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COMMISSION REGULATION (EU) …/…

of XXX

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

(Text with EEA relevance)

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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), (d), (e), (h) and (i) of Article 5(1), 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, Annex I to the Regulation establishes a Union list of substances that may be used in the manufacture of plastic food contact materials and articles, while Annex II establishes additional restrictions applicable to plastic materials and Articles.

(2) Since the last amendment to the Regulation, the European Food Safety Authority ('the Authority') has published further scientific opinions on particular substances that may be used in food contact materials ('FCM') as well as on the use of already authorised substances. In addition, certain ambiguities to the application of the Regulation were identified. In order to ensure that the Regulation takes account of 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 Authority adopted a favourable scientific opinion[3] on the use of isostructural salt complexes of terephthalic acid (generically described as 1,4-benzene dicarboxylic acid, FCM substance No 785) with the following lanthanides: lanthanum (La), europium (Eu), gadolinium (Gd) and terbium (Tb) used alone or in combination and in varying proportions, as additives in plastics intended to come into contact with foods. The Authority concluded that those salts are not of a safety concern for the consumer if used as additives in polyethylene, polypropylene or polybutene plastic materials and articles intended to come into contact with all food types under contact conditions of up to 4 hours at 100°C or for long-term storage at ambient temperature. This conclusion is made on the basis that, if migration from the plastic food contact material to the food or food simulant were to occur, the lanthanides should be present in the food or the food simulant in dissociated ionic form and the migration of the sum

[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 2018; 16(11)5449

of the four lanthanide ions (La, Eu, Gd, Tb) when used alone or in combination should not exceed 0,05 mg/kg food.

(4) The Authority noted that, in light of the chemical characteristics of the isostructural lanthanide salts of terephthalic acid and of the four lanthanides (La, Eu, Gd, Tb) themselves, it is not necessary to restrict the use of these additives to the three polyolefin type of plastics specified in the application dossier the applicant provided to the Authority as no undesirable interactions with plastics (including, but not limited to polyolefins) leading to formation and possible migration of undesirable reaction and transformation products are to be expected. This conclusion is made on the same basis as for the polyolefin plastics that, if migration from the plastic food contact material to the food or food simulant were to occur, the lanthanides should be present in the food or the food simulant in dissociated ionic form and the migration of the sum of the four lanthanide ions (La, Eu, Gd, Tb), when used alone or in combination, should not exceed 0,05 mg/kg food. Therefore, it is appropriate to authorise the lanthanides for use in all types of plastic materials and articles as salts of already authorised substances, provided that these restrictions are met.

(5) Article 6(3)(a) of the Regulation allows for the use of salts of certain metals and of ammonium of authorised acids, alcohols and phenols, based on the conclusion that these salts will dissociate in the human stomach to the corresponding cations and the phenols, alcohols and acids[4]. As the Authority concluded that the four lanthanides should also dissociate, and for the purpose of simplification, those four lanthanides should also be included in the scope of Article 6(3)(a), in order to authorise their use as counter ions of already authorised acids, alcohols and phenols in all types of plastic materials and articles. Therefore it is appropriate to amend this Article to include those four lanthanides.

(6) Article 10 of the Regulation sets out general restrictions related to plastic materials and articles, which are laid down in Annex II to the Regulation. Specifically, point 1 of this Annex restricts the migration of certain elements from plastic materials and articles into food or food simulants. The elements to which these limits apply may be present in plastic materials and Articles on the basis of several provisions set out in Chapter II of the Regulation. They may be present in the plastic because they are intentionally used as an additive or starting substance included in Annex I, or because their use is subject to a derogation under Article 6, including if they would be present in the plastic as an impurity or other non-intentionally added substance. The migration limits set in point 1 of Annex II to the Regulation therefore also apply to the metals which are present in the plastic material or article on the basis of Article 6(3)(a) of the Regulation. When the four lanthanides are added to the list of metals set out in Article 6(3)(a) their limits should therefore also be added to point 1 of Annex II.

