EUROPEAN
COMMISSION

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COMMISSION REGULATION (EU) …/…

of XXX

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 addition of new substances

(Text with EEA relevance)

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COMMISSION REGULATION (EU) …/…

of XXX

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 addition of new substances

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC[1], and in particular Article 5(1), second subparagraph, points (a), (d), (e), (h), and (i), Article 11(3) and Article 12(6) thereof,

Whereas:

(1) Commission Regulation (EU) No 10/2011[2] lays down specific rules as regards plastic materials and articles intended to come into contact with food. In particular, Annex I to Regulation (EU) No 10/2011 establishes a Union list of authorised substances that may be intentionally used in the manufacture of plastic materials and articles intended to come into contact with food.

(2) Since the last amendment to Regulation (EU) No 10/2011, the European Food Safety Authority ('the Authority') has published further scientific opinions on new substances that may be used in food contact materials ('FCM') as well as on the use of already authorised substances. In addition, certain ambiguities related to the application of that Regulation were identified. In order to ensure that Regulation (EU) No 10/2011 takes into account scientific and technical progress, in particular the most recent findings of the Authority, and in order to remove any doubt as regards its correct application, that Regulation should be amended.

(3) The substance 'wood flour and fibers, untreated' (FCM No 96, 'wood') is presently authorised as an additive in plastic food contact materials on the basis of an evaluation[3] by the Scientific Committee on Food which concluded that wood flour and fibres are an inert material. However, in its opinion of November 2019 the Authority could not validate the grounds for that conclusion. It stated that wood cannot be considered inert *per se*, due to the many low molecular weight substances it contains. Moreover, the opinion indicates no conditions under which the use of wood in plastics may be considered safe, and notes that due to the chemical differences in the composition of plant materials the safety of migrants from these materials must be evaluated on a case-by-case basis, considering beyond species also origin, processing,

[1] OJ L 338, 13.11.2004, p. 4.

[2] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (OJ L 12, 15.1.2011, p. 1).

[3] EFSA Journal 2019;17(11):5902

treatment for compatibilisation with the host polymer and assessment of the low molecular weight constituents migrate into food. As the present authorisation of wood does not take into account those aspects and thus cannot sufficiently account for the safe use of that substance in plastic, and the Authority did not provide for other restrictions that would nevertheless ensure the safe use of this substance in plastic, the authorisation should be revoked.

(4) Following a request by the Commission, the Authority adopted on 29 April 2020 a scientific opinion[4] reviewing the 451 substances listed in Annex I to Regulation (EU) No 10/2011, for which no specific migration limit ('SML') is set pursuant to Article 5(1)(e) of that Regulation. It considered that 284 of those substances needed to be re-evaluated in order to determine whether a specific migration limit is required and classified them in three priority groups. Three substances were placed into the 'high priority group'. Of these three substances, styrene (FCM No 193) is known to be widely used and is already subject to a re-evaluation, while on the substance lauric acid, vinyl ester (FCM No 436) a user provided the Authority with additional data which showed its re-evaluation would be of a lower priority. However, no user of the third substance, salicylic acid (FCM No 121), contacted either the Commission or the Authority after it was placed in the high priority list and after the Commission services consulted the stakeholders over a potential revocation of its authorisation. The Authority however cannot evaluate the use of a substance without a known user as it is to take account of the intended conditions of use of the material or article in which the substance would be used, and only a user can provide such information. Moreover, if provided, such information would to a large extent determine the scope of any future authorisation which would be likely more limited than the present wide authorisation. Consequently, as no specific use or user of salicylic acid is known, and given the uncertainty over the conditions of use under which the use of this substance would comply with Regulation (EC) No 1935/2004, it is appropriate to revoke the present authorisation of salicylic acid.

(5) Based on an opinion of the Authority adopted in 2005[5], five substances from a group commonly known as 'phthalates', namely FCM No 157 ('DBP'), FCM No 159 ('BBP'), FCM No 283 ('DEHP'), FCM No 728 ('DINP') and FCM No 729 ('DIDP'), are authorised as additives for use as plasticisers and technical support agents in plastic FCM, subject to specific restrictions of use and migration limits.

