

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)**

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 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 rise 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.

⁽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⁾ EFSA Journal 2009; 7(10):1364.

- (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/dm².
- (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 ⁽¹⁾. 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) ⁽²⁾. 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 dm² 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 ⁽³⁾. 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

⁽¹⁾ EFSA Journal 2014; 12(6):3712.

⁽²⁾ EFSA Journal 2015;13(7):4171.

⁽³⁾ EFSA Journal 2007, 555-563, 1-31, doi: 10.2903/j.efsa.2007.555.

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.

- (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 ⁽¹⁾ 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 μ g/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 ⁽²⁾ 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 μ g/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 ⁽³⁾ 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 ⁽⁴⁾ 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.

⁽¹⁾ *EFSA Journal* 2014;12(11):3909.

⁽²⁾ *EFSA Journal* 2014;12(10):3866.

⁽³⁾ *EFSA Journal* 2015;13(1):3979.

⁽⁴⁾ *EFSA Journal* 2014;12(6):3718.

- (22) The Authority has adopted a scientific opinion ⁽¹⁾ 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 ⁽²⁾ 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 ⁽³⁾. 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 ⁽⁴⁾ 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 ⁽⁵⁾ 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.
- (26) The authorisation of the substances with FCM Nos 871, 1031 and 1052 provided for in this Regulation, requires that the migration of the low molecular weight oligomeric fraction less than 1 000 Da shall not in total exceed a migration limit of 50 µg/kg food. Analytical methods to determine the migration of this oligomeric fraction 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.
- (27) The Authority has adopted a scientific opinion ⁽⁶⁾ on the use of the additive fatty acids, C16–18 saturated, hexaesters with dipentaerythritol (FCM No 1053). Since any content of lower esters (e.g. penta-, tetra-,) does not give rise to a safety concern, the Authority concluded that the use of fatty acids, C16–18 saturated, esters with dipentaerythritol does not endanger human health, provided that the substance is produced using a fatty acid precursor obtained from edible fats or oils. Therefore, the additive fatty acids, C16–18 saturated, esters with dipentaerythritol should be included in the Union list without restricting it to hexaesters, subject to the requirement that its fatty acid precursor is obtained from edible fats or oils.
- (28) The Authority has adopted a scientific opinion ⁽⁷⁾ on the safety of aluminium from dietary intake, which establishes a tolerable weekly intake of 1 mg aluminium per kg body weight per week. Applying the conventional exposure assumptions for food contact materials, the migration limit would have to be set at 8,6 mg/kg food. The opinion however notes that the current dietary exposure of a significant part of the Union's population likely exceeds this level. Therefore, it is appropriate to limit the contribution from exposure by food contact materials to the overall exposure by applying an allocation factor of 10 % to the conventionally derived migration limit. Therefore, a migration limit for aluminium of 1 mg/kg food is considered appropriate for food contact materials.

⁽¹⁾ *EFSA Journal* 2015;13(2):4019.

⁽²⁾ *EFSA Journal* 2015;13(4):4063.

⁽³⁾ *EFSA Journal* 2016;14(3):4408.

⁽⁴⁾ *EFSA Journal* 2014;12(10):3867.

⁽⁵⁾ *EFSA Journal* 2014;12(10):3863.

⁽⁶⁾ *EFSA Journal* 2015;13(2):4021.

⁽⁷⁾ *EFSA Journal* (2008) 754, 1-34.