(7) The addition of the four lanthanides to Article 6(3)(a) further lengthens the list of substances set out in that provision. For reasons of clarity and good drafting practice such lists should not be set out in the enacting terms of the Regulation but in an Annex. As point 1 of Annex II already applies to most metals presently listed in Article 6(3)(a) this point can be used to also clarify whether it is permitted to use certain salts of these substances in accordance with Article 6(3)(a) without adding another list to the Regulation. It is therefore appropriate to clarify and simplify the Regulation by removing the names of the metals from Article 6(3)(a) and by amending Annex II to include them in point 1 of Annex II. For this purpose, it is appropriate to

[4] EFSA Journal 2009; 7(10):1364

replace the present list of limits in point 1 of Annex II with a table that lists all metals presently included in Article 6(3)(a) and those included in point 1 of Annex II and with the specific conditions of use and migration limits of those metals. As Article 6(3)(a) also provides that ammonium salts of authorised acids, alcohols and phenols are authorised in the same way as the specified metals, it is appropriate that ammonium is also included in point 1 of Annex II.

(8) The substance 1,3 phenylenediamine (CAS No 0000108-45-2, FCM No 236) is a Primary Aromatic Amine currently included in Annex I of the Regulation to be used as a starting substance in plastic materials and articles intended to come into contact with food provided it does not migrate. However to verify compliance with this requirement it should not be detected in the food or the food simulant above the 0,01 mg/kg food or food simulant detection limit, in accordance with the second subparagraph of Article 11(4) of Regulation (EU) 10/2011. The advances in analytical capabilities allow the detection of 1,3 phenylenediamine at 0,002 mg/kg food or food simulant. It is therefore appropriate to amend Annex I of the Regulation to set this value as a specific detection limit for this substance to reflect this improvement in analytical capability and to maximise the health protection of consumers.

(9) The Authority adopted a favourable scientific opinion[5] on the use of the substance montmorillonite clay modified with hexadecyltrimethylammonium bromide (FCM No 1075), as an additive in plastic food contact materials. In that opinion, the Authority concluded that the substance is not of safety concern for the consumer if it is used as an additive at up to 4% (w/w) in polylactic acid plastics intended for storage of water at ambient temperature or below. The Authority noted that once dispersed in the polylactic acid plastic, the particles can form platelets that can be in one or two dimensions in the nanoparticle range (< 100 nanometres). These platelets are not expected to migrate as they are oriented parallel to the plastic packaging film surface and they are fully embedded in the polymer. Therefore, that additive should be included in the Union list of authorised substances with the restriction that those specifications should be met.

(10) The Authority adopted a favourable scientific opinion[6] on the use of the substance phosphorous acid, triphenyl ester, polymer with alpha-hydro-omega-hydroxypoly[oxy(methyl-1,2-ethanediyl)], C10-16 alkyl esters (FCM No 1076 and CAS No 1227937-46-3), as an additive in plastic food contact materials. In that opinion, the Authority concluded that this substance is not of safety concern for the consumer if it is used as an additive at up to 0,2% (w/w) in high impact polystyrene ('HIPS') materials and articles intended for contact with aqueous, acidic, low-alcohol and fatty foods, for long-term storage at room temperature and below, including hot-fill and/or heating up to 100°C for up to 2 hours, and if its migration does not exceed 0,05 mg/kg food. To ensure that the migration levels established by the Authority are not exceeded, this substance should not be used in contact with foods for which food simulants C and/or D1 is assigned in Annex III to the Regulation. Therefore, that additive should be included in the Union list of authorised substances with the restriction that those specifications should be met.