(6) Following an opinion in 2017 by the European Chemicals Agency ('ECHA') on restriction proposals for some of these phthalates[6], the Commission requested the Authority to re-assess the risk to public health from phthalates that are authorised to be used in plastic FCM. The Authority consequently adopted a scientific opinion on 18 September 2019[7], confirming the individual TDIs set out in its 2005 opinion for all five phthalates but only on a temporary basis (t-TDI), because of a number of limitations and uncertainties related to the assessment, which should be addressed in the future.

4 EFSA Journal 2020;18(6):6124

5 EFSA Journal 2005; 3(9):747.

6 ECHA Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC) Opinion on an Annex XV dossier proposing restrictions on four phthalates (DEHP, BBP, DBP, DIBP); ECHA/RAC/RES-O-0000001412-86-140/F and ECHA/SEAC/RES-O-0000001412-86-154/F respectively. Available online https://echa.europa.eu/documents/10162/a265bf86-5fbd-496b-87b4-63ff238de2f7.

7 EFSA Journal 2019;17(12):5838.

(7) Based on a common mechanism of action underlying the reprotoxic effects of DBP, BBP and DEHP, the Authority also established a new group t-TDI, taking into account their relative potencies. The Authority further considered it appropriate to include DINP in the group t-TDI as a conservative approach based on its transient effects on foetal testosterone levels, whilst accounting for the higher potency of DINP on the liver. The authority set the group t-TDI for DBP, BBP, DEHP and DINP at 50 micrograms per kilogram of bodyweight (µg/kg bw) expressed as DEHP equivalent strength. The Authority did not include DIDP in the group t-TDI and set an individual t-TDI of 150 µg/kg bw based on effects on the liver, consistent with its findings from 2005.

(8) In order to further characterise the risk, the Authority carried out a dietary exposure assessment as part of the same opinion. Whilst it was unable to specifically determine the contribution from plastic FCM, it estimated dietary exposure for all five phthalates, which represent the worst-case estimates of exposure from FCM sources. Based on an aggregated dietary exposure assessment for DBP, BBP, DEHP and DINP, it concluded that dietary exposure contributes up to 14% of the group t-TDI of 50 µg/kg bw for the average consumer and up to 23% of the group t-TDI for high consumers. The estimates for DIDP indicate that dietary exposure is far below the t-TDI of 150 µg/kg bw for both average and high consumers.

(9) Additionally, the Authority considered consumers' exposure to other phthalates, notably 1,2-bis(2-methylpropyl) benzene-1,2-dicarboxylate (diisobutyl phthalate or 'DIBP'; FCM No 1085; CAS number 84-69-5). The Authority noted that DIBP substantially adds to the overall exposure and risk to consumers from phthalates, from food and from other sources, and that such exposure together with its potency with regard to reproductive effects should also be taken into account by the risk manager. The Authority further noted that consumers' exposure to phthalates arises from sources other than the diet. Significant contribution to total phthalate exposure comes from their presence in consumer articles and construction materials and subsequent dermal contact with them, as well as from inhalation of air and dust in the indoor environment.

(10) In order to take into account the group t-TDI for DBP, BBP and DEHP and the Authority's conclusions as regards DIBP, and, in particular, to ensure that exposure to these phthalates from plastic FCM does not exceed the group t-TDI, a new total specific migration limit (SML(T)) should be established. However, for the sake of clarity and simplification, in particular in establishing compliance or when carrying out official controls in cases where one of these phthalates has been used alone, individual SMLs should be maintained for the authorised phthalates in addition to the SML(T)s.

(11) Although the Authority also included DINP in the group t-TDI, an SML(T) was previously established for DINP together with DIDP because they are mixtures that overlap chemically and could not be distinguished analytically in the case of co-occurrence. Although there have been advances in analytical methods since the establishment of that SML(T), further validation work is still required before DINP and DIDP can be routinely differentiated by competent authorities when undertaking official controls. It is therefore appropriate to maintain a separate SML(T) for the sum of DINP and DIDP and to prohibit the use of DINP together with DBP, BBP and DEHP in order to avoid any potential co-exposure from the same plastic FCM.

