Commission Regulation (EU) 2016/1416 of 24 August 2016 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) 2016/1416

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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 Article 5(1)(a), (c), (d), (e), (h), (i) and (j), Article 11(3) and Article 12(6) thereof,

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. 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) The definition of 'non-fatty foods' in point (16) of Article 3 of the Regulation contains a reference to food simulants laid down in an annex to the Regulation. As the definition was intended to refer to food simulants listed in Table 2 of Annex III, the reference should be corrected accordingly.

(4) Regulation (EU) No 10/2011 uses the term 'hot-fill' in the context of setting restrictions on the use of certain authorised monomers in materials and articles intended to act as a receptacle for hot food. In order to clarify the scope of such restrictions, it is appropriate to provide a definition of the term specifying the temperatures at which such restrictions apply.

(5) Article 6(3) of Regulation (EU) No 10/2011 establishes a derogation as regards the use of salts of specified metals derived from authorised acids, phenols or alcohols, even

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though these salts are not included in the Union list of authorised substances. As the conclusion of the Authority on which the derogation is based was not specific to certain categories of salts[3], the qualification in point (a) of Article 6(3) that the derogation extends to 'double salts and acid salts' is superfluous. Since that qualification could be interpreted as supporting an *a contrario* interpretation according to which there could be categories of salts to which the definition does not apply, it should be clarified that the derogation applies to all salts of the listed metals, and the qualification should be deleted.

(6) Article 11(2) of the Regulation sets a generic specific migration limit for all substances for which no specific migration limit has been set. The absence of a prescribed limit for particular substances reflects the view that such specification was not necessary for the purposes of ensuring compliance with the safety criteria laid down in Article 3 of Regulation (EC) No 1935/2004. As the migration levels from all substances are already subject to compliance with an overall migration limit, the existence of a parallel generic specific limit is unnecessary and gives rises to a duplication of migration testing and development of testing methods. In order to avoid the imposition of unnecessarily burdensome testing obligations, the provision establishing generic specific migration limits should be deleted.

(7) Pursuant to Article 13(3), and Annex I and Annex II to the Regulation, there are certain substances in respect of which it must not be possible to detect any level of migration. The prohibition is justified on the grounds that any degree of migration of such substances could pose a risk to health. As the presence of a particular substance can only be determined in so far as it reaches a detectable threshold, its absence can also only be determined by reference to that threshold. As the rules governing the establishment and expression of detection thresholds are repeated throughout the Regulation, it is appropriate to simplify the Regulation by deleting repetitions of those rules and by consolidating such rules within a single provision in the Regulation.

(8) As specific migration limits are expressed in mg/kg food, the same measurement unit should also be used for the verification of compliance of a cap or closure, as a consistent approach avoids the potential for conflicting results. It is therefore appropriate to remove the option to express the migration from caps or closures in mg/dm^2.

(9) Pursuant to Article 18(4) of the Regulation, the compliance of materials and articles that were not yet in contact with food is to be verified in accordance with detailed rules laid down in Section 3.1 of Chapter 3 of Annex V. As the provisions laid down in Sections 3.2, 3.3 and 3.4 of the same Chapter may also be relevant to verification of compliance, it is appropriate to amend Article 18(4) so that it refers to the Chapter 3 as a whole.

(10) Table 1 of Annex I to the Regulation contains the Union list of authorised substances which includes a reference to simulant D. Since the Regulation distinguishes between food simulants D1 and D2, the references to food simulant D should be replaced by more specific references to food simulant D1 or D2 for all substances.

(11) The substance silicon dioxide, silanated (food contact material ('FCM') substance No 87) is currently authorised for use as an additive in all plastics. Also covered under FCM No 87 is a sub-category of this substance, synthetic amorphous silicon dioxide,

silanated, which is produced using primary particles in nanoform. Under Article 9(2) of the Regulation, substances in nanoform are only to be used if explicitly authorised and mentioned in the specifications in Annex I. Taking account of the available scientific information, and the absence of migration of primary nanoparticles of this synthetic form, the Authority has concluded that that synthetic amorphous silicon dioxide, silanated, produced from primary particles in nanoform does not raise a safety concern when only aggregates larger than 100 nm and larger agglomerates are present in the final material[(4)]. The Union list should therefore be amended to add a specification of substance FCM No 87 as regards the form in which it may be used in the final material.