- (29) The Authority has adopted a scientific opinion on dietary reference values for zinc ⁽¹⁾. This confirms the opinion expressed by the Scientific Committee on Foods (SCF) in 2002 ⁽²⁾ which sets the tolerable upper level of zinc for adults to 25 mg per day. In Annex II to Regulation (EU) No 10/2011, the migration limit for zinc is set at 25 mg/kg food. As dietary exposure from other sources significantly contributes to the total exposure, and according to the Authority, the upper level could be exceeded in combination with the current migration limit. Therefore to reduce the contribution from food contact materials to the total exposure to zinc, and taking into account that the total dietary exposure to zinc is in the range of the upper limit but generally below, it is appropriate to use an allocation factor of 20 % for the exposure from food contact material. It is therefore appropriate to amend the migration limit specified in Annex II to the Regulation to 5 mg/kg food.
- (30) A single specification of the amount of saponifiable matter in vegetable oil to be used for food simulant D2 is sufficient to specify that food simulant. Therefore, any further specifications are not necessary and the note below Table 1 of Annex III to the Regulation should be deleted.
- (31) The Regulation does not lay down specific migration testing provisions for fresh unpeeled fruits and vegetables as no food simulant has been assigned to these products. Possible health risks to consumers from migrating substances, including substances that should not be present to any extent can therefore remain undetected. A food simulant should thus be assigned to those products in Table 2 of Annex III to Regulation (EU) No 10/2011. Those fruits and vegetables vary widely in properties, but are dry. Food simulant E is suitable for dry foods but may overestimate the contact surface depending on size and shape of the fruits and vegetables. Moreover, fruits and vegetables may be peeled before consumption removing part of the migrants. The overestimation should be addressed with a correction factor and the correction procedure should be set out in point 3 of Annex III to the Regulation.
- (32) Only food simulant A is assigned for fresh vegetables that are peeled and/or cut. As such vegetables can be acidic, it is appropriate that food simulant B is also specified for peeled and/or cut vegetables. Therefore, that category should be added to Table 2 of Annex III to the Regulation.
- (33) Testing in several different food simulants provides no added value if it is scientifically evident that one food simulant always yields the highest migration results for a specific substance or material, and this food simulant can therefore be considered as the most severe for such a substance or material. Therefore, a general derogation to the assignment of food simulants should be included in Annex III to the Regulation to allow the testing in only one food simulant if appropriate scientific evidence is documented showing that that food simulant is the most severe.
- (34) Point 5 of Annex IV to the Regulation requires a written confirmation that the requirements laid down in Regulation (EC) No 1935/2004 are met. However, most of the provisions set out in Regulation (EC) No 1935/2004 cannot directly apply to plastic materials or articles, or to the substances used to manufacture those materials or articles. Therefore the reference to Regulation (EC) No 1935/2004 should be made more specific by adding references to the provisions of that Regulation to which confirmation of compliance is required.
- (35) Substances found in food already in contact with a material or article that is being tested for its compliance, do not necessarily originate from that material or article, but may originate from other sources, including other food contact materials or articles with which the food has been in contact previously. Therefore, the amount of a substance present in the food which does not originate from the tested material or article should not be taken into account to determine the compliance with the Regulation. This correction should equally apply to all substances for which the Regulation sets a specific migration limit or for which no migration is permitted. While Section 1.4 of Chapter 1 of Annex V to the Regulation already includes a requirement to take account of contamination from other sources, it is appropriate, in the interests of legal certainty, to clarify that prior to comparing tests results to the applicable specific migration limit, the test result should be corrected to take into account contamination from other sources.
- (36) The migration testing conditions should always be at least as strict as the real conditions of use. Therefore, the second paragraph of Section 2.1.3 of Chapter 2 of Annex V to the Regulation should be amended to make it clear that the testing conditions cannot be adjusted to conditions that are less strict than the real conditions of use.

⁽¹⁾ *EFSA Journal* 2014;12(10):3844.

⁽²⁾ SCF/CS/NUT/UPPLEV/62 Final, http://ec.europa.eu/food/fs/sc/scf/out177_en.pdf

- (37) Business operators use food processing equipment that is capable of precisely controlling the time and temperature conditions at which the food and the equipment, or, if the food is already packaged, its packaging, are in contact, such as during pasteurisation and sterilisation of the food. Such equipment must always be operated in accordance with good manufacturing practice. Therefore when using the exact worst foreseeable processing conditions applied in such equipment as testing conditions for migration testing, this testing will be representative for the actual migration, and will rule out possible adverse effects to human health. The standardised testing conditions set out in Table 1 and 2 of Annex V may significantly overestimate migration, and consequently place an unreasonable burden on business operators. Therefore it is appropriate to amend the Regulation to allow the use of actual processing conditions used in such equipment as testing conditions for migration testing.
- (38) Certain worst foreseeable conditions of use may occur in practice under which it is not technically feasible to use food simulant D2 for testing. Appropriate alternative food simulants and rules for verification of compliance should be specified for such conditions.
- (39) The title and titles of columns of Tables 1 and 2 of Section 2.1.3 of Chapter 2 of Annex V to the Regulation do not clearly set out that the temperature specified for testing represents the temperature of the food simulant used during the test. Those tables should therefore be amended to ensure correct application of the specified testing conditions.
- (40) The temperature specified for testing above 175 °C is not representative for all foreseeable conditions to which food contact materials may be subjected. Therefore, appropriate rules for testing above 175 °C should be added to Table 2 of Section 2.1.3 of Chapter 2 of Annex V to the Regulation.
- (41) Section 2.1.4 of Annex V to the Regulation specifies testing conditions for contact times beyond 30 days. Those conditions include a formula and provide specific conditions which can both be used to determine a testing temperature for testing at accelerated conditions. It however does not clarify that the formula should only be applied when the standardised testing conditions do not apply. This section also does not clearly specify test conditions for storage at frozen conditions or when an article or material is initially filled under hot-fill conditions. This section should therefore be amended to ensure the formula is only applied for conditions not specified by the standard conditions, and to clarify the test condition for hot-fill and frozen conditions.
- (42) Section 2.1.6 of Annex V to Regulation (EU) No 10/2011 specifies that when testing repeated use materials the migration limit should already be respected in the first migration test when testing the migration of substances for which the Regulation specifies that the specific migration is set as non-detectable. This however should include all substances for which this is the case and therefore also include those specified in Annex II to the Regulation. It is therefore appropriate to delete the specific reference from the Regulation and to clarify that this rule applies to all substances for which the migration should be non-detectable.
- (43) If the migration behaviour of a material or article is well established, a single test may suffice to screen its compliance with the Regulation. Provided that a justification for such substitution on the basis of the known behaviour of the material is documented, a series of tests representative for various time and temperature combinations that would foreseeably be used in the real use of a material or article, can be substituted by a single test. Such a substitution may significantly reduce the testing burden, without compromising the high level of human health protection that this Regulation seeks to achieve. Therefore, it is appropriate to provide for the possibility of applying a single screening test in appropriate circumstances.
- (44) Table 3 in Chapter 3 of Annex V to the Regulation currently states that the standardised testing condition OM6 represents the worst case conditions for food simulants A, B and C. However, it also represents the worst case conditions for food simulant D1, and this food simulant can also be used in this test. Therefore, the Regulation should be corrected to include references to food simulant D1 in this context.
- (45) According to the text provided below Table 3 in Section 3.1 of Annex V to the Regulation, the standardised testing condition OM7 represents the worst case conditions for 'fatty food simulants'. However, it only represents the worst case conditions for food simulant D2 and the Regulation should be clarified accordingly.

