

REGULATIONS

COMMISSION REGULATION (EU) 2015/174

of 5 February 2015

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

(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 points (a), (c), (d) and (e) of Article 5(1), Article 11(3) and Article 12(6) thereof,

Whereas:

- (1) Annex I to Commission Regulation (EU) No 10/2011 ⁽²⁾ establishes a Union list of authorised substances ('the Union list') which may be used in the manufacture of plastic materials and articles.
- (2) Tartaric acid (food contact material (FCM) substance No 161) was assessed by the Scientific Committee for Foods (SCF) in 1991 ⁽³⁾. The SCF gave a favourable opinion only to the natural occurring form of tartaric acid (L-(+)-tartaric acid). It explicitly excluded the DL form of tartaric acid. It followed from the SCF assessment that only L-(+)-tartaric acid does not endanger human health, while this has not been shown for all other forms of that substance. Therefore, it should be clear from the name of the substance as included in Table 1 of Annex I to Regulation (EU) No 10/2011 that it refers only to L-(+)-tartaric acid. Therefore, the name of FCM substance No 161 should be amended accordingly.
- (3) The European Food Safety Authority (the Authority) adopted an opinion re-evaluating the tolerable daily intake (TDI) of phenol ⁽⁴⁾. Phenol (FCM No 241) is included as a starting substance in Table 1 of Annex I to Regulation (EU) No 10/2011. The generic specific migration limit (SML) of 60 mg/kg set out in Article 11(2) of Regulation (EU) No 10/2011 applies to that substance. In the re-evaluation of phenol, the Authority reduced the TDI from 1,5 mg/kg body weight ('bw')/day to 0,5 mg/kg bw/day. The Authority noted that the exposure from all sources was above the TDI, while exposure from food contact materials was likely to be in the range of the TDI. In addition to the TDI, an allocation factor of 10 % for the exposure from food contact materials should be used to achieve a sufficient reduction in phenol exposure. The setting of the migration limit takes into account a conventional exposure assumption that 1 kg of food is consumed daily by a person of 60 kg body weight. Therefore, on the basis of the TDI, the allocation factor and the exposure assumption a specific migration limit of 3 mg/kg for phenol should be set to ensure that phenol does not endanger human health.
- (4) 1,4-Butanediol formal (FCM No 344) was evaluated by the SCF in 2000 ⁽⁵⁾. The SCF concluded that a SML of 0,05 mg/kg should be set for that substance. Column 8 of Table 1 of Annex I to Regulation (EU) No 10/2011 incorrectly states that migration of the substance shall be non-detectable and should therefore be corrected.
- (5) The SCF proposed to determine the residual content of the substance 1,4-butanediol formal (FCM No 344) in the material instead of verifying compliance against the SML, because no suitable method to determine the substance in a food or simulant was available. Suitable methods to determine the substance in a food or simulant

⁽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⁾ Report of the Scientific Committee for foods, 25th series, EUR 13416, 1991.

⁽⁴⁾ EFSA Journal 2013; 11(4):3189.

⁽⁵⁾ Opinion of the Scientific Committee on Food on the 11th additional list of monomers and additives for food contact materials, SCF/CS/PM/GEN/M8313, November 2000.

are available now. Therefore, verifying compliance by determining the residual should be replaced by migration testing. 1,4-butanediol formal may hydrolyse in contact with foods or simulants to form 1,4-butanediol (FCM No 254) and formaldehyde (FCM No 98). Therefore the total specific migration limits set for these substances should not be exceeded. As a result 1,4-butanediol formal should be added to group restrictions 15 and 30. As hydrolysis occurs only in certain cases, rules which indicate when verification of compliance to these group restrictions is needed should be added to Table 3.