(12) Taking into account that the aggregated exposure from both FCMs and sources other than FCMs is expected to be in the order of the t-TDI, and that accumulation may occur in the food manufacturing chain due to migration from food processing equipment as well as from food packaging, and taking account that there is a significant level of uncertainty regarding the present exposure estimates, it is appropriate to account for the exposure by means of an allocation factor of 20% for DBP, BBP, DEHP and DINP in plastic FCM. Taking into account the need to also maintain the SML(T) for DINP and DIDP, it is appropriate to use that allocation factor for all five phthalates when setting the SML(T) and the individual SMLs.

(13) The substance diethyl[[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]methyl] phosphonate (FCM No 1007) is presently authorised for use up to 0,2 % (w/w) based on the final polymer weight in the polymerisation process to manufacture poly(ethylene terephthalate) ('PET'). Following an application for the extension of use of this substance, on 26 January 2022, the Authority adopted a favourable scientific opinion[8] on its use up to 0,1 % w/w based on the final polymer weight in the polymerisation process to manufacture poly(ethylene 2,5-furandicarboxylate) ('PEF'). The Authority concluded that, when used in this amount, migration of the substance could not be detected due to its incorporation in the polyester chain. Because of that incorporation, there is also no reason to assume that, when used in PEF at a use level of 0,2 % w/w, migration of the substance would be substantially higher. As the safe use of the substance thus stems from its full incorporation into the polymer, and for the sake of consistency and simplicity, it is appropriate to extend the existing authorisation for the use level of this substance in PET at 0.2 % w/w also to the manufacture of PEF.

(14) Commission Regulation (EU) 2019/1338[9] authorised the substance Poly((R)-3-hydroxybutyrate-co-(R)-3-hydroxyhexanoate) ('PHBH', FCM No 1059). However, it appears the specification of the permitted use of that substance requires clarification. On the one hand, since PHBH is a macromolecule obtained from microbial fermentation and Regulation (EU) No 10/2011 requires that it is specified that a macromolecule is obtained from such fermentation, the reference to this production method should be added to the specification of PHBH. In addition, the authorisation allows for a short heating up phase, without specifying what that means. This absence of a maximum temperature could allow for heating at temperatures beyond those foreseen in the opinion of the Authority on which basis the substance was authorised, which indicates that a plastic manufactured with the substance could melt above 120ºC. Moreover, absence of a maximum temperature implies that it is not clear which testing conditions should be used to verify compliance with Regulation (EU) No 10/2011 as regards the specification concerning the 'short heating up phase'. The specification should therefore be clarified by indicating a condition of use as that does not exceed the temperature conditions foreseen in the opinion.

(15) On 19 September 2019, the Authority adopted a favourable scientific opinion[10] on the use of the substance 1,2,4-tris(2-ethylhexyl) benzene-1,2,4-tricarboxylate ester (FCM No 1078, CAS number 3319-31-1), as an additive (plasticiser) in poly(vinyl chloride)

[8] doi: 10.2903/j.efsa.2022.7172

[9] Commission Regulation (EU) 2019/1338 of 8 August 2019 amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (OJ L 209, 9.8.2019, p. 5).

[10] EFSA Journal 2019; 17(10):5864 ; the Authority refers in its opinion to 'trimellitic acid, tris(2-ethylhexyl) ester', whereas this Regulation refers to its IUPAC name '1,2,4-tris(2-ethylhexyl) benzene-1,2,4-tricarboxylate'.

('PVC') FCM. In that opinion, the Authority concluded that overall the use of FCM No 1078 does not raise a safety concern if its migration does not exceed 5 mg/kg food. The Authority however indicated that due to the additional contribution from other sources that may add to the exposure from plastic FCMs, the application of an allocation factor should be considered. In view of the absence of directly measured exposure data for this substance for the overall population from all sources, it is appropriate to apply an allocation factor of 20% until appropriate scientific data is provided. Moreover, in its opinion, the Authority stated that its evaluation does not cover the use of this substance in contact with 'infant foods'. Therefore, it has not been demonstrated that the use of this substance in contact with 'infant foods' would meet the requirements of Article 3 of Regulation (EC) No 1935/2004. Therefore, it is appropriate to add a restriction that prevents the use of this substance in contact with such foods. For the sake of clarity and consistency with similar restrictions, it is appropriate to refer to the definition of 'infant' laid down in Article 2(2)(a) of Regulation (EU) No 609/2013 of the European Parliament and of the Council[11].