- (46) It is not always technically feasible to test overall migration with food simulant D2. In Section 3.2 of Annex V, the Regulation only specifies a substitute test for the standardised testing condition OM7. However substitute tests for conditions OM1 to OM6 should also be specified to allow for overall migration testing when food simulant D2 cannot be used under these standardised testing conditions. Therefore it is appropriate to include appropriate substitute tests in this section.
- (47) It is not always technically feasible to test overall migration of repeated use Articles in an oily medium using the same sample three times. Therefore an alternative testing approach should be specified.
- (48) Regulation (EU) No 10/2011 does not specify a method for verifying compliance with the overall migration limit set out in Article 12 of the Regulation. However, the accuracy of the determination as to whether materials or articles comply with the prescribed limit is dependent on the existence of an appropriate verification method. It is therefore appropriate to include a reference to Regulation (EC) No 882/2004 ⁽¹⁾ which specifies rules for the selection of appropriate methods for the verification of compliance.
- (49) The Regulation does not clearly specify that the application of the Fat Consumption Reduction Factor (FRF) should not allow the specific migration of a single substance to exceed the overall migration limit. It is therefore appropriate to include such a prohibition in Section 4.1 of Chapter 4 of Annex V to the Regulation.
- (50) Regulation (EU) No 10/2011 should therefore be amended accordingly.
- (51) 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.
- (52) 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) Article 3 is amended as follows:

(a) point 16 is replaced by the following:

‘(16) “non-fatty food” means a food for which in migration testing only food simulants other than food simulants D1 or D2 are laid down in Table 2 of Annex III to this Regulation;’;

(b) point 18 is replaced by the following:

‘(18) “specification” means composition of a substance, purity criteria for a substance, physico-chemical characteristics of a substance, details concerning the manufacturing process of a substance or further information concerning the expression of migration limits;’;

(c) a new point 19 is added:

‘(19) “hot-fill” means the filling of any article with a food with a temperature not exceeding 100 °C at the moment of filling, after which the food cools down to 50 °C or below within 60 minutes, or to 30 °C or below within 150 minutes.’;

⁽¹⁾ Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p. 1).

(2) in Article 6(3), point (a) is replaced by the following:

‘(a) all salts of aluminium, ammonium, barium, calcium, cobalt, copper, iron, lithium, magnesium, manganese, potassium, sodium, and zinc of authorised acids, phenols or alcohols;’

(3) Article 11 is amended as follows:

(a) paragraph 2 is deleted;

(b) paragraph 3 is replaced by the following:

‘3. By derogation from paragraph 1, additives which are also authorised as food additives by Regulation (EC) No 1333/2008 or as flavourings by Regulation (EC) No 1334/2008 shall not migrate into foods in quantities having a technical effect in the final foods and shall not:

(a) exceed the restrictions provided for in Regulation (EC) No 1333/2008 or in Regulation (EC) No 1334/2008 or in Annex I to this Regulation for foods for which their use is authorised as food additive or flavouring substances; or

(b) exceed the restrictions set out in Annex I to this Regulation in foods for which their use is not authorised as food additive or flavouring substances.’;

(c) the following paragraph 4 is added:

‘4. Where it is specified that no migration of a particular substance is permitted, compliance shall be established using appropriate migration test methods selected in accordance with Article 11 of Regulation (EC) No 882/2004 that can confirm the absence of migration above a specified limit of detection.

For the purposes of the first subparagraph, unless specific detection limits have been set for particular substances or groups of substances, a detection limit of 0,01 mg/kg shall apply.’;

(4) in Article 13, paragraph 3 is replaced by the following:

‘3. Substances under paragraph 2(b) shall not migrate into food or food simulant, in accordance with Article 11(4). The detection limit set out in the second subparagraph of Article 11(4) shall apply to groups of substances if they are structurally and toxicologically related, including isomers or substances with the same relevant functional group, or to individual substances that are not related, and shall include possible set-off transfer.’;

(5) in Article 17(3), point (a) is replaced by the following:

‘(a) mg/kg using the actual content of the container for which the closure is intended applying the total contact surface of sealing article and sealed container if the intended use of the article is known, while taking into account the provisions of paragraph 2.’;

(6) Article 18 is amended as follows:

(a) 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 of Annex V.’;

(b) paragraph 7 is replaced by the following:

‘7. Before comparing specific and overall migration test results with the migration limits the correction factors set out in point 3 of Annex III and Chapter 4 of Annex V shall be applied in accordance with the rules set out therein.’;

(7) Annexes I, II, III, IV and V 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 14 September 2017 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*.