- (6) The Authority adopted a favourable scientific opinion ⁽¹⁾ on a possible extension of the use of starting substance 1,4:3,6-dianhydrosorbitol (FCM No 364) to the use as a co-monomer for the production of polyesters, if used at levels of up to 40 mol % of the diol component in combination with ethylene glycol and/or 1,4-bis(hydroxymethyl)cyclohexane, and if polyesters made using 1,4:3,6-dianhydrosorbitol together with 1,4-bis(hydroxymethyl)cyclohexane are not used in contact with foods containing more than 15 % alcohol. The extension of the use of the substance to the new specifications does not endanger human health if those conditions are met. Therefore, the authorisation of FCM substance No 364 should be amended to include the additional specifications.
- (7) The Authority adopted a favourable scientific opinion ⁽²⁾ on a possible extension of the use of the substance kaolin (FCM No 410) to include particles in the nanoform with a thickness less than 100 nm and incorporated up to 12 % in ethylene vinyl alcohol (EVOH) copolymer. The extension of the use of the substance to the new specification does not endanger human health if those conditions are met. Therefore, the authorisation of FCM substance No 410 should be amended to include a specification and restriction on particle size.
- (8) The Union list includes a substance identified as 'charcoal, activated' (FCM No 713, CAS No 64365-11-3). Another substance is also used on the market, identified as 'activated carbon' (CAS No 7440-44-0). In practice the two substances are the same, and their names are used interchangeably and are synonymous. Therefore, it should be made clear that FCM substance No 713 covers the substance under the name 'charcoal, activated' and applies to both CAS numbers. The authorisation of FCM substance No 713 should therefore be amended by adding the CAS No for activated carbon.
- (9) On the basis of new toxicological data the Authority adopted a favourable scientific opinion ⁽³⁾ which allows increasing the migration limit for the additive 1,3,5-tris(2,2-dimethylpropanamido)benzene (FCM No 784). to 5 mg/kg food. Therefore, the authorisation of substance FCM No 784 should be amended accordingly.
- (10) The restriction which is defined for polyethyleneglycol (EO = 1-50) ethers of linear and branched primary (C₈-C₂₂) alcohols (FCM No 799) refers to the purity criteria for ethylene oxide laid down in Commission Directive 2008/84/EC ⁽⁴⁾. That Directive has been repealed by Commission Regulation (EU) No 231/2012 ⁽⁵⁾ which specifies the purity criteria for certain food additives setting out a maximum ethylene oxide content for those additives. That maximum should also apply to substances with FCM No 799.
- (11) The group of substances 'acids, fatty (C₈-C₂₂), esters with pentaerythritol' (FCM No 880) is listed in Table 1 of Annex I to Regulation (EU) No 10/2011 with CAS No 85116-93-4. This CAS number refers only to a subgroup of FCM No 880, and is therefore inappropriate. For the group with FCM No 880 no CAS number is defined. Therefore, the listing of FCM substance No 880 in Table 1 of Annex I should be amended by deleting the CAS number.
- (12) The Authority adopted a favourable scientific opinion ⁽⁶⁾ on the possible extension of the use of the substance 2,2,4,4-tetramethylcyclobutane-1,3-diol (FCM No 881) to single use applications. The opinion concluded that for single use applications, the substance does not raise a safety concern if used as co-monomer in the production of polyesters at use levels up to 35 mol % of the diol component, in contact with all food types other than spirits and highly fatty foods to be simulated by food simulant D2 (vegetable oil) for long time storage at room temperature or below and hot fill. In its evaluation the authority only considered migration tests with 10 % ethanol and 3 % acetic acid as basis for full evaluation. Therefore, the extension of use should also not include foods with an alcohol content over 10 %. Therefore, if the permitted use of this substance is extended accordingly and includes the new specifications, the use of this substance does not endanger human health. Therefore, the authorisation of FCM substance No 881 should be amended accordingly.

⁽¹⁾ EFSA Journal 2013; 11(6):3244.

⁽²⁾ EFSA Journal 2014; 12(4):3637.

⁽³⁾ EFSA Journal 2013; 11(7):3306.

⁽⁴⁾ Commission Directive 2008/84/EC of 27 August 2008 laying down specific purity criteria on food additives other than colours and sweeteners (OJ L 253, 20.9.2008, p. 1).

⁽⁵⁾ Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).

⁽⁶⁾ EFSA Journal 2013; 11(10):3388.

