EUROPEAN
COMMISSION

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COMMISSION REGULATION (EU) No …/..

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)

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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC[1], and in particular points (a), (c), (d) and (e) of Article 5(1), Article 11(3) and Article 12(6) thereof,

Whereas:

(1) In the definition of 'non-fatty foods' provided for in Article 3(16) of Commission Regulation (EU) No 10/2011[2] ('the Regulation'), a reference to food simulants is made to the wrong table. Therefore it is appropriate to correct the reference to Table 2 of Annex V, which should read Table 2 of Annex III.

(2) Rubber food contact materials are excluded from the scope of the Regulation. Rubbers and plastics are both polymeric materials which may be produced from the same starting materials, which may be elastic, which may either be thermoset or thermoplastic, which may be cross-linked, and which may be added to each other. Conventional definitions of rubbers and plastics are based on these properties and therefore do not distinguish unambiguously between the two materials. This presently causes problems in determining the compliance of rubber-like materials under the Regulation and therefore a clarification by defining 'rubber' under the Regulation is appropriate.

(3) Rubber materials and articles are excluded from the Regulation because of differences in chemistry for which the Regulation does not provide. In particular, vulcanisation of rubbers involves a chemistry based on sulphur or equivalent curatives, but not based on other substances including zinc chloride and cross linking monomers. Vulcanisation is therefore pertinent to distinguish rubbers from plastics, and such rubber materials should therefore not be in the scope of the Regulation. Already vulcanised rubber used as an additive to plastics should remain in the scope of the Regulation as its vulcanisation chemistry is no longer relevant at that stage. It is therefore appropriate that the definition of 'rubber' in the Regulation is based accordingly on vulcanisation and that the definition of 'vulcanisation' is added to the Regulation.

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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).

(4) The Regulation provides derogation to the listing requirement for salts of authorised acids, phenols or alcohols. However this derogation was intended to be also applicable to multiple salts and hydrates of salts. This is not clear from the current text. Therefore the Regulation should be amended to extend the derogation to multiple salts and salt hydrates.

(5) This Regulation for the first time restricts the migration of oligomers containing certain substances. Testing for oligomer migration is technically challenging. Enforcement and other laboratories should have adequate analytical methods available. To ensure that compliance of a material to which such oligomer migration limits apply can be verified by enforcement laboratories and by the users of such materials, and to ensure the uniformity of such verification of compliance on the Union market, testing methods should therefore be made publically available via the European Union reference laboratory for material intended to come into contact with foodstuffs established as laid down in Regulation (EC) No 882/2004 to ensure a capability regarding their uniform application by business operators and competent authorities before the substances can be placed on the market.

(6) In Article 13(3) of the Regulation the phrase 'with statistical certainty' appears. This phrase is meaningless but is intended to indicate that measurement uncertainty should be taken into account. Therefore it is appropriate to include a statement on measurement uncertainty, and to delete 'with statistical certainty'.

(7) Specific migration should be expressed in mg/kg food. Currently migration from caps can also be expressed in mg/dm². Therefore it is appropriate to remove the possibility to express the migration from caps in mg/dm² by amending Article 17(3)(a).

(8) Article 18(4) defines simulants that should be used for determining overall migration. It is not appropriate to specify these simulants in Article 18(4) as these are specified in Annex III. Therefore the specification of simulants in Article 18(4) should be deleted

(9) To ensure a clear procedure and to minimise the burden, rules should be established regarding the publication of methods by the European Union reference laboratory for material intended to come into contact with foodstuffs if the publication of such rules is required before a substance can be placed on the market. Therefore such rules should be added to the Regulation.

(10) Table 1 of Annex I to the Regulation establishes a Union list of authorised substances ('the Union list') which may be used in the manufacture of plastic materials and articles.

(11) Article 13(2)(b) of the Regulation allows that plastic materials can be produced with layers containing substances that are not included on the Union list, provided that these layers are used behind a functional barrier. Such substances should be risk assessed according to internationally recognised scientific principles as is required under Article 19 of this Regulation. Article 19 however does not provide a reference to Article 13(2)(b). To ensure that also substances allowed under Article 13(2)(b) are subject to risk assessment, the Regulation should be corrected and a reference to Article 13(2)(b) should be added to Article 19.