The provisions on the specific migration limits for aluminium and for zinc set out in point 2(a) of the Annex and the assignments of food simulants in point 3(c) of the Annex shall apply from 14 September 2018.

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

Done at Brussels, 24 August 2016.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

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

(1) Annex I is amended as follows:

(a) in point 1, the paragraph referring to Column 8 of Table 1 is replaced by the following:

‘Column 8 (SML [mg/kg]): the specific migration limit applicable for the substance. It is expressed in mg substance per kg food. It is marked as ND (“not-detectable”) if the substance is one in respect of which no migration is permitted, to be determined in accordance with Article 11(4).’;

(b) in point 1, the last paragraph before Table 1 is deleted;

(c) in point 1, in column 10 of Table 1, in the entries for the substances with FCM substance Nos 72, 642, 672, 776, 782, 923 and 974, the word ‘should’ is replaced by the word ‘shall’;

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

(i) in column 10, in the entries for the substances with FCM substance Nos 93, 199, 262, 326, 637, 768, 803, 810, 815, 819 and 884, the words ‘simulant D’ are replaced by the words ‘simulant D1 and/or D2’;

(ii) the entries concerning substances with FCM substance Nos 87, 391, 641, 752, 779 and 974 are replaced by the following:

‘87	86285		Silicon dioxide, silanated	yes	no	no			For synthetic amorphous silicon dioxide, silanated: primary particles of 1–100 nm which are aggregated to a size of 0,1–1 µm and may form agglomerates within the size distribution of 0,3 µm to the mm size.’
‘391	22932	0001187-93-5	perfluoromethyl perfluorovinyl ether	no	yes	no	0,05		Only to be used in: — anti-stick coatings; — fluoro- and perfluoropolymers intended for repeated use applications where the contact ratio is 1 dm ² surface in contact with at least 150 kg food.’
‘641	22331	0025513-64-8	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	no	yes	no	0,05’		

'752	39890	0087826-41-3 0069158-41-4 0054686-97-4 0081541-12-0	bis(methylbenzylidene)sorbitol	yes	no	no'			
'779	39815	0182121-12-6	9,9-bis(methoxymethyl)fluorene	yes	no	yes	0,05		(2)'
'974	74050	939402-02-5	phosphorous acid, mixed 2,4-bis(1,1-dimethylpropyl)phenyl and 4-(1,1-dimethylpropyl)phenyl triesters	yes	no	yes	5		SML expressed as the sum of the phosphite and phosphate forms of the substance, 4-tert-amylphenol and 2,4-di-tert-amylphenol. The migration of 2,4-di-tert-amylphenol shall not exceed 1 mg/kg food.'

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

'871		0287916-86-3	dodecanoic acid, 12-amino-, polymer with ethene, 2,5-furandione, α -hydro- ω -hydroxypoly (oxy-1,2-ethanedyl) and 1-propene	yes	no	no			Only to be used in polyolefins at levels of up to 20 weight %. These polyolefins shall only be used in contact with foods for which Table 2 of Annex III assigns food simulant E, at ambient temperature or below, and when migration of the total oligomeric fraction of less than 1 000 Da does not exceed 50 μ g/kg food.	(23)'
'1031		3238-40-2	furan-2,5-dicarboxylic acid	no	yes	no	5		Only to be used as a monomer in the production of polyethylene furanoate. The migration of the oligomeric fraction of less than 1 000 Da shall not exceed 50 μ g/kg food (expressed as furan-2,5-dicarboxylic acid).	(22) (23)
1034		3710-30-3	1,7-octadiene	no	yes	no	0,05		Only to be used as a cross-linking co-monomer in the manufacture of polyolefins for contact with any type of foods for long term storage at room temperature, including when packaged under hot-fill conditions.'	

'1045		1190931-27-1	perfluoro{acetic acid, 2-[(5-methoxy-1,3-dioxolan-4-yl)oxy]}, ammonium salt	yes	no	no			Only to be used as a polymer production aid during the manufacture of fluoropolymers under high temperature conditions of at least 370 °C.	
1046			zinc oxide, nanoparticles, coated with [3-(methacryloxypropyl) trimethoxysilane (FCM No 788)	yes	no	no			Only to be used in unplasticised polymers. The restrictions and specifications specified for FCM substance No 788 shall be respected.	
1048		624-03-3	ethylene glycol dipalmitate	yes	no	no		(2)	Only to be used when produced from a fatty acid precursor that is obtained from edible fats or oils.	
1050			zinc oxide, nanoparticles, uncoated	yes	no	no			Only to be used in unplasticised polymers.	
1051		42774-15-2	N,N'-bis(2,2,6,6-tetramethyl-4-piperidiny) isophthalamide	yes	no	no	5			
1052		1455-42-1	2,4,8,10-tetraoxaspiro[5,5]undecane-3,9-diethanol,β3,β3,β9,β9-tetramethyl- ("SPG")	no	yes	no	5		Only to be used as a monomer in the production of polyesters. The migration of oligomers of less than 1 000 Da shall not exceed 50 µg/kg food (expressed as SPG).	(22) (23)
1053			fatty acids, C16–18 saturated, esters with dipentaerythritol	yes	no	no			Only to be used when produced from a fatty acid precursor that is obtained from edible fats or oils'	