- (13) The Authority adopted a scientific opinion ⁽¹⁾ on the use of three new substances in nanoform, (butadiene, ethyl acrylate, methyl methacrylate, styrene) copolymer cross-linked with divinylbenzene (FCM No 859), (butadiene, ethyl acrylate, methyl methacrylate, styrene) copolymer not cross-linked (FCM No 998) and (butadiene, ethyl acrylate, methyl methacrylate, styrene) copolymer cross-linked with 1,3-butanediol dimethacrylate (FCM No 1043). The Authority has no safety concern in case those substances are used at a maximum combined weight percentage of 10 % w/w in non-plasticised polyvinyl chloride in contact with all food types at ambient temperature or below, including long-term storage, and when used individually or in combination as additives, and when the diameter of the particles is larger than 20 nm, and for at least 95 % by number the diameter is larger than 40 nm. Therefore, the use of those substances does not endanger human health when used in accordance with those specifications, and these substances should be inserted accordingly in Table 1 of Annex I to Regulation (EU) No 10/2011.
- (14) The Authority adopted a favourable scientific opinion ⁽²⁾ on the use of the new polymer production aid 2H-perfluoro-[(5,8,11,14-tetramethyl)-tetraethyleneglycol ethyl propyl ether] (FCM No 903). That substance should only be used as a polymer production aid in the polymerisation process of fluoropolymers. During that process the sintering or processing conditions set out in the opinion should be applied. The use of this substance does not endanger human health when used in accordance with those specifications and it should be added to Table 1 of Annex I to Regulation (EU) No 10/2011.
- (15) The Authority adopted a favourable scientific opinion ⁽³⁾ on the use of the new additive ethylene-vinyl acetate copolymer wax (FCM No 969), provided that the substance is used as an additive up to 2 % w/w in only polyolefin materials and articles and the migration of low molecular weight oligomeric fraction below 1 000 Da does not exceed 5 mg/kg food. The use of this substance does not endanger human health when used in accordance with those specifications and it should be added to Table 1 of Annex I to Regulation (EU) No 10/2011.
- (16) The Authority adopted a favourable scientific opinion ⁽⁴⁾ on the use of the new additive polyglycerol (FCM No 1017). The opinion concluded that the substance does not raise a safety concern if it is used as plasticiser at a maximum use level of 6,5 % w/w in polymer blends of aliphatic-aromatic polyesters. As the opinion states that the substance is a naturally occurring hydrolysis product of an authorised food additive (E475) with authorised use levels up to 10 g/kg food, it can be concluded that the substance would be of no safety concern when migration is above the generic specific migration limit referred to Article 11(2) of Regulation (EU) No 10/2011. The Authority reached its conclusion also on the basis that the substance would not decompose during its processing in plastic material. Therefore, the use of the substance would not endanger human health if the generic specific migration limit is respected and decomposition of the substance during processing is avoided. Therefore, this additive should be added to Table 1 of Annex I to Regulation (EU) No 10/2011, with an additional specification preventing its decomposition during processing.
- (17) The mixture 'polyethyleneglycol (EO = 2-6) monoalkyl (C₁₆-C₁₈) ether' (FCM No 725) is a subgroup of the mixture, 'polyethyleneglycol (EO = 1-50) ethers of linear and branched primary (C₈-C₂₂) alcohols' (FCM No 799.) The SML and other restrictions for FCM No 799 are based on a more recent scientific evaluation ⁽⁵⁾. The entry for FCM No 725 is covered by the entry for FCM No 799 and should therefore be removed from Table 1 of Annex I to Regulation (EU) No 10/2011.
- (18) To limit the administrative burden to business operators, plastic materials and articles which have been lawfully placed on the market based on the requirements set out in Regulation (EU) No 10/2011 before the entry into force of this Regulation and which do not comply with this Regulation should be able to be placed on the market until 26 February 2016. They should be able to remain on the market until exhaustion of stocks.
- (19) Regulation (EU) No 10/2011 should therefore be amended accordingly.
- (20) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹⁾ EFSA Journal 2014; 12(4):3635.

⁽²⁾ EFSA Journal 2012; 10(12):2978.

⁽³⁾ EFSA Journal 2014; 12(2):3555.

⁽⁴⁾ EFSA Journal 2013; 11(10):3389.

⁽⁵⁾ FCM 725 was evaluated by the SCF, http://europa.eu.int/comm/food/fs/sc/scf/out20_en.pdf. FCM 799 was evaluated by EFSA, EFSA Journal (2008) 698-699.

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

Plastic materials and articles complying with the requirements of Regulation (EU) No 10/2011 as applicable before 26 February 2015 may be placed on the market until 26 February 2016. Those plastic materials and articles may remain on the market after that date until exhaustion of stocks.

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, 5 February 2015.

For the Commission

The President

Jean-Claude JUNCKER

ANNEX

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

(1) Table 1 is amended as follows:

(a) the entries concerning FCM substances Nos 161, 241, 344, 364, 410, 713, 784, 799, 880 and 881 are replaced by the following:

161	92160	000087-69-4	L-(+)-tartaric acid	yes	no	no				
241	22960	0000108-95-2	phenol	no	yes	no	3			
344	13810	0000505-65-7	1,4-butanediol formal	no	yes	no	0,05	15 30		(21)
	21821									
364	15404	0000652-67-5	1,4:3,6-dianhydrosorbitol	no	yes	no	5		<p>Only to be used as:</p> <p>(a) a co-monomer in poly (ethylene-co-isosorbide terephthalate);</p> <p>(b) a co-monomer at levels of up to 40 mole % of the diol component in combination with ethylene glycol and/or 1,4-bis(hydroxymethyl)cyclohexane, for the production of polyesters.</p> <p>Polyesters made using dianhydrosorbitol together with 1,4-bis(hydroxymethyl)cyclohexane shall not be used in contact with foods containing more than 15 % alcohol.</p>	
410	62720	0001332-58-7	kaolin	yes	no	no			<p>Particles can be thinner than 100 nm only if incorporated at a quantity of less than 12 % w/w in an ethylene vinyl alcohol copolymer (EVOH) inner layer of a multi-layer structure, in which the layer in direct contact with the food provides a functional barrier preventing migration of particles into the food.</p>	

