Commission Regulation (EU) 2019/37 of 10 January 2019 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance)

COMMISSION REGULATION (EU) 2019/37

of 10 January 2019

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), (d), (e), (h) and (i) 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 which may be used in the manufacture of plastic materials and articles intended to come into contact with food. Annex III to that Regulation assigns food simulants to be used for tests to demonstrate compliance of plastic materials and articles not yet in contact with food with the migration limits referred to in Articles 11 and 12 of that Regulation.

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

(3) The name of the substance 1,2,3,4-tetrahydronaphthalene-2,6-dicarboxylic acid, dimethyl ester (FCM substance No 1066 and CAS No 23985-75-3) authorised by Commission Regulation (EU) 2018/831[(3)] as listed in Table 1 of point 1 of Annex I to Regulation (EU) No 10/2011 contains a typographical error in the English version of the document. It is therefore necessary to correct this entry in Table 1 of point 1 of Annex I to Regulation (EU) No 10/2011.

(4) On the basis of the favourable scientific opinion of the Authority[(4)], on the use of substance [3-(2,3-epoxypropoxy)propyl]trimethoxy silane (FCM substance No 1068, CAS No 2530-83-8) as a component of sizing agents to treat glass fibres imbedded

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in low diffusivity plastics such as in polyethylene terephthalate (PET), polycarbonate (PC), polybutylene terephthalate (PBTP), thermoset polyesters, and epoxy bisphenol vinyl ester intended for single and repeated use with long-term storage at room temperature, short-term repeated contact at increased or high temperature and for all foods, the substance was authorised by Regulation (EU) 2018/831 as an additive or polymer production aid in column 5 of Table 1 of point 1 of Annex I to Regulation (EU) No 10/2011. As this substance is intended to react with the polymeric backbone of the plastic material and may become part of it, it should be considered as a starting material or monomer in the manufacture of sizing agents to treat glass fibres imbedded in low diffusivity plastics such as in polyethylene terephthalate (PET), polycarbonate (PC), polybutylene terephthalate (PBTP), thermoset polyesters, and epoxy bisphenol vinyl ester. It is therefore necessary to amend this entry in Table 1 of point 1 of Annex I to Regulation (EU) No 10/2011 to include this substance in column 6 of Annex I to that Regulation in order to clarify its intended uses.

(5) The Authority adopted two favourable scientific opinions[(5)(6)] on the use of the substance poly((*R*)-3-hydroxybutyrate-co-(*R*)-3-hydroxyhexanoate) (FCM substance No 1059, CAS number 147398-31-0), which is a biodegradable (co)polymer obtained from microbial fermentation used in the manufacture of packaging articles intended to be in contact with whole fruit and vegetables. In those two opinions, the Authority concluded that this substance is not of a safety concern for the consumer if it is used either alone or blended with other polymers in contact with (dry/solid) foods for which food simulant E is assigned in Table 2 of Annex III to Regulation (EU) No 10/2011, under contact conditions up to 6 months or more at room temperature or below, including hot-fill or short heating up phases. The Authority further concluded that the specific migration of the degradation product crotonic acid should not exceed 0,05 mg/kg food. That substance should therefore be included in the Union list of authorised substances with the restriction that these specifications should be met.

(6) Crotonic acid (FCM substance No 467 and CAS No 3724-65-0) is authorised as an additive or a monomer in the manufacture of plastics intended to come into contact with foods. A specific migration limit of 0,05 mg/kg food was introduced in the entry for this substance in Table 1 of point 1 of Annex I to Regulation (EU) No 10/2011 by Commission Regulation (EU) 2017/752[(7)] replacing the previous compliance verification by residual content per food contact surface area (QMA). Compliance verification of crotonic acid by QMA with a limit of 0,05 mg/6 dm^2 is also included in the entry of the substance 3-hydroxybutanoic acid-3-hydroxypentanoic acid, copolymer (FCM substance No 744, CAS No 80181-31-3) in Table 4 of Annex I to Regulation (EU) No 10/2011 and should also be replaced by the specific migration limit assigned to FCM substance No 467. In light of the fact that the same specific migration limit for crotonic acid is to be applicable for FCM substances 467, 744, and 1059, it is appropriate to introduce a group restriction for crotonic acid for FCM substances 467, 744, and 1059 in Table 2 of Annex I to Regulation (EU) No 10/2011, and amend the corresponding individual entries in Tables 1 and 4 of that Annex.

(7) The Authority adopted a favourable scientific opinion[(8)] on the use of the substance dimethyl carbonate (FCM substance No 1067 and CAS No 616-38-6) as a monomer

in the manufacture of plastics intended to come into contact with foods. The Authority concluded that the substance is not of a safety concern for the consumer if used as co-monomer together with 1,6-hexanediol for making a polycarbonate pre-polymer and then reacted with 4,4′-methylenediphenyldiisocyanate and diols such as polypropylene glycol and 1,4-butanediol to form a thermoplastic polyurethane. The use of this material should be further restricted to contain up to 30 % of the polycarbonate pre-polymer and to be used only for repeated use articles in short–term contact (≤ 30 min) at room temperature with foods for which simulants A and B are assigned in Table 2 of Annex III to Regulation (EU) No 10/2011. Therefore, the substance should be included in the Union list of authorised substances provided these restrictions are met.