(e) in point 2, in Table 2, the entry concerning the group restriction with Group Restriction No 2 is replaced by the following:

'2	89 227 263 1048	30	expressed as ethyleneglycol'
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- (f) in point 3, in column 2 of Table 3, in the entries for Notes 4 and 5, the word 'should' is replaced by the word 'shall';
- (g) in point 3, in Table 3, the following entries are added:

'(22)	When used in contact with non-alcoholic foods for which Table 2 of Annex III assigns food simulant D1, food simulant C shall be used for verification of compliance instead of food simulant D1;
(23)	When a final material or article containing this substance is placed on the market, a well described method to determine whether the oligomer migration complies with the restrictions specified in column 10 of Table 1 shall form part of the supporting documentation referred to in Article 16. This method shall be suitable for use by a competent authority to verify compliance. If an adequate method is publicly available, reference shall be made to that method. If the method requires a calibration sample, a sufficient sample shall be supplied to the competent authority on its request.'

(2) Annex II is amended as follows:

(a) point 1 is replaced by the following:

'1. Plastic materials and articles shall not release the following substances in quantities exceeding the specific migration limits below:

Aluminium = 1 mg/kg food or food simulant

Barium = 1 mg/kg food or food simulant

Cobalt = 0,05 mg/kg food or food simulant

Copper = 5 mg/kg food or food simulant

Iron = 48 mg/kg food or food simulant

Lithium = 0,6 mg/kg food or food simulant

Manganese = 0,6 mg/kg food or food simulant

Zinc = 5 mg/kg food or food simulant.';

(b) point 2 is replaced by the following:

'2. Primary aromatic amines which are not listed in Table 1 of Annex I shall not migrate or shall not otherwise be released from plastic materials and articles into food or food simulant in accordance with Article 11(4). The detection limit referred to in the second subparagraph of Article 11(4) applies to the sum of primary aromatic amines released.';

(3) Annex III is amended as follows:

(a) Table 1 'List of food simulants' is replaced in its entirety by the following:

Table 1

List of food simulants

Food simulant	Abbreviation
Ethanol 10 % (v/v)	Food simulant A
Acetic acid 3 % (w/v)	Food simulant B

Food simulant	Abbreviation
Ethanol 20 % (v/v)	Food simulant C
Ethanol 50 % (v/v)	Food simulant D1
Any vegetable oil containing less than 1 % unsaponifiable matter	Food simulant D2
poly(2,6-diphenyl-p-phenylene oxide), particle size 60-80 mesh, pore size 200 nm	Food simulant E'

(b) point 3, excluding Table 2, is replaced by the following:

3. Specific assignment of food simulants to foods for migration testing of materials and articles not yet in contact with food

For testing migration from materials and articles not yet in contact with food the food simulants that corresponds to a certain food category shall be chosen according to Table 2 below.

For testing migration from materials and articles intended to come into contact with foods not listed in Table 2 below, or a combination of foods, the general food simulant assignments in point 2 shall be used for specific migration testing, and for overall migration testing the food simulant assignments in point 4 shall be applicable.

Table 2 contains the following information:

- Column 1 (Reference number): contains the reference number of the food category
- Column 2 (Description of food): contains a description of the foods covered by the food category
- Column 3 (Food simulants): contains sub-columns for each of the food simulants

The food simulant for which a cross is contained in the respective sub-column of column 3 shall be used when testing migration of materials and articles not yet in contact with food.

For food categories where in sub-column D2 or E the cross is followed by an oblique stroke and a figure, the migration test result shall be corrected by dividing the result by this figure. The corrected test result shall then be compared to the migration limit to establish compliance. The test results for substances that shall not migrate in detectable quantities shall not be corrected in this way.

For food category 01.04 food simulant D2 shall be replaced by 95 % ethanol.

For food categories where in sub-column B the cross is followed by (*) the testing in food simulant B can be omitted if the food has a pH of more than 4,5.

