acid and the mono-, di-, tri- and tetraesters of diphosphoric acid	
1083		2421- 28-5	Benzophenone- 3,3',4,4'- tetracarboxylic dianhydride (‘BTDA’)	no	ye s	no	0.05		Only to be used at up to 43% (w/w) as a co- monomer in the production of polyimides for use in contact with foods for which only simulants B and/or D2 are laid down in table 2 of Annex III at temperatures up to 250°C.”	

“(*) Infant, 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).”

(2) in point 2, table 2 is amended as follows:

(a) entry 7 is replaced by the following:

“7	19 20 1081	1,2	expressed as tertiary amine”
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(b) entry 26 is replaced by the following:

“26	728	1,8	expressed as the sum of the substances”
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	729		
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(c) entry 32 is replaced by the following:

"32	8	60	expressed as the sum of the substances (plasticisers) * Diisobutyl phthalate, FCM No 1085, with synonyms 1,2-bis(2-methylpropyl) benzene-1,2-dicarboxylate or 'DIBP' and CAS number 84-69-5 is not listed as an authorised substance in Table 1. However, it may co-occur with other phthalates as a consequence of its use as an aid to polymerisation and is included in group restrictions with the assignment FCM No 1085."
	72		
	73		
	138		
	140		
	157		
	159		
	207		
	242		
	283		
	532		
	670		
	728		
	729		
	775		
	783		
	797		
798			
810			
815			
1078			
1085*			

(d) the following entries are added:

"36	157 159 283 1085*	0,6	sum of phthalic acid, dibutyl ester (DBP), diisobutyl phthalate (DIBP), phthalic acid, benzyl butyl ester (BBP) and phthalic acid, bis(2-ethylhexyl) ester (DEHP) expressed as DEHP equivalents using the following equation: $DBP*5 + DIBP*4 + BBP*0,1 + DEHP*1$. * See remark on FCM No 1085 in row 32
37	793 1080	0,05	expressed as the sum of triethanolamine and the hydrochloride adduct expressed as triethanolamine
38	822 1080	0,002	expressed as perchlorate – note 4 of table 3 applies"

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

"(30)	There is a risk that migration limits may be exceeded; migration increases with the thickness of the plastic in which the substance is contained, and with a decreasing polarity of the polymer and a decreasing degree of esterification of the substance itself"
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