(11) The Authority adopted a favourable scientific opinion on the use of the substance titanium dioxide surface-treated with fluoride-modified alumina (FCM No 1077) as an

[5] EFSA Journal 2019; 17(1):5552
[6] EFSA Journal 2019; 17(5):5679

additive in plastic food contact materials[7]. In that opinion, the Authority noted that the substance, which is a defined mixture of particles of which a certain number have a diameter in the nanoparticle range (< 100 nanometres), is embedded in the polymer and does not migrate. The Authority concluded that this substance is not of safety concern to the consumer if it is used as an additive at up to 25,0% (w/w) in all polymer types in contact with all food types for any time and temperature conditions. The Authority also concluded that the use of this substance in polar polymers which swell when in contact with foods for which food simulant B (3,0% w/v acetic acid) is assigned in Annex III to the Regulation could exceed the respective specific migration limits of 0,15 mg/kg and 1,0 mg/kg food or food simulant for fluoride and aluminium respectively, if used in certain contact conditions. Significant exceedance of those limits was shown in contact conditions exceeding 4 hours at 100 °C. Migration testing or modelling should therefore be used to exclude the possible exceedance of those limits under the intended and foreseeable use of a material containing this additive. This risk should be communicated to users of such materials and control authorities via a note on the verification of compliance. Therefore, it is appropriate to include this additive in the Union list of authorised substances, allowing its use as an additive at up to 25,0% (w/w) and with a note on the verification of compliance, warning that the migration limits can be exceeded under certain conditions.

(12) Antimony trioxide (CAS No 001309-64-4, FCM No 398) is currently included in Annex I of Regulation (EU) 10/2011 to be used as an additive or polymer production aid in plastic materials and articles intended to come into contact with food, with a specific migration limit of 0,04 mg/kg food or food simulant established in the opinion[8] of the Authority on this substance adopted in 2004, expressed as antimony, and with a note on the verification of compliance in Table 3 of Annex I that this specific migration limit may be exceeded at very high temperatures. Migration limit of 0,04 mg/kg is based on the Tolerable Daily Intake ('TDI') for antimony and a 10% allocation factor to account for the contribution of exposure to antimony from sources other than plastic materials and articles intended to come into contact with foods. This migration limit together with the accompanying note on the verification of compliance should therefore apply for the migration of antimony from plastic materials and articles intended to come into contact with food. It is therefore appropriate that Annex II of Regulation (EU) 10/2011 is amended to include antimony provided that its migration does not exceed 0,04 mg antimony/kg food or food simulant, and to also include the note on the verification of compliance of Table 3 of Annex I of that Regulation applicable to the antimony specific migration limit.

(13) The Authority has adopted opinions on arsenic (As), cadmium (Cd), chromium (Cr), lead (Pb), and mercury (Hg). These metals are not included in Annex I of Regulation (EU) 10/2011 and therefore are not authorised to be used in plastic materials and articles intended to come into contact with food. The adverse health effects of these metals are well established and transfer of these metals from plastics materials and articles to food should not occur at levels harmful to human health. While the levels of these metals are normally controlled in the subsequent manufacturing stages of plastic materials and articles in accordance with Article 4(d) of the Regulation, they can nevertheless end up being present as impurities in final plastic materials and articles based on the derogations set out in Article 6(4)(a), and adversely affect the health of the consumer. While the safety of these metals should principally be controlled in

[7] EFSA Journal 2019; 17(6):5737

[8] EFSA Journal 2004; 24 (1-13):2903

accordance with Article 19 of the Regulation and the documentation provided according to the provisions of Articles 15 and 16 of the Regulation, such work may not be implemented uniformly, is burdensome and difficult to verify by competent authorities. Therefore it is important to establish clarity with regard to the levels that should be verified analytically. It is therefore appropriate to amend Annex II of Regulation (EU) 10/2011 to establish limits on the migration of these metals to ensure a uniform approach to verification of compliance, the application of a uniform level of health protection, and the proper functioning of the single market.

(14) Some metals already exert adverse health effects at levels in the food below what can be quantified analytically using techniques applied by official control laboratories. In such a case, a non-detect limit in accordance with Article 11(4) of the Regulation is the appropriate means to verify the level of migration. The European Union Reference Laboratory for Food Contact Materials, designated in accordance with Regulation (EU) 2017/625[9] ('EURL-FCM') has conducted work with the national reference laboratories which shows that analytical methods are already available that are suitable to detect the migration of metals from plastic materials at lower levels that is presently the case and which can be routinely used by the majority of involved laboratories. Even though some of these limits may change because of further analytical developments in the future, it is appropriate to assign the detection limits that can be achieved now to those metals in order to establish a maximum possible and uniform level of safety. Therefore it is appropriate to clarify the detection limits for metals in table 1 of Annex II to the Regulation, and to redraft that table to provide a clearer framework for future changes to such limits.