(12) The transitional period for applying the provisions of the Regulation to additives used in glass fibre sizing will end on 31 December 2015. Further analysis has established that the composition of glass fiber sizing agents is more complex than initially anticipated and that specific rules under the Regulation are required in addition or in place of application of Article 5. The Commission is currently consulting with the

Authority on such rules. Therefore it is appropriate to clarify that the transitional provisions apply to all constituents of glass fibre sizing for glass fibre reinforced plastics and to continue the application of Article 19 for one year.

(13) The word 'should' is used several times in the Annex I and Annex V of the Regulation for obligatory provisions. Therefore 'should' should be replaced with 'shall' in those Annexes to the Regulation.

(14) In column 10 of the Union list several references are made to simulant D. The present Regulation does not specify simulant D any more, but specifies simulant D1 and D2. Therefore references to simulant D should be replaced by a reference to simulant D1 or D2 for all substances in which the reference to simulant D is specified as part of the restriction in column 10.

(15) The substance silicon dioxide, silanated (food contact material ('FCM') substance No 87), is authorised for use as an additive in all types of plastics, without restriction. This substance is produced on the basis of synthetic amorphous silicon dioxide in nanoform. Under Article 9(2) Substances in nanoform should only be used if explicitly authorised and mentioned in the specifications in Annex I. Taking account of the available scientific information on this substance, the European Food Safety Authority ('the Authority') concluded that the use of this substance does not raise any safety concern when in the final material only agglomerates larger than 100 nm are present[3]. Therefore, the Union list should be amended to specify that the substance can be used in its nanoform when no particles of a smaller size than 100 nm remain in the final material.

(16) The Authority adopted a favourable scientific opinion[4] 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 %, in contact with dry foods as represented by simulant E, at contact conditions at ambient temperature or below, and when migration of the low molecular weight oligomeric fraction less than 1000 Da does in total not exceed 50 μg/kg food, the use of this substance does not endanger human health. Therefore it should be added to the Union list with the restriction that these specifications should be met.

(17) The Authority adopted a favourable scientific opinion[5] on the use of the starting substance furan-2,5-dicarboxylic acid (FCM No 1031). When used as a 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 1000 Da does not exceed 50 μg/kg food. When compliance is verified for contact with non alcoholic foods for which Table 2 of Annex III assigns food simulant D1, there is a risk of an interaction between the simulant and the plastic which would not occur in contact with such foods. According to the opinion food simulant C would be considered sufficiently conservative for such foods. Therefore it should be added to the Union list with the restriction that these specifications should be met, and a note on the verification of compliance should be added.

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3 EFSA Journal 2014;12(6):3712.
4 EFSA Journal 2014;12(11):3909.
5 EFSA Journal 2014;12(10):3866.

(18) The Authority adopted a favourable scientific opinion[6] 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. Therefore it should be added to the Union list with the restriction that these specifications should be met.

(19) The Authority adopted a favourable scientific opinion[7] 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 with the restriction that these specifications should be met.

(20) The Authority adopted a favourable scientific opinion[8] on the use of the additive ethylene glycol dipalmitate (FCM No 1048). The Authority concluded that when the substance is produced using an fatty acid precursor conventionally obtained from edible fats or oils and the migration of ethylene glycol is controlled by including it in the group SML(T) for ethylene glycol, the use of this additive does not endanger human health. Therefore this additve should be added to the Union list with the restriction that these specifications should be met, and entry (2) of table 2 of Annex I should be amended to include it.

(21) The Authority adopted a favourable scientific opinion[9] 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 the migration does not exceed 5 mg/kg food, the use of this additive does not endanger human health. Therefore it should be added to the Union list with a migration limit of 5 mg/kg food.

(22) The Authority adopted a favourable scientific opinion[10] 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 used as a monomer in the production of polyesters, its migration does not exceed 5 mg/kg food, and the migration of the oligomers of less than 1000 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 added to the Union list with with the restriction that these specifications should be met.

(23) The Authority adopted a favourable scientific opinion[11] on the use of the additive fatty acids, C16–18 saturated, hexaesters with dipentaerythritol (FCM No 1053). Because any content of lower esters (e.g. penta-, tetra-, etc.) is not of a safety concern, the Authority concluded that the use of the substance fatty acids, C16–18 saturated, esters with dipentaerythritol does not endanger human health, provided that the substance is produced using an fatty acid precursor obtained from edible fats or oils.

