Commission Regulation (EU) 2017/752 of 28 April 2017 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) 2017/752

of 28 April 2017

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 Article 5(1)(a), (c), (d), (e), (h), (i) and (j), and Article 11(3),

Whereas:

(1) Commission Regulation (EU) No 10/2011[(2)] ('the Regulation') lays down specific rules as regards plastic materials and articles intended to come into contact with foods.

(2) Since the last amendment to the Regulation, the European Food Safety Authority ('the Authority') has published further reports on particular substances that may be used in food contact materials 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 the Regulation reflects the most recent findings of the Authority and in order to remove any doubt as regards its correct application, the Regulation should be amended and corrected.

(3) The authorisation of several substances in Table 1 of Annex I to the Regulation refers to note (1) in Table 3 of that Annex. Compliance is therefore verified by residual content per food contact surface area (QMA) pending the availability of an analytical method for determining the specific migration. As adequate migration testing methods are available, and the specific migration limits have been specified, the possibility to verify compliance by residual content should be removed from the entries for substances with FCM substance Nos 142, 168, 202, 387, 462, 467, 481, 502, 662, and 779.

(4) The Authority adopted a favourable scientific opinion[(3)] on the use of the substance diethyl[[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]methyl]phosphonate, with the CAS number 976-56-7 and the FCM substance No 1007. The Authority concluded that the substance is not of a safety concern for the consumer if used up to 0,2 % w/w based on the final polymer weight in the polymerisation process to manufacture poly(ethylene terephthalate) (PET) intended for contact with all types of foods under

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2017/752. (See end of Document for details)*

any contact conditions of time and temperature. Therefore, that substance should be added to the Union list of authorised substances with the restriction that it is only to be used in the polymerisation process to manufacture PET and at up to 0,2 % (w/w). As the Authority indicated that the substance is used in the polymerisation process and becomes part of the polymeric backbone of the final polymer, it should be listed as a starting substance.

(5) The Authority adopted a favourable scientific opinion[4] on the use of the substance (methacrylic acid, ethyl acrylate, n-butyl acrylate, methyl methacrylate and butadiene) copolymer in nanoform, with the FCM substance No 1016. The Authority concluded that the substance is not of a safety concern for the consumer if used as an additive at up to 10 % w/w in non-plasticised PVC or up to 15 % w/w in non-plasticised PLA, used in contact with all food types, at room temperature or below, for long-term storage. Therefore, this additive should be included in the Union list of authorised substances with the restriction that those specifications should be met.

(6) The Authority adopted a favourable scientific opinion[5] on the use of the additive montmorillonite clay modified by dimethyldialkyl(C16-C18)ammonium chloride with FCM No 1030. The Authority concluded that the use of the mixture does not give rise to a safety concern if the substance is used at up to 12 % w/w in polyolefins intended for dry foods to which simulant E is assigned in Annex III to Regulation (EU) No 10/2011, and when used at room temperature or below, and if the migration of the substances 1-chlorohexadecane and 1-chlorooctadecane which can be present as impurities or degradation products does not exceed 0,05 mg/kg food. The Authority noted that the particles can form platelets that can be in one dimension in the nano range but that the migration of such platelets is not expected if these are oriented parallel to the film surface and when fully embedded in the polymer. Therefore, that additive should be included in the Union list of authorised substances with the restriction that those specifications should be met.

(7) The Authority adopted a favourable scientific opinion[6] on the use of the additive α-tocopherol acetate with FCM No 1055, CAS Nos 7695-91-2 and 58-95-7. The Authority concluded that the use of the substance as antioxidant in polyolefins does not give rise to a safety concern. The Authority noted that the substance hydrolyses to α-tocopherol and acetic acid which are both authorised food additives under Regulation (EC) No 1333/2008 of the European Parliament and of the Council[7]. Consequently, there is a risk that the restrictions set out by Regulation (EC) No 1333/2008 applicable to those two hydrolysis products could be exceeded. Therefore, that additive should be included in the Union list of authorised substances with the restriction that it can only be used as an antioxidant in polyolefins, and a note should be added that the restrictions set out in Regulation (EC) No 1333/2008 have to be met.