(16) Furthermore, since group restriction 32 in table 2 of Annex I to Regulation (EU) No 10/2011 sets out a SML(T)s for plasticisers and that the substance FCM No 1078 is also a plasticiser, it is appropriate to apply this group restriction also to that substance. In addition, to clear any doubt over the nature of this group restriction, it is appropriate to indicate that it concerns plasticisers.

(17) Following an application for authorisation of the use of the substance (triethanolamine-perchlorate, sodium salt) dimer (FCM No 1080), as an additive in rigid PVC for repeated use bottles intended for contact with water, the Authority adopted on 29 April 2020 a favourable scientific opinion[12] on that use. The Authority concluded that its use would be safe if in contact with water and acidic aqueous foods, such as fruit juices, as, in both water and acidic aqueous foods, the substance (triethanolamine-perchlorate, sodium salt) dimer fully dissociates into triethanolamine and perchlorate. Those two substances are already included in the Union list of authorised substances, triethanolamine as FCM No 793 with a migration limit of 0,05 mg/kg, and perchlorate as FCM No 822 with a migration limit of 0,002 mg/kg. The Authority concluded that those limits should also apply to FCM No 1080 because, if the substance is used in plastic in contact with water and acidic aqueous foods, its safety is fully controlled by the migration limits established for those two substances due to its dissociation. The Authority furthermore confirmed that the migration of FCM No 822 should be expressed as perchlorate[13]. It is therefore appropriate to establish two group restrictions in table 2 of Annex I to Regulation (EU) No 10/2011, encompassing the FCM substance No 1080 together with FCM substance No 793 in one group, and with FCM substance No 822 expressed as perchlorate in the other group. It is therefore appropriate to amend substances FCM No 793 and 822 accordingly, and to include the substance (triethanolamine-perchlorate, sodium salt)

11 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).

12 EFSA Journal 2020;18(5):6046.

13 Scientific panel on FCM, Enzymes, and processing aids (CEP), Minutes of the 19th meeting of the working group on FCM 2018-2021, 30 September 2020, point 7(1).

dimer (FCM No 1080) as an additive in the Union list of authorised substances, with the restrictions that it should only be used in contact with water and acidic aqueous foods.

(18) Following an application for the authorisation of the use of the substance N, N-bis(2-hydroxyethyl)stearylamine partially esterified with saturated C16/C18 fatty acids (FCM No 1081), as an additive, in plastic FCM in contact with dry foods, acidic foods and alcoholic beverages with storage up to six months at ambient temperature, the Authority adopted a partially favourable scientific opinion[14] on that use. As part of its evaluation, the Authority considered the migration data provided by the applicant for testing for storage conditions above six months at room temperature and below. The Authority concluded that N,N-bis(2-hydroxyethyl)stearylamine is not a safety concern for the consumer when used at up to 2% (w/w) in all polymers intended for contact only with dry foods, provided that the migration of the sum of N,N-bis(2-hydroxyethyl)stearylamine and its mono- and di-ester, calculated as N,N-bis(2-hydroxyethyl)stearylamine, does not exceed, the SML(T) for FCM substances No 19 and 20, in which according to the Authority the migration of the mono- and di-ester of N,N-bis(2-hydroxyethyl)stearylamine was also to be included. Therefore, it is appropriate to authorise the use of this substance at up to 2% (w/w) for manufacturing plastic FCM intended to be in contact only with dry foods at room temperature, and it should be included in the group restriction laid down for the substances with FCM No 19 and 20.

(19) However, the Authority also considered that the data provided did not enable the safety assessment of the substance with FCM No 1081 when in contact with acidic foods and alcoholic beverages, and indicated that migration would be high in particular in contact with fatty foods. Therefore, it is appropriate that the foreseeable risk that consumers would use a plastic containing this substance in contact with foods other than dry foods is mitigated. To that purpose, this substance should only be used in applications for use by food business operators to package food. In addition, the Authority noted that migration may increase with a lower degree of esterification and may exceed migration limits in case of a higher thickness of the plastic material in which it is applied, and that also other parameters, such as the polarity of the polymer, could be relevant. Therefore, it is appropriate to indicate in a note on the verification of compliance that there is a risk that migration limits may be exceeded based on the thickness of the material, the polarity of the polymer and the degree of esterification of the substance itself.