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6 EFSA Journal 2015;13(1):3979.
7 EFSA Journal 2014;12(6):3718.
8 EFSA Journal 2015;13(2):4019.
9 EFSA Journal 2014;12(10):3867.
10 EFSA Journal 2014;12(10):3863.
11 EFSA Journal 2015;13(2):4021

Therefore it should be added to the Union list with with the restriction that this specification should be met, and without restricting it to hexaesters.

(24) The Authority adopted an opinion[12] on the safety of aluminium from dietary intake. This establishes a tolerably weekly intake of 1 mg aluminium per kg body weight per week. Using the conventional exposure assumptions for food contact materials, a migration limit of 8,6 mg/kg food would follow. The opinion also notes that the current dietary exposure of a significant part European population likely exceeds this level. Therefore it would be appropriate to apply an allocation factor of 10% to the conventionally derived migration limit. Therefore a migration limit for aluminium of 0,9 mg/kg food is appropriate for food contact materials. To prevent exaggerated analytical precision in view of the uncertainties in deriving this limit, it should be rounded to 1 mg/kg food. This limit should therefore be specified in Annex II of the Regulation, and the Regulation should be amended accordingly.

(25) The Authority adopted an opinion on the risks to public health related to the presence of nickel in food and drinking water[13]. 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 close to the TDI or above it, particularly when considering the young population. Therefore it would be appropriate to apply an allocation factor of 10% to the conventionally derived migration limit. Therefore a migration limit for nickel of 0,0168 mg/kg food is appropriate for food contact materials. To prevent exaggerated analytical precision in view of the uncertainties in deriving this limit, it should be rounded to 0,02 mg/kg food. This limit should therefore also be specified in Annex II of the Regulation, and the Regulation should be amended accordingly.

(26) The Authority adopted an opinion on dietary reference values for zinc[14]. This reconfirms an opinion expressed by the scientific committee on foods (SCF) in 2002[15] which sets tolerable upper intake level of zinc from to 25 mg/kg food. In Annex II of the Regulation the migration limit for zinc is also set at 25 mg/kg food. As dietarty exposure from other sources significantly contributes to the total exposure, the upper intake level would be exceeded when migration of zinc up to the migration limit occurs. Therefore to reduce the contribution from food contact material to the total exposure to zinc, and taking 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 approapriate to amend the migration limit specified in Annex II to 5 mg/kg food.

(27) Only a specification of the amount of saponifiable matter in vegetable oil to be used for simulant D2 is sufficient to specify this simulant. It is therefore appropriate to delete any other specification and to amend the note below Table 1 of Annex III.

(28) No simulants have been assigned for fresh fruits and vegetables that are unpeeled and uncut. These fruits and vegetables are generally dry and therefore food simulant E is appropriate. As materials and articles will only be in partial contact with these fruits or vegetables, or the fruits or vegetables may be washed and or peeled by the consumer, migration testing with food simulant E would give a significant overestimation. As in practice many contact situations may occur for instance depending on the type of fruit or vegetable, it is not practicable to describe. Therefore to reduce the overestimation

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12 The EFSA Journal (2008) 754, 1-34

13 EFSA Journal 2015;13(2).

14 EFSA Journal 2014;12(10):3844.

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

the migration results obtained by conventional migration testing with food simulant E should be devided by 10. Therefore this condition should be added to Table 2 of Annex III, and an explanation of the notation should added to point 3 of Annex III and to paragraph 4.2 of annex V.

(29) No simulants have been assigned for fresh fruits that are peeled and or cut. It is appropriate that food simulant A and B are specified for this type of fruit. Therefore this category should be added to Table 2 of Annex III.

(30) It is not useful to test in several food simulants if it is scientifically evident that one food simulant is the most severe for a specific substance or material. Therefore it is appropriate to add a general derogation to the assignements of food simulants in Annex III allow the testing in only one simulant if appropriate scientific evidence is documented showing that this simulant is the most severe.

