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)

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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 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[(6)] 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[(7)] 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[8] 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 (C_8-C_{22}) alcohols (FCM No 799) refers to the purity criteria for ethylene oxide laid down in Commission Directive 2008/84/EC[9]. That Directive has been repealed by Commission Regulation (EU) No 231/2012[10] 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 (C_8-C_{22}), 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[11] 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.

(13) The Authority adopted a scientific opinion[12] 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[13] 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[14] 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[15] 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 (C_{16}-C_{18}) ether' (FCM No 725) is a subgroup of the mixture, 'polyethyleneglycol (EO = 1-50) ethers of linear and branched primary (C_8-C_{22}) alcohols' (FCM No 799.) The SML and other restrictions for FCM No 799 are based on a more recent scientific evaluation[16]. 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,

HAS ADOPTED THIS REGULATION:

(**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.

(**6**) EFSA Journal 2013; 11(6):3244.

(**7**) EFSA Journal 2014; 12(4):3637.

(**8**) EFSA Journal 2013; 11(7):3306.

(**9**) 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).

(**10**) 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).

(**11**) EFSA Journal 2013; 11(10):3388.

(**12**) EFSA Journal 2014; 12(4):3635.

(**13**) EFSA Journal 2012; 10(12):2978.

(**14**) EFSA Journal 2014; 12(2):3555.

(**15**) EFSA Journal 2013; 11(10):3389.

(**16**) 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.