(20) The Authority adopted a favourable scientific opinion[15] on the use of the substance phosphoric acid, mixed esters with 2-hydroxyethyl methacrylate (FCM No 1082) in polymethylmethacrylate-based composites intended for repeated contact with all food types. The Authority concluded that that substance is not a safety concern for the consumer if used as a co-monomer at up to 0.35% w/w, and provided that its migration does not exceed 0.05 mg/kg food expressed as the sum of the mono-, di- and triesters of phosphoric acid and the mono-, di-, tri- and tetraesters of diphosphoric acid. Although the Authority referred to the use of this substance in ‘composites’, that term may cover also materials which are not polymers and, therefore, which are not plastic within the meaning of Regulation (EU) No 10/2011. Consequently it is appropriate to authorise the use of this starting substance in the manufacture of

[14] EFSA Journal 2020;18(3):6047.
[15] EFSA Journal 2020;18(5):6120.

polymethylmethacrylate up to 0.35% w/w and to lay down a migration limit in according to the opinion of the Authority.

(21) The Authority adopted a favourable scientific opinion[16] on the use of the starting substance benzophenone-3,3',4,4'-tetracarboxylic dianhydride ('BTDA') (FCM No 1083). The Authority concluded that the use of the substance BTDA is not a safety concern for the consumer if it is applied at up to 43% as a co-monomer in the production of polyimides for contact with foods at temperatures up to 250°C, provided that the migration of BTDA does not exceed 0.05 mg/kg. Therefore it is appropriate to authorise the use of this starting substance for the use in polyimides at up to 43% w/w polymer, intended for use in contact with foods at temperatures up to 250°C, and subject to a migration limit of 0.05 mg/kg food.

(22) In order to allow operators to adapt to the changes to certain existing authorisations set out in this Regulation, it is appropriate to provide that plastic materials and articles complying with Regulation (EU) No 10/2011, as applicable before the date of the entry into force of this Regulation, are allowed to be first placed on the market for a transition period of 18 months after the entry into force of this Regulation and remain on the market until the exhaustion of stocks. However, the production of final plastic materials and articles typically involves the supply of several products and substances from intermediate manufacturing stages by other operators. For the sake of consumer safety, the transition to full compliance with this Regulation should be achieved as efficiently as possible, and with minimum delay. Therefore, operators manufacturing intermediate products and substances that do not yet comply with this Regulation, should be required to inform the users of these products already within nine months following the entry into force of this Regulation that these products, as provided, cannot be used to manufacture plastic materials and articles to be placed on the market after the transition period of 18 months ends.

(23) This Regulation revokes the authorisations for the substances 'wood flour and fibres, untreated' (FCM No 96) and salicylic acid (FCM No 121) because it cannot be established that those authorisations, as they currently stand, are in accordance with Regulation (EU) No 1935/2004 given that information about specific substances or specific uses of those substances would be required to ensure that those authorisations do not go beyond what is safe. However, in order to ensure a smooth transition to potential more limited authorisations in case operators that have been manufacturing or using these substances before the entry into force of this Regulation consider that some specific uses comply with Regulation (EU) No 1935/2004, it is appropriate to allow the placing on the market of plastic materials and articles manufactured with those substances provided that an application for authorisation of those specific uses is submitted within a proportionate period after the entry into force of this Regulation. With regards to untreated wood flour and fibres, since the Authority in its opinion on wood[3] considered that wood like materials need to be evaluated on a case-by-case basis, specific to the species, such an application should be specific to a certain wood species.

(24) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

[16] EFSA Journal 2020;18(7):6183.

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Annex I to Regulation (EU) No 10/2011

Annex I to Regulation (EU) No 10/2011 is amended in accordance with the Annex to this Regulation.

Article 2

Transitional measures

1. Plastic materials and articles complying with Regulation (EU) No 10/2011 as applicable before the entry into force of this Regulation, which were first placed on the market before *[enter date 18 months after the date of entry into force of this Regulation]* may remain on the market until the exhaustion of stocks.