(31) The Regulation specifies that certain constituents of plastic materials and articles should not migrate at detectable levels. These materials and articles should always comply to this specification in the first migration test when used in repeat use articles. The migration testing rules set out in points 2.1.6 and 4.2 of Annex V now specifically refer to such specifications set out in Annex I. These rules should also apply to other substances that should only migrate in non-detectable amounts including those specified in Annex II. It is therefore appropriate to delete the specific reference from the Regulation and to clarify that it applies to all substances.

(32) According to recital 32 of the Regulation methods used to replace migration testing should give results that are at least as severe as the migration testing results. In the Regulation the wording 'more severe' is also used in this context. This is not consistent and causes problems in the interpretation of the text. Therefore 'more severe' should be replaced with 'at least as severe' in these cases.

(33) The second paragraph of point 2.1.3 of Annex V may suggest that migration testing conditions can be selected such that physical or other changes do not take place during the testing, but that these changes could still take place under the real usage conditions of the material and article. However the migration testing conditions should always be at least as severe as the real conditions of use. Therefore it is appropriate to clarify the second paragraph by deleting the last section of the last sentence of the paragraph.

(34) 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 alternatives food simulants and rules for verification of compliance should be specified for such conditions. Therefore it is appropriate to add such alternatives and rules to the Regulation.

(35) Table 1 of point 2.1.3 of Annex V does not clearly set out that the time specified for testing represents the time during which a simulant or food should be in contact with the food contact material during the test. Therefore the table head for column 2 should be amended to ensure correct interpretation of the specified testing times.

(36) The temperature specified for testing above 175°C is not representative for all temperatures therefore appropriate rules for testing above 175°C should be added to table 2 of point 2.1.3 of Annex V.

(37) The Regulation specifies conditions for contact times above 30 days. This specification is not clear on whether the specified formula should be used or the standard testing conditions, and on the specification of hot-fill and frozen storage conditions. These specifications should therefore be amended to ensure that the

formula is only used for contact conditions in which the standard conditions do not apply and to clearly specify test conditions for hot-fill and frozen usage conditions.

(38) The Regulation uses the word 'overestimate' in a context in which this is not always clear whilst the text 'as severe as' would be clear in such instances. Therefore the Regulation should be amended accordingly.

(39) In some cases it is more efficient and appropriate to screen whether a material or article complies with the Regulation using a single test instead of a series of tests representative for time and temperature combinations that would foreseeably be used in the real use of a material or article, provided a justification for this substitution is documented. Therefore a rule for allowing such a single screening test should be specified in the Regulation.

(40) The Regulation states that testing condition OM6 represents the worst case conditions for simulants A, B and C. However, it also represents the worst case condition for simulant D1, and this simulant can also be used in this test. Therefore the Regulation should be corrected to include references to simulant D1.

(41) The Regulation states that testing condition OM7 represents the worst case conditions for 'fatty food simulants'. However, it represents the worst case condition for simulant D2 only. Therefore the Regulation should be corrected such that only reference to simulant D2 is made.

(42) It is not always technically feasible to test overall migration using one of the specified tests for overall migration testing. The Regulation only specifies an alternative test for OM7, however, also tests for OM1 to OM6 should be specified.

(43) It is not always technically feasible to test overall for repeated use in an oily medium using the same sample three times. Therefore an alternative testing approach should be specified in the Regulation.

(44) The Regulation does not clearly describe that the application of the FRF should not allow that specific migration would exceed the generic specific migration limit. Therefore it is appropriate to clarify the text of point 4.1 of Annex V.

(45) To limit the administrative burden to business operators, plastic materials and articles which have been lawfully placed on the market based on the requirements set out in Regulation (EU) No 10/2011 before the entry into force of this Regulation and which do not comply with this Regulation should be able to be placed on the market until [*insert a precise date which will be 12 months after the entry into force of this Regulation*]. They should be able to remain on the market until exhaustion of stocks.

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

(47) 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

Annex I to Regulation (EU) No 10/2011 is amended in accordance with the Annex to this Regulation.

Article 2

Plastic materials and articles complying with the requirements of Regulation (EU) No 10/2011 as applicable before [entry into force of this Regulation] may be placed on the market until [12 months after the entry into force of this Regulation]. Those plastic materials and articles may remain on the market after that date until exhaustion of stocks.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

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

Done at Brussels,

For the Commission
The President
[…]