(8) The Authority also noted that the FCM substance No 1067 may also be used for the manufacture of other polycarbonates or under other conditions. In those cases, the Authority concluded that use of the substance is not of a safety concern for the consumer if the migration of dimethyl carbonate does not exceed 0,05 mg/kg food and the total migration of polycarbonate oligomers with a molecular weight below 1 000 Da does not exceed 0,05 mg/kg food. Therefore, those uses of the substance should be authorised provided those restrictions are met.

(9) The authorisation of the FCM substance No 1067 provided for in this Regulation for the manufacture of other polycarbonates or under other conditions, requires that the total migration of polycarbonate oligomers with a molecular weight below 1 000 Da does not exceed 0,05 mg/kg food. Analytical methods to determine the migration of these oligomers are complex. A description of those methods is not necessarily available to competent authorities. Without a description it is not possible for the competent authority to verify that the migration of oligomers from the material or article complies with the migration limit for these oligomers. Therefore, business operators placing on the market the final article or material containing that substance should be required to provide a description of the method and a calibration sample if required by the method.

(10) The Authority adopted a favourable scientific opinion[9] on the use of the substance isobutane (CAS number 75-28-5, FCM substance No 1069) as a foaming agent for plastics intended to come into contact with food. In that opinion, the Authority concluded that this substance is not of a safety concern for the consumer if it is used as a foaming agent in plastics intended to come into contact with food. Therefore, this use of the substance should be authorised. The class of compounds collectively termed ‘foaming agents’ also includes surfactants and are often understood to be surfactants only. To avoid potential confusion and in line with the function of this substance which was evaluated by the Authority, the synonymous term ‘blowing agent’ should be used in the entry for this substance in Table 1 of Annex I to Regulation (EU) No 10/2011.

(11) Table 3 of Annex III to Regulation (EU) No 10/2011 assigns food simulants to be used for tests to demonstrate compliance of plastic materials and articles not yet in contact with food with the overall migration limit laid down to in Article 12 of that Regulation. There is an ambiguity between rows 3 and 4 in their reference to the food simulants which are to be used for the overall migration testing of the products listed, and in particular of milk products. The third row refers to aqueous and alcoholic foods and

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milk products in general and provides for the use of food simulant D1 (50 % ethanol). The fourth row refers to aqueous, acidic and alcoholic foods and milk products and provides for the use of food simulant D1 and of food simulant B (3 % acetic acid). Food simulant B is to be used for acidic products with a pH value below 4,5 as laid down in point 2 of Annex III to Regulation (EU) No 10/2011. Milk products are mentioned in both rows because although milk itself has a relatively neutral pH (pH 6,5-6,8), certain processed (fermented or soured) milk products have acidic pH ranges between 4,0 and 4,5. This dichotomy could erroneously be interpreted to mean that acidic milk products are also included in the third row and thus could be tested only with food simulant D1 instead of with food simulant B as laid down in the fourth row. It is therefore appropriate to clarify the third and fourth rows of Table 3 by specifying the pH of the listed milk products using the pH value of 4,5 as the cut-off value.

(12) Annexes I and III to Regulation (EU) No 10/2011 should therefore be amended and corrected accordingly.

(13) 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:

Article 1

Annexes I and III to Regulation (EU) No 10/2011 are amended in accordance with the Annex to this Regulation.

Article 2

Plastic materials and articles complying with Regulation (EU) No 10/2011 as applicable before the entry into force of this Regulation may be placed on the market until 31 January 2020 and may remain on the market 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, 10 January 2019.

For the Commission

The President

Jean-Claude JUNCKER

ANNEX

Annexes I and III to Regulation (EU) No 10/2011 are amended as follows:

(1) in Annex I, Table 1 is amended as follows:

(a) the entries concerning FCM substances No 467, 744, 1066, and 1068 are replaced by the following:

467	14800 45600	3724-65-0	crotonic acid	yes	yes	no		(35)		
‘744	18888	080181-31-3	3-hydroxybutanoic acid-3-hydroxypentanoic acid, copolymer	no	yes	no		(35)	The substance is used as product obtained by bacterial fermentation. In compliance with the specifications mentioned in the Table 4 of Annex I.’	
‘1066		23985-72-3	1,2,3,4-tetrahydronaphthalene-2,6-dicarboxylic acid, dimethyl ester	no	yes	no	0,05		Only to be used as a co-monomer in the manufacture of a polyester non-food contact layer in a plastic multilayer material,	