2. In case a product from an intermediate stage of the manufacturing of plastic materials and articles or a substance intended for the manufacturing of such a product, material or article, which complies with Regulation (EU) No 10/2011 as applicable before the entry into force of this Regulation and which is first placed on the market after *[enter date 9 months after the date of entry into force of this Regulation]* does not comply with this Regulation, the declaration of compliance available for that substance or product shall indicate that it does not comply with the present rules, and that it can only be used in the manufacture of plastic materials and articles to be placed on the market before *[enter date 18 months after the date of entry into force of this Regulation]*.

3. Plastic materials and articles manufactured with salicylic acid (FCM 121) or manufactured with untreated wood flour or fibres from a specific wood species may continue to be first placed on the market after [*enter date 18 months after entry into force of this Regulation*] provided that the following conditions are fulfilled:

   (a) an application for the authorisation of that substance or of that untreated wood flour or fibre from a specific wood species has been submitted to the competent authority in accordance with Article 9 of Regulation (EC) No 1935/2004 before [*enter date 9 months after entry into force of this Regulation*];

   (b) the use of that substance or of that untreated flour or fibre from a specific wood species to manufacture a plastic material and article, and the use thereof, is limited to the intended conditions of use described in the application;

   (c) the information provided to the Authority in accordance with Article 9(1)(b) of Regulation (EC) No 1935/2004 includes a statement that the application is an application in accordance with this paragraph, and

   (d) The Authority has considered the application valid.

4. Plastic materials and articles manufactured with the substance or the untreated wood flour or fibre subject to an application may then continue to be used until the applicant withdraws its application or until the Commission adopts a decision granting or refusing the authorisation for the use of that substance or wood flour or fibre pursuant to Article 11(1) of Regulation (EC) No 1935/2004.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in *the Official Journal of the European* Union.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN

347 **ANNEX**

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

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

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

352 (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)”

353 (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) ”

354 (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)”

355 (e) entry 452 on 2,4-bis(2,4-dimethylphenyl)-6-(2-hydroxy-4-n-octyloxyphenyl)-
356 1,3,5-triazine is replaced by the following:

“452	38885	000272 5-22-6	2,4-bis(2,4-dimethylphenyl)-6-(2-hydroxy-4-n-octyloxyphenyl)-1,3,5-triazine	yes	no	yes	5			”

(f) entry 728 on phthalic acid, diesters with primary, saturated C_8-C_{10} branched alcohols, more than 60 % C_9 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)”

(g) entry 793 on triethanolamine is replaced by the following:

“793	94000	000010 2-71-6	triethanolamine	yes	no	no		(37) ”		

(h) 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) ”		

(i) 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]phospho	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	”

			nate						poly(ethylene 2,5-furandicarboxylate) (PEF)	

(j) entry 1059 on poly((R)-3-hydroxybutyrate-co-(R)-3-hydroxyhexanoate) is replaced by the following:

"1059		147398-31-0	Poly((R)-3-hydroxybutyrate-co-(R)-3-hydroxyhexanoate) ('PHBH')	no	yes	no		(35)	The substance is a macromolecule obtained 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.	(23)"

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

"1078		3319-31-1	1,2,4-tris(2-ethylhexyl) benzene-1,2,4-tricarboxylate	yes	no	no	1	(32)	Not to be used in contact with foods intended for infants (*)	
1080		156157-97-0	(triethanolamine-perchlorate, sodium salt) dimer	yes	no	no		(37) (38)	Only to be used in contact with foods for which only simulants A and/or B are assigned in table 2 of Annex III	
1081		-	N, N-bis(2-hydroxyethyl)stearylamine 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	yes	no	no	0.05		Only to be used at up to 0,35% (w/w) to manufacture polymethylmethacrylate-based composites.	

1083		2421-28-5	Benzophenone-3,3',4,4'-tetracarboxylic dianhydride ('BTDA')	no	yes	no	0.05		Only to be used at up to 43% (w/w) as a co-monomer in the production of polyimides for repeated use contact with acidic or fatty foods 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"

(b) entry 26 is replaced by the following:

"26	728 729	1,8	expressed as the sum of the substances"

(c) entry 32 is replaced by the following:

"32	8 72 73 138 140 157 159 207 242 283 532 670 728 729 775 783 797 798 810 815 1078	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."

	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 based on the thickness of the plastic in which the substance is contained, the polarity of the polymer and the degree of esterification of the substance itself”