(15) Specifically, the Authority adopted an opinion on inorganic arsenic in food[10] in which it identified a range of benchmark dose ('$BMDL_{01}$') values (at 99% confidence limit) between 0,3 and 8 µg of arsenic/kg body weight per day for cancers of the lung, skin and bladder as well as skin lesions. The Authority further estimated that dietary exposures to inorganic arsenic for average and high level consumers are within the range of the $BMDL_{01}$ values, and that there is little or no margin for any additional exposure, and therefore the possibility of a risk to some consumers cannot be excluded. Based on the lower $BMDL_{01}$ value, on a 10% allocation factor to account for the contribution of exposure to arsenic from sources other than plastic materials and articles intended to come into contact with food, and taking into account conventional exposure assumptions for food contact materials, the migration of arsenic from plastic materials and articles intended to come into contact with foods that may contain arsenic, should not exceed the level of 0,002 mg arsenic/kg food or food simulant. However, according to the EURL-FCM reliable detection of arsenic in food or food simulant has not been tested among National Reference Laboratories below the level of detection as laid down in Article 11(4) to the Regulation. Therefore it

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9 Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (OJ L 95, 7.4.2017, p. 1).

10 EFSA Journal 2009; 7(10):1351

advised to retain the non-detect (ND) limit for arsenic of 0,01 mg/kg food instead. It is therefore appropriate to amend Annex II of Regulation (EU) 10/2011 accordingly.

(16) The Authority furthermore adopted an opinion on cadmium in food[11] in which it identified a Tolerable Weekly Intake ('TWI') of 2,5 μg of cadmium/kg body weight per week for kidney toxicity. In that opinion, the Authority also noted association of cadmium intakes with increased risk of cancers of the lung, endometrium, bladder and breast. The Authority estimated that the mean exposure for adults is close to, or slightly exceeding, the TWI and subgroups of consumers such as vegetarians, children, smokers and people living in highly contaminated areas may exceed the TWI by about twofold. The Authority concluded that although the risk for adverse effects on kidney function taking into account dietary exposures across Europe is very low, the current exposure to cadmium should be reduced. Based on the TWI, on a 10% allocation factor to account for the contribution of exposure to cadmium from sources other than plastic materials and articles intended to come into contact with food, and taking into account conventional exposure assumptions for food contact materials, the migration of cadmium from plastic materials and articles intended to come into contact with food, should not exceed the level of 0,002 mg/kg in food or food simulant. Therefore, cadmium should not be detected in the food or the food simulant above the 0,002 mg/kg food or food simulant. It is therefore appropriate to amend Annex II of Regulation (EU) 10/2011 accordingly.

(17) The Authority also adopted an opinion on the risks to public health related to the presence of chromium in food and drinking water[12]. In this opinion, the Authority acknowledged that there is a lack of data on the presence of hexavalent chromium in food and decided to consider that essentially all of chromium analytically identified in food is likely to be trivalent chromium as food is, largely, a reducing medium that would not favour oxidation of trivalent chromium to hexavalent chromium. The Authority added however that, even if a small proportion of the total chromium in food is in the more toxic hexavalent form, it could contribute substantially to hexavalent chromium exposure from food. Hexavalent chromium can be present in drinking water including bottled drinking water. Although the more advanced available analytical techniques can distinguish between the trivalent and hexavalent chromium species, this species analytical differentiation can be cumbersome and difficult for competent authorities and business operators. It is therefore appropriate to take into account these considerations when ensuring compliance of plastic materials and articles, intended to come into contact with food that may contain chromium, with the Regulation.