For food categories where in sub-column D2 the cross is followed by (**) the testing in food simulant D2 can be omitted if it can be demonstrated that there is no "fatty contact" with the plastic food contact material.;

(c) Table 2 is amended as follows:

(i) the entries with reference numbers 04.01 and 04.04 are replaced by the following:

'04.01	Fruit, fresh or chilled:						
	A. unpeeled and uncut						X/10'
	B. peeled and/or cut	X	X (*)				
'04.04	Vegetables, fresh or chilled:						
	A. unpeeled and uncut						X/10'
	B. peeled and/or cut	X	X (*)				

(ii) in the entry with reference number 04.05 is replaced by the following:

'04.05	Processed vegetables:						X'
	A. Dried or dehydrated vegetables whole, sliced or in the form of flour or powder.						
	B. (<i>obsolete</i>)						
	C. Vegetables in the form of purée, preserves, pastes or in its own juice (including pickled and in brine).		X (*)	X			
	D. Preserved vegetables:						
	I. In an oily medium	X					X
II. In an alcoholic medium					X		

(d) the following point 5 is added:

'5. General derogation to the assignment of food simulants

By derogation from the assignments of food simulants in points 2 to 4 of this Annex, where testing with several food simulants is required, a single food simulant shall be sufficient if on the basis of evidence acquired using generally recognised scientific methods this food simulant is shown to be the most severe food simulant for the particular material or article being tested under the applicable time and temperature conditions selected in accordance with Chapters 2 and 3 of Annex V.

The scientific basis on which this derogation is used shall in such cases form part of the documentation required under Article 16 of this Regulation.;

(4) in Annex IV, point (5) is replaced by the following:

'(5) confirmation that the plastic materials or articles, products from intermediate stages of manufacture or the substances meet the relevant requirements laid down in this Regulation and in Article 3, 11(5), 15 and 17 of Regulation (EC) No 1935/2004.;

(5) Annex V is amended as follows:

(a) Section 1.4 of Chapter 1 is replaced by the following:

‘1.4. Account of substances originating from other sources

In case there is evidence linked to the food sample that a substance partially or wholly originates from a source or sources other than the material or article for which the test is being carried out, the test results shall be corrected for the amount of that substance originating from the other source or sources before comparing the test results to the applicable specific migration limit’;

(b) in Section 2.1.3 of Chapter 2, the text before Table 1 is replaced in its entirety by the following:

‘The sample shall be placed in contact with the food simulant in a manner representing the worst of the foreseeable conditions of use as regard contact time in Table 1 and as regard contact temperature in Table 2.

By way of derogation to the conditions set out in Tables 1 and 2, the following rules apply:

- (i) If it is found that carrying out the tests under the combination of contact conditions specified in Tables 1 and 2 causes physical or other changes in the test specimen which do not occur under worst foreseeable conditions of use of the material or article under examination, the migration tests shall be carried out under the worst foreseeable conditions of use in which these physical or other changes do not take place;
- (ii) if the material or article during its intended use is subjected only to precisely controlled time and temperature conditions in food processing equipment, either as part of food packaging or as part of the processing equipment itself, testing may be done using the worst foreseeable contact conditions that can occur during the processing of the food in that equipment;
- (iii) if the material or article is intended to be employed only for hot-fill conditions, only a 2-hour test at 70 °C shall be carried out. However, if the material or article is intended to be used also for storage at room temperature or below, the test conditions set out in Tables 1 and 2 of this Section or in Section 2.1.4 of this Chapter apply depending on the duration of storage.

If the testing conditions representative for the worst foreseeable conditions of intended use of the material or article, are not technically feasible in food simulant D2, migration tests shall be done using ethanol 95 % and isooctane. In addition a migration test shall be done using food simulant E if the temperature under the worst foreseeable conditions of intended use exceeds 100 °C. The test that results in the highest specific migration shall be used to establish compliance with this Regulation.’;

(c) in Table 1, the title of the table is replaced by the following:

‘Selection of test time’;

(d) in Table 1, the title of column 2 is replaced by the following:

‘Time to be selected for testing’;

(e) Table 2 is replaced by the following:

‘Table 2

Selection of test temperature

Worst foreseeable contact temperature	Contact temperature to be selected for testing
$T \leq 5 \text{ °C}$	5 °C
$5 \text{ °C} < T \leq 20 \text{ °C}$	20 °C

Worst foreseeable contact temperature	Contact temperature to be selected for testing
$20\text{ °C} < T \leq 40\text{ °C}$	40 °C
$40\text{ °C} < T \leq 70\text{ °C}$	70 °C
$70\text{ °C} < T \leq 100\text{ °C}$	100 °C or reflux temperature
$100\text{ °C} < T \leq 121\text{ °C}$	121 °C (*)
$121\text{ °C} < T \leq 130\text{ °C}$	130 °C (*)
$130\text{ °C} < T \leq 150\text{ °C}$	150 °C (*)
$150\text{ °C} < T < 175\text{ °C}$	175 °C (*)
$175\text{ °C} < T \leq 200\text{ °C}$	200 °C (*)
$T > 200\text{ °C}$	225 °C (*)

(*) This temperature shall be used only for food simulants D2 and E. For applications heated under pressure, migration testing under pressure at the relevant temperature may be performed. For food simulants A, B, C or D1 the test may be replaced by a test at 100 °C or at reflux temperature for duration of four times the time selected according to the conditions in Table 1.'