(12) The Authority has adopted a scientific opinion on the extension of the use of perfluoromethyl perfluorovinylether (MVE, FCM No 391)[(5)]. According to that opinion the substance is not a safety concern if used as a monomer for fluoro- and perfluoropolymers intended for repeated use applications, where the contact ratio is 1 dm^2 surface in contact with not less than 150 kg food such as in sealing and gaskets. It is therefore appropriate to add this application to the specifications set out in relation to substance FCM No 391.

(13) The authorisation of the substance 'mixture of (35-45 % w/w) 1,6-diamino-2,2,4-trimethylhexane and (55-65 % w/w)1,6-diamino-2,4,4-trimethylhexane' (FCM No 641) refers in column 11 to note (10) in Table 3 of Annex I to the Regulation. Compliance is therefore verified by residual content per food contact surface area (QMA) in case of reaction with food or simulant. Verification of compliance by QMA is only appropriate if a migration testing method is unavailable or impractical. As adequate migration testing methods are available, and a specific migration limit has been specified, the possibility to verify compliance by residual content should be removed from the entry for this substance in the Regulation.

(14) The authorisation of the substance bis(methylbenzylidene)sorbitol (FCM No 752) refers in column 3 to four CAS numbers. These CAS numbers have been incorrectly separated in print. Therefore the authorisation of this substance should be corrected by separating the CAS numbers correctly.

(15) The Authority adopted a scientific opinion concerning substance FCM No 779 in 2007[(6)]. In its opinion the Authority observed that analytical methods for the verification of compliance to the migration limits are available and well described. Nevertheless, the present authorisation of this substance contains a reference to note (1) of Table 3 of Annex I to the Regulation, which states that, pending the availability of an analytical method, compliance should be verified by residual content per food contact surface area (QMA). Verification of compliance by QMA is only appropriate if a migration testing method is unavailable or impractical. Since the Authority considers that analytical methods are available and well described, the reference to note (1) should be deleted. The Authority further notes in its opinion that a risk exists that migration levels in fatty foods may exceed the applicable migration limit, which was not referred to in the present authorisation. It is therefore appropriate to insert a reference to note (2) of Table 3 of Annex I to the Regulation so as to ensure that this risk is considered as part of the verification of compliance.

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(16) At present, the substance with FCM No 974 is included in the Union list and may be used provided that the migration of its hydrolysis product 2,4-di-tert-amylphenol (CAS number 120-95-6), does not exceed 0,05 mg/kg. The migration of FCM No 974 is expressed as the sum of phosphite and phosphate forms and the hydrolysis product 4-t-amylphenol. The Authority has adopted a scientific opinion according to which the migration limit applicable to this hydrolysis product could, without giving rise to health concerns, be extended to 1 mg/kg food, provided that the migration from the product is added to the sum of the phosphite and phosphate forms and the hydrolysis product 4-t-amylphenol, and that the sum of these four substances is subject to the existing 5 mg/kg specific migration limit for FCM No 974. The specifications of FCM No 974 should therefore be amended accordingly.

(17) The Authority has adopted a scientific opinion[7] on the use of the additive dodecanoic acid, 12-amino-, polymer with ethene, 2,5-furandione, α-hydro-ω-hydroxypoly (oxy-1,2-ethanediyl) and 1-propene, FCM No 871. When used as an additive in polyolefins at levels of up to 20 weight % at ambient temperature or below in contact with dry foods as represented by food simulant E, and when migration of the low molecular weight oligomeric fraction less than 1 000 Da does not in total exceed 50 μg/kg food, the use of this additive does not endanger human health. It is therefore appropriate to include this additive in the Union list and to authorise its use in accordance with those specifications.

(18) The Authority has adopted a scientific opinion[8] on the use of the starting substance furan-2,5-dicarboxylic acid (FCM No 1031). When used as a monomer in the production of polyethylene furanoate (PEF) polymer this substance does not raise a safety concern for the consumer when the migration of the substance itself does not exceed 5 mg/kg food, and when migration of the oligomers less than 1 000 Da does not exceed 50 μg/kg food. It is therefore appropriate to include this starting substance in the Union list and to authorise its use in accordance with the specified migration limits.