(8) The Authority adopted a favourable scientific opinion[8] on the use of the additive ground sunflower seed hulls with FCM No 1060. The Authority concluded that the use of the substance is not a safety concern if used as an additive in plastics intended for contact with dry foods, if these are used at room temperature or below. The seed hulls should be obtained from sunflower seeds that are fit for human consumption and

the plastic containing the additive should be subjected to processing temperatures not higher than 240 °C. Therefore, that additive should be included in the Union list of authorised substances with the restriction that it can only be used in contact with foods to which food simulant E is assigned in Table 2 of Annex III, and if it is obtained from sunflower seed suitable for human consumption, and the resulting plastic containing the additive is not subjected to processing temperatures higher than 240 °C.

(9) The Authority adopted a favourable scientific opinion[9] on the use of the defined mixture with FCM No 1062, composed of 97 % tetraethyl orthosilicate (TEOS) with CAS No 78-10-4 and 3 % hexamethyldisilazane (HMDS) with CAS No 999-97-3. The Authority concluded that the mixture is not of a safety concern if used at up to 0,12 % (w/w) as a starting substance during the recycling of PET. Therefore, the mixture should be added as a starting substance to the Union list of authorised substances with the restriction that it is only used during PET recycling and at up to 0,12 % (w/w).

(10) The Authority adopted an opinion on the risks to public health related to the presence of nickel in food and drinking water[10]. The opinion establishes a tolerable daily intake of 2,8 μg Ni per kg body weight per day, and indicates that the mean chronic dietary exposure to Ni is above the TDI, particularly when considering the young population. Consequently, it is appropriate to apply an allocation factor of 10 % to the conventionally derived migration limit. Therefore, it is appropriate to apply a migration limit of 0,02 mg/kg food to the migration of nickel from plastic food contact materials. That limit should therefore be added to the specification for metal migration in Annex II to the Regulation.

(11) Point 4 of Annex III to the Regulation assigns combinations of simulants representative for different food types that should be used for overall migration testing. The text of point 4 is not sufficiently clear and should therefore be clarified.

(12) Point 8(iii) of Annex IV to the Regulation lays down that the Declaration of Compliance issued by a business operator could specify the ratio of food contact surface area to volume used to establish the compliance of the material or article. However, it is not always clear to the operator receiving the material or article whether this ratio would also be the highest ratio at which it would comply with Article 17 and 18 of the Regulation. In other cases, specifying a surface to volume ratio may be without meaning for understanding whether compliance can be assumed at the proportions of the final material or article. In these cases, equivalent information would be needed, such as the minimum packaging volume in case of caps and closures. Therefore, point 8(iii) of Annex IV to the Regulation should be clarified by referring to the highest surface to volume ratio for which compliance has been established in accordance with Articles 17 and 18 or equivalent information.

(13) Regulation (EU) No 10/2011 should therefore be amended accordingly.

(14) In order to limit the administrative burden and to provide business operators with sufficient time to adjust their practices to comply with the requirements of this Regulation, transitional measures should be provided.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2017/752. (See end of Document for details)*

(15) 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, II, III and IV 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 19 May 2018 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*.

Point 2 of the Annex shall apply from 19 May 2019.

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

Done at Brussels, 28 April 2017.

For the Commission

The President

Jean-Claude JUNCKER

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) 2017/752. (See end of Document for details)*

ANNEX

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

(1) Annex I is amended as follows:

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

(i) in column 11 as regards the entries for the substances with FCM substance numbers 142, 168, 202, 387, 462, 467, 481, 502, 662 and 779, the reference to note '(1)' is deleted;

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

1007		976-56-7	diethyl [(3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]methyl]phosphonate	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)		
'1016			(methacrylic acid, ethyl acrylate, n-butyl acrylate, methyl methacrylate and butadiene) copolymer in nanoform	yes	no			Only to be used up to: (a)	10 % w/w in non-plasticised PVC;	