- (f) Section 2.1.4 of Chapter 2 is replaced by the following:

'2.1.4. Specific conditions for contact times above 30 days at room temperature and below

For contact times above 30 days (long term) at room temperature and below, the specimen shall be tested in accelerated test conditions at elevated temperature for a maximum of 10 days at 60 °C (*).

- (a) Testing for 10 days at 20 °C shall cover all storage times at frozen condition. This test can include the freezing and defrosting processes if labelling or other instructions ensure that 20 °C is not exceeded and the total time above – 15 °C does not exceed 1 day in total during the foreseeable intended use of the material or article.
- (b) Testing for 10 days at 40 °C shall cover all storage times at refrigerated and frozen conditions including hot-fill conditions and/or heating up to $70\text{ °C} \leq T \leq 100\text{ °C}$ for maximum $t = 120/2^{((T-70)/10)}$ minutes.
- (c) Testing for 10 days at 50 °C shall cover all storage times of up to 6 months at room temperature, including hot-fill conditions and/or heating up to $70\text{ °C} \leq T \leq 100\text{ °C}$ for maximum $t = 120/2^{((T-70)/10)}$ minutes.
- (d) Testing for 10 days at 60 °C shall cover storage above 6 months at room temperature and below, including hot-fill conditions and/or heating up to $70\text{ °C} \leq T \leq 100\text{ °C}$ for maximum $t = 120/2^{((T-70)/10)}$ minutes.
- (e) For storage at room temperature the testing conditions can be reduced to 10 days at 40 °C if it is shown by scientific evidence that migration of the respective substance in the polymer has reached equilibration under this test condition.

- (f) For worst foreseeable conditions of intended use not covered by the test conditions set out in points (a) to (e), the testing time and temperature conditions shall be based on the following formula:

$$t_2 = t_1 * \text{Exp} (9627 * (1/T_2 - 1/T_1))$$

t₁ is the contact time

t₂ is the testing time

T₁ is the contact temperature in Kelvin. For room temperature storage this is set at 298K (25 °C). For refrigerated conditions it is set at 278K (5 °C). For frozen storage it is set at 258 K (- 15 °C).

T₂ is the testing temperature in Kelvin.

- (*) When testing at these accelerated test conditions the test specimen shall not undergo any physical or other changes compared to the real conditions of use, including a phase transition of the material.;

- (g) the first paragraph of Section 2.1.5 of Chapter 2 is replaced by the following:

'If a material or article is intended for different applications covering different combinations of contact time and temperature the testing shall be restricted to the test conditions which are recognised to be the most severe on the basis of scientific evidence.;

- (h) in Section 2.1.6 of Chapter 2, the third paragraph is replaced by the following:

'The material or article shall respect the specific migration limit already in the first test for substances that are prohibited from migrating or from being released in detectable quantities under Article 11(4).;

- (i) the first paragraph of Section 2.2 of Chapter 2 is replaced by the following:

'To screen if a material or article complies with the migration limits any of the following approaches can be applied which are considered at least as severe as the verification method described in section 2.1.;

- (j) Section 2.2.3 of Chapter 2 is replaced by the following:

'2.2.3. *Migration modelling*

To screen for specific migration, the migration potential can be calculated based on the residual content of the substance in the material or article applying generally recognised diffusion models based on scientific evidence that are constructed in a way that must never underestimate real levels of migration.;

- (k) Section 2.2.4 of Chapter 2 is replaced by the following:

'2.2.4. *Food simulant substitutes*

To screen for specific migration, food simulants can be replaced by substitute food simulants if it is based on scientific evidence that the substitute food simulants result in migration that is at least as severe as migration that would be obtained using the food simulants specified in Section 2.1.2;

- (l) in Section 2.2 of Chapter 2, the following paragraph 2.2.5 is added:

'2.2.5. *Single test for successive combinations of time and temperature*

If the material or article is intended for a food contact application where it is successively subject to two or more time and temperature combinations, a single migration contact test time can be defined based on the highest contact test temperature from Section 2.1.3 and/or 2.1.4 by using the equation as described in point (f) of Section 2.1.4. The reasoning justifying that the resulting single test is at least as severe as the combined time and temperature combinations shall be documented in the supporting documentation provided for in Article 16.;

(m) Table 3 in Chapter 3 is replaced by the following:

‘Table 3

Standardised conditions for testing the overall migration

Column 1	Column 2	Column 3
Test number	Contact time in days [d] or hours [h] at contact temperature in [°C] for testing	Intended food contact conditions
OM1	10 d at 20 °C	Any food contact at frozen and refrigerated conditions.
OM2	10 d at 40 °C	Any long term storage at room temperature or below, including when packaged under hot-fill conditions, and/or heating up to a temperature T where 70 °C ≤ T ≤ 100 °C for a maximum of $t = 120/2^{(T-70)/10}$ minutes.
OM3	2 h at 70 °C	Any food contact conditions that include hot-fill and/or heating up to a temperature T where 70 °C ≤ T ≤ 100 °C for maximum of $t = 120/2^{(T-70)/10}$ minutes, which are not followed by long term room temperature or refrigerated storage.
OM4	1 h at 100 °C	High temperature applications for all types of food at temperature up to 100 °C.
OM5	2 h at 100 °C or at reflux or alternatively 1 h at 121 °C	High temperature applications up to 121 °C.
OM6	4 h at 100 °C or at reflux	Any food contact conditions at a temperature exceeding 40 °C, and with foods for which point 4 of Annex III assigns simulants A, B, C or D1.
OM7	2 h at 175 °C	High temperature applications with fatty foods exceeding the conditions of OM5.’