(19) The Authority has noted that PEF containing a substance with FCM No 1031 can safely be used in contact with non-alcoholic foods in accordance with its specified migration limits. However when the compliance of such a plastic is verified with food simulant D1 in accordance with the food simulant assignments in Table 2 of Annex III, there is a risk of interaction between this food simulant and the plastic. As this interaction would not occur in contact with the non-alcoholic foods for which this food simulant is assigned, the use of food simulant D1 for verification of compliance would give unrealistic results in such cases. According to the Authority, therefore, when verifying whether the use of this substance complies with this Regulation, food simulant C should be used for non-alcoholic foods to which Table 2 of Annex III assigns food simulant D1. It is therefore appropriate to add a note on the verification of compliance to substance with FCM No 1031 to indicate that food simulant D1 should be substituted with food simulant C in case of testing.

(20) The Authority has adopted a scientific opinion[9] on the use of the starting substance 1,7-octadiene (FCM No 1034). When used as a crosslinking co-monomer in the manufacture of polyolefins for contact with any type of foods for long term storage at

room temperature, including hot-fill conditions, and the migration of the substance does not exceed 0,05 mg/kg food, the use of this substance does not endanger human health. It is therefore appropriate to include that additive in the Union list and to authorise its use in accordance with those specifications.

(21) The Authority has adopted a scientific opinion[10] on the use of the polymer production aid perfluoro{acetic acid, 2-[(5-methoxy-1,3-dioxolan-4-yl)oxy]}, ammonium salt (FCM No 1045). When used as polymer production aid during the manufacture of fluoropolymers which are produced under high temperature conditions of at least 370 C the use of this substance does not endanger human health. Therefore, it should be added to the Union list and its use authorised subject to compliance with those specifications.

(22) The Authority has adopted a scientific opinion[11] on the use of the additive ethylene glycol dipalmitate (FCM No 1048). The Authority concluded that when the substance is produced using a fatty acid precursor conventionally obtained from edible fats or oils and the migration of ethylene glycol is limited by including it in the group SML(T) for ethylene glycol, the use of this additive does not endanger human health. Therefore, that additive should be included in the Union list subject to the requirement that it complies with those specifications. In particular, it should be added to the group to which the SML(T) applies and entry (2) of Table 2 of Annex I to Regulation (EU) No 10/2011 should be amended accordingly.

(23) The Authority has adopted a scientific opinion[12] on the use of the additive zinc oxide, nanoparticles, uncoated (FCM No 1050) and zinc oxide, nanoparticles, coated with [3-(methacryloxy)propyl] trimethoxysilane (FCM No 1046). The Authority concluded that these additives do not migrate in nanoform from polyolefins. In a further opinion the Authority extended this conclusion to the migration of zinc oxide nanoparticles to unplasticised polymers[13]. It therefore stated that its safety evaluation focused on the migration of soluble ionic zinc, which should respect the specific migration limit for zinc specified in Annex II to the Regulation. For the coated form of zinc oxide, nanoparticles, the levels of migration of [3-(methacryloxy)propyl]trimethoxysilane should remain within the existing specific migration limits for this substance, namely 0,05 mg/kg. Therefore, the two additives should be included in the Union list.

(24) The Authority has adopted a scientific opinion[14] on the use of the additive N,N′-bis(2,2,6,6-tetramethyl-4-piperidinyl) isophthalamide (FCM No 1051). The Authority concluded that when its migration does not exceed 5 mg/kg food, the use of this additive does not endanger human health. Therefore, it should be included in the Union list subject to a migration limit of 5 mg/kg food.

(25) The Authority has adopted a scientific opinion[15] on the use of the starting substance 2,4,8,10-tetraoxaspiro[5,5]undecane-3,9-diethanol,β3,β3,β9,β9-tetramethyl- (‘SPG’, FCM No 1052). The Authority concluded that when this substance is used as a monomer in the production of polyesters, when its migration does not exceed 5 mg/kg food, and when the migration of the oligomers of less than 1 000 Da does not exceed 50 μg/kg food (expressed as SPG), the use of this additive does not endanger human health. Therefore, it should be included in the Union list and its use authorised subject to compliance with those specifications.