713	43480	0064365-11-3	charcoal, activated	yes	no	no			Only for use in PET at maximum 10 mg/kg of polymer. Same purity requirements as for Vegetable Carbon (E 153) set out by Commission Regulation (EU) No 231/2012 (*) with exception of ash content which can be up to 10 % (w/w).	
		0007440-44-0								
784	95420	0745070-61-5	1,3,5-tris (2,2-dimethylpropa-namido) benzene	yes	no	no	5			
799	77708		polyethylene-glycol (EO = 1-50) ethers of linear and branched primary (C ₈ -C ₂₂) alcohols	yes	no	no	1,8		In compliance with the maximum ethylene oxide content as laid down in the purity criteria for food additives in Commission Regulation (EU) No 231/2012.	
880	31348		acids, fatty (C ₈ -C ₂₂), esters with pentaerythritol'	yes	no	no				
881	25187	0003010-96-6	2,2,4,4-tetramethylcyclobutane-1,3-diol	no	yes	no	5		Only for: (a) repeated use articles for long term storage at room temperature or below and hotfill; (b) single use materials and articles as a co-monomer at a maximum use level of 35 mole % of the diol component of polyesters, and if such materials and articles are for long term storage at room temperature or below of food types which have an alcohol content of up to 10 % and for which Table 2 of Annex III does not assign simulant D2. Hot fill conditions are allowed for such single use materials and articles.	

(*) Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).'

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

859			(butadiene, ethyl acrylate, methyl methacrylate, styrene) copolymer cross-linked with divinylbenzene, in nanoform	yes	no	no			<p>Only to be used as particles in non-plasticised PVC up to 10 % w/w in contact with all food types at room temperature or below including long-term storage.</p> <p>When used together with the substance with FCM No 998 and/or the substance with FCM No 1043, the restriction of 10 % w/w applies to the sum of those substances.</p> <p>The diameter of particles shall be > 20 nm, and for at least 95 % by number it shall be > 40 nm.</p>	
903		37486-69-4	2H-perfluoro-[(5,8,11,14-tetramethyl)-tetraethylene-glycol ethyl propyl ether]	yes	no	no			<p>Only to be used as a polymer production aid in the polymerisation of fluoropolymers intended for:</p> <p>(a) repeated and single use materials and articles when sintered or processed (non-sintered) at temperatures at or above 360 °C for at least 10 minutes or at higher temperatures for equivalent shorter times;</p> <p>(b) repeated use materials and articles when processed (non-sintered) at temperatures from 300 °C and up to 360 °C for at least 10 minutes.</p>	
969		24937-78-8	ethylene-vinyl acetate copolymer wax	yes	no	no			<p>Only to be used as a polymeric additive up to 2 % w/w in polyolefins.</p> <p>The migration of low molecular weight oligomeric fraction below 1 000 Da shall not exceed 5 mg/kg food.</p>	
998			(butadiene, ethyl acrylate, methyl methacrylate, styrene) copolymer not cross-linked, in nanoform	yes	no	no			<p>Only to be used as particles in non-plasticised PVC up to 10 % w/w in contact with all food types at room temperature or below including long-term storage.</p>	

								When used together with the substance with FCM No 859 and/or the substance with FCM No 1043, the restriction of 10 % w/w applies to the sum of those substances. The diameter of particles shall be > 20 nm, and for at least 95 % by number it shall be > 40 nm.	
1017		25618-55-7	polyglycerol	yes	no	no		To be processed under conditions preventing the decomposition of the substance and up to a maximum temperature of 275 °C.	
1043			(butadiene, ethyl acrylate, methyl methacrylate, styrene) copolymer cross-linked with 1,3-butanediol dimethacrylate, in nano-form	yes	no	no		Only to be used as particles in non-plasticised PVC up to 10 % w/w in contact with all food types at room temperature or below including long-term storage. When used together with the substance with FCM No 859 and/or the substance with FCM No 998, the restriction of 10 % w/w applies to the sum of those substances. The diameter of particles shall be > 20 nm, and for at least 95 % by number it shall be > 40 nm.'	

(c) The entry concerning FCM substance No 725 is deleted.

(2) In Table 2, the entries concerning group restrictions Nos 15 and 30 are replaced by the following:

'15	98 196 344	15	expressed as formaldehyde
30	254 344 672	5	expressed as 1,4-butanediol'

(3) In Table 3, the following entry is added:

'(21)	In case of reaction with foods or simulants verification of compliance shall include verification that the migration limits of the hydrolysis products, formaldehyde and 1,4-butanediol, are not exceeded.'
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