(n) in Section 3.1 of Chapter 3, the paragraphs below Table 3 are replaced by the following:

‘Test OM7 also covers food contact conditions described for OM1, OM2, OM3, OM4 and OM5. It represents the worst case conditions for food simulant D2 in contact with non-polyolefins. In case it is technically not feasible to perform OM 7 with food simulant D2 the test can be replaced as set out in Section 3.2.

Test OM6 covers also food contact conditions described for OM1, OM2, OM3, OM4 and OM5. It represents worst case conditions for food simulants A, B, C and D1 in contact with non-polyolefins.

Test OM5 covers also food contact conditions described for OM1, OM2, OM3, and OM4. It represents the worst case conditions for all food simulants in contact with polyolefins.

Test OM2 covers also food contact conditions described for OM1 and OM3.’

(o) Section 3.2 of Chapter 3 is replaced by the following:

‘3.2. Substitute overall migration tests for tests with food simulant D2

If it is not technically feasible to perform one or more of the tests OM1 to OM6 in food simulant D2, migration tests shall be done using ethanol 95 % and isooctane. In addition a test shall be done using food simulant E in case the worst foreseeable conditions of use exceed 100 °C. The test that results in the highest specific migration shall be used to establish compliance with this Regulation.

In case it is technically not feasible to perform OM7 with food simulant D2 the test can be replaced by either test OM8 or test OM9 as appropriate given the intended or foreseeable use. Both tests involve testing at two test conditions for which a new test sample shall be used for each test. The test condition that results in the highest overall migration shall be used to establish compliance with this Regulation.

Test number	Test conditions	Intended food contact conditions	Covers the intended food contact conditions described in
OM8	Food simulant E for 2 hours at 175 °C and food simulant D2 for 2 hours at 100 °C	High temperature applications only	OM1, OM3, OM4, OM5 and OM6
OM9	Food simulant E for 2 hours at 175 °C and food simulant D2 for 10 days at 40 °C	High temperature applications including long term storage at room temperature	OM1, OM2, OM3, OM4, OM5 and OM6’

(p) Section 3.3 of Chapter 3 is replaced by the following:

‘3.3. Verification of compliance

3.3.1. Single use articles and materials

At the end of the prescribed contact time, to verify compliance the overall migration is analysed in the food simulant using an analytical method in accordance with the requirements of Article 11 of Regulation (EC) No 882/2004.

3.3.2. Repeated use articles and materials

The applicable overall migration test shall be carried out three times on a single sample using another portion of food simulant on each occasion. The migration shall be determined using an analytical method in accordance with the requirements of Article 11 of Regulation (EC) No 882/2004. The overall migration in the second test shall be lower than in the first test, and the overall migration in the third test shall be lower than in the second test. Compliance with the overall migration limit shall be verified on the basis of the level of the overall migration found in the third test.

If it is not technically feasible to test the same sample three times, such as when testing in oil, the overall migration test can be carried out by testing different samples for three different periods of time lasting one, two and three times the applicable contact test time. The difference between the third and the second test results shall be considered to represent the overall migration. Compliance shall be verified on the basis of this difference, which shall not exceed the overall migration limit. In addition, it shall not be higher than the first result and the difference between the second and the first test results.

By derogation from the first paragraph, if, on the basis of scientific evidence, it is established that for the material or article being tested the overall migration does not increase in the second and third tests and if the overall migration limit is not exceeded in the first test, the first test alone shall be sufficient.’;

- (q) the first paragraph of Section 3.4 of Chapter 3 is replaced by the following: 'To screen if a material or article complies with the migration limits, any of the following approaches can be applied which are considered at least as severe as the verification method described in Sections 3.1 and 3.2.:'
- (r) Section 3.4.2 of Chapter 3 is replaced by the following:
- '3.4.2. *Food simulant substitutes*
- To screen for overall migration, food simulants can be replaced if based on scientific evidence the substitute food simulants result in migration that is at least as severe as migration that would be obtained using the food simulants specified in Annex III.:'
- (s) in Section 4.1 of Chapter 4, the fifth paragraph is replaced by the following:
- 'The specific migration in food or food simulant shall not exceed 60 mg/kg food before application of the FRF.:'
- (t) in Section 4.1 of Chapter 4, the following paragraph is added:
- 'When testing is performed in food simulant D2 or E and when the test results are corrected in application of the correction factor laid down in Table 2 of Annex III this correction may be applied in combination with the FRF by multiplying both factors. The combined correction factor shall not exceed 5, unless the correction factor laid down in Table 2 of Annex III exceeds 5.:'
- (u) Sections 4.2 and 4.3 of Chapter 4 are deleted.
-