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COMMISSION REGULATION (EU) .../...

of **XXX**

**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) .../...

of **XXX**

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/EEC¹, and in particular Article 5(1)(a), (c), (d), (e), (h), (i) and (j), and Article 11(3),

Whereas:

- (1) Commission Regulation (EU) No 10/2011² ('the Regulation') lays down specific rules as regards plastic materials and articles intended to come into contact with foods. In particular, it establishes a Union list of substances which may be used in the manufacture of plastic food contact materials and articles.
- (2) Since the Regulation's adoption, 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 substances that have been authorised previously. 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) For food categories to which only food simulant E is assigned in Table 2 of Annex III to the Regulation ('dry foods'), no specific food simulant is assigned for overall migration testing in point 4 of Annex III. This could, when read in conjunction with the general assignment of food simulants to foods under point 2 of that Annex, appear to derogate from overall migration testing for materials and articles intended to come into contact with dry foods. The present wording however does not provide for such derogation, as the assignment for all types of food in point 4 of Annex III would apply also to dry foods. Application of the assignment of simulants for all foods would however lead to unrealistic testing results for materials and articles intended to come in contact only with dry foods. Overall migration testing for plastic materials and articles only intended to come into contact with dry foods is particularly burdensome as the testing method used for other food categories cannot be used, and overall migration testing only indirectly ensures the protection of human health. Therefore, derogation from testing for overall migration should be provided for plastic materials

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).

and articles that are intended to be used, and are foreseeably used, only in contact with foods belonging to the food categories to which food simulant E is assigned in Table 2 of Annex III to the Regulation.

- (4) The authorisation of several substances in Table 1 of Annex I to the Regulation refers in column 11 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 the following ten substances in the Regulation, the substances with FCM substance Nos 142, 168, 202, 387, 462, 467, 481, 502, 662, and 779.
- (5) The Authority adopted a favourable scientific opinion³ 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 this 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 any contact conditions of time and temperature. Therefore, this 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.
- (6) The Authority adopted a favourable scientific opinion⁴ 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 this mixture does not give rise to safety concerns for the consumer if the substance is to be used at up to 12 % w/w in polyolefins intended for dry foods to which simulant E is assigned in Annex III of 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, this additive should be added to the Union list of authorised substances with the restriction that these specifications should be met.
- (7) The Authority adopted a favourable scientific opinion⁵ 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 this substance as antioxidant in polyolefins does not give rise to a safety concern. The Authority noted that this 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 Council⁶. Consequently, there is a risk that the restrictions set out by that Regulation applicable to these two hydrolysis products could be exceeded. Therefore, this additive should be

³ EFSA Journal 2016;14(7):4536.

⁴ EFSA Journal 2015;13(11):4285.

⁵ EFSA Journal 2016;14(3):4412.

⁶ OJ L 354, 31.12.2008, p. 16, Regulation (EC) No 1333/2008 of the European Parliament and of the council of 16 December 2008 on food additives.

added to 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 under Regulation (EC) No 1333/2008 have to be met.

- (8) The Authority adopted a favourable scientific opinion⁷ on the use of the additive ground sunflower seed hulls with FCM No 1060. The Authority concluded that the use of this substance is not a safety concern for the consumer 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, this additive should be added to 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 opinion⁸ 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 this mixture is not of a safety concern for the consumer if used at up to 0.12% (w/w) as a starting substance during the recycling of PET. Therefore, this mixture should be added as a starting substance to the Union list of authorised substances with the restriction that it is only to be 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 water⁹. This 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 food contact materials. This 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 drafting of this point is not sufficiently clear and should therefore be clarified.
- (12) Point 8(iii) of Annex IV of the Regulation lays down that the Declaration of Compliance issued by a business operator is to specify the ratio of food contact surface area to volume used to establish the compliance of the material or article. This parameter would need to be used for verification of compliance if the operator receiving the material or article would need to increase the surface to volume ratio. However, the parameter referred to in the provision concerned is without purpose if the migration observed at that surface to volume ratio is not known. To determine compliance without knowledge of the actual migration, the maximum surface to volume ratio should be specified, instead of surface to volume ratio used to determine

⁷ EFSA Journal 2016;14(7):4534.

⁸ EFSA Journal 2016;14(1):4337.

⁹ EFSA Journal 2015;13(2):4002.

compliance. Therefore point 8(iii) of Annex IV to the Regulation should be amended to include a reference to the maximum surface to volume ratio at which the material would still be compliant.

- (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.
- (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

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

- (1) In Article 18, paragraph 4 is replaced by the following:
 - "4. For materials and articles not yet in contact with food verification of compliance with the overall migration limit shall be carried out in food simulants as set out in Annex III in accordance with the rules set out in Chapter 3, Sections 3.1 to 3.3 of Annex V.
 - By way of derogation from the first subparagraph, and without prejudice to Article 12, verification of compliance with the overall migration limit of materials and articles that are intended to be used, and are foreseeably used, only in contact with foods belonging to the food categories to which food simulant E is assigned in Table 2 of Annex III may be omitted.";
- (2) Annexes I, II, III and IV 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, including point 8(iii) of its Annex IV as regards the contents of the written declaration referred to in Article 15 of Regulation (EU) No 10/2011, may be placed on the market until *[enter date 12 months after the date of entry into force of this Regulation]* 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 *[enter date 24 months after the date of entry into force of this Regulation]*

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

Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER

DRAFT - This discussion document is not necessarily representative of any finally adopted text on this subject - DRAFT



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ANNEX I

ANNEX

to the

COMMISSION REGULATION

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

ANNEX

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

(1) Annex I is amended as follows:

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

(i) in column 11, in the entries for the substances with FCM substance Nos 142, 168, 202, 387, 462, 467, 481, 502, 662 and 779, the text "(1)" is deleted;

(b) (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	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)"
"1030			montmorillonite clay modified by dimethyldialkyl(C16-C18)ammonium chloride	yes	no	no			Only to be used up to 12% (w/w) in polyolefins in contact with dry foods to which simulant E is assigned in table 2 of Annex III at room temperature or below; the sum of the specific migration of 1-chlorohexadecane and 1-chlorooctadecane shall not exceed 0.05 mg/kg food; can be used in the nano-form as platelets that are only in 1 dimension thinner than 100 nm. Such platelets shall be oriented parallel to the polymer surface and shall be fully embedded in the polymer"

"1055		7695-91-2 58-95-7	α -tocopherol acetate	yes	no	no			Only to be used as antioxidant in polyolefins	(24)
1060			ground sunflower seed hulls	yes	no	no			Only to be used at room temperature or [?] below in contact with foods for which Table 2 of Annex III assigns food simulant E. The seed hulls shall be obtained from sunflower seeds that are fit for human consumption. The processing temperature of the plastic containing the additive shall not exceed 240°C	
1062			mixture composed of 97% tetraethyl orthosilicate (TEOS) with CAS No 78-10-4 and 3% hexamethyldisilazane (HMDS) with CAS No 999-97-3	no	yes	no			Only to be used for the production of recycled PET and at up to 0.12 % (w/w)";	

(c) in point 3, in Table 3, the following entry is added:

"(24)	The substance or its hydrolysis products are authorised food additives and compliance with Article 11(3) shall be verified";
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- (2) in Annex II, the following restriction for Nickel is inserted in alphabetical order in between the restrictions for Manganese and Zinc:

"Nickel = 0,02 mg/kg food or food simulant.";

- (3) in Annex III, point 4 is replaced by the following:

"4. Food simulant assignment for testing overall migration

For tests to demonstrate compliance with the overall migration limit food simulants shall be chosen as set out in table 3:

Table 3

Food simulant assignment for demonstrating compliance with the overall migration limit

Foods covered	Food simulants in which testing shall be performed
all types of food	1) distilled water or water of equivalent quality or food simulant A; 2) food simulant B; and 3) food simulant D2

all types of food except for acidic foods	1) distilled water or water of equivalent quality or food simulant A; and 2) food simulant D2
all aqueous and alcoholic foods and milk products	food simulant D1
all aqueous, acidic and alcoholic foods and milk products	1) food simulant D1; and 2) food simulant B
all aqueous foods and alcoholic foods up to an alcohol content of 20 %	food simulant C
all aqueous and acidic foods and alcoholic foods up to an alcohol content of 20 %	1) food simulant C; and 2) food simulant B";

(4) in Annex IV, point 8(iii) is replaced by the following:

"(iii) the maximum ratio of food contact surface area to volume at which the material or article will comply with the applicable migration limits;"