(18) The Authority established a TDI of 0,3 mg/kg body weight per day for trivalent chromium for diffuse duodenal epithelial hyperplasia and haematoxicity. The Authority estimated that the dietary intakes of trivalent chromium for average and high level consumers in Europe amount to 5 and 8% of the TDI respectively. Based on the TDI and on a 20% allocation factor to account for the contribution of exposure to chromium from sources other than plastic materials and articles intended to come into contact with food and taking into account conventional exposure assumptions for food contact materials, a specific migration limit of 3,6 mg trivalent chromium/kg food or food simulant is appropriate. It is therefore appropriate to amend Annex II of Regulation (EU) 10/2011 to include trivalent chromium provided that the migration

[11] EFSA Journal 2009; 980 (1-131)

[12] EFSA Journal 2014;12(3):3595.

from plastic materials and articles intended to come into contact with food does not exceed 3,6 mg trivalent chromium/kg food or food simulant.

(19) In addition, the Authority also established a benchmark dose (at 90% confidence limit) ('$BMDL_{10}$') of 1,0 mg/kg body weight per day for hexavalent chromium. Since this species of chromium is genotoxic and carcinogenic, the Authority considered that a Margin of Exposure ('MOE') above 10 000 is required for the exposure to be of low concern. Taking into account the $BMDL_{10}$, the MOE of 10.000, a 20% allocation to account for the contribution of exposure to hexavalent chromium from sources other than plastic materials and articles intended to come into contact with food, and taking into account conventional exposure assumptions for food contact materials, the migration of hexavalent chromium from plastic materials and articles intended to come into contact with foods should not exceed the level of 0,0012 mg hexavalent chromium/kg food or food simulant to exclude adverse health effects. However, according to the EURL-FCM reliable detection of total chromium in food or food simulant has not been tested among National Reference Laboratories below the level of detection as laid down in Article 11(4) to the Regulation. Therefore it advised to retain the non-detect (ND) limit for chromium of 0,01 mg/kg food instead.

(20) In the light of the large difference in toxicity between trivalent and hexavalent chromium and the difficulty to distinguish between the two chromium species without using burdensome analytical methods, to verify compliance of plastic materials and articles, intended to come into contact with food that may contain chromium, with the Regulation, Annex II of Regulation (EU) 10/2011 should be amended to include the detection limit for chromium which was derived on the basis of the toxicity of hexavalent chromium as the limit for chromium migration into food or food simulant. The migration of all chromium, regardless of its oxidation state, from plastic materials and articles intended to come into contact with foods, should therefore not be detectable in food or food simulant above the level of 0,01 mg food or food simulant. However if the operator placing the material on the market can prove on the basis of pre-existing documentary evidence that the presence of hexavalent chromium in the material can be excluded because it is not used or formed during the entire production process, the migrating species should be considered trivalent chromium only and therefore a migration limit of 3,6 mg/kg food should apply in accordance with the second subparagraph of Article 11(4) of Regulation (EU) 10/2011. It is therefore appropriate to amend Annex II to Regulation (EU) 10/2011 accordingly.

(21) The Authority adopted an opinion on the risks to public health related to the presence of lead in food[13]. It determined the 95th percentile lower confidence limit of the benchmark dose (BMD) of 1 % extra risk ($BMDL_{01}$) of 0,5 μg lead/kg body weight as a reference point for the risk characterisation of lead when assessing the risk of intellectual deficits in children measured by the Full Scale IQ score. A 1 % increase of systolic blood pressure annually or on average in the whole population was considered a public health issue, corresponding to 1,5 μg lead/kg body weight per day for effects on systolic blood pressure, and a $BMDL_{10}$ value (at 90% confidence limit) of 0,63 μg lead/kg body weight per day for effects on prevalence of chronic kidney disease. The Authority concluded that in adults, children, and infants, the margins of exposure were such that the possibility of an effect from lead in some consumers, particularly in children, cannot be excluded at any level of exposure, and a health based guidance value could not be derived. The Authority also concluded that protection of children

[13] EFSA Journal 2010; 8(4):1570

against the potential risk of neurodevelopmental effects would be protective for all other adverse effects of lead, in all populations.

(22) Lead should not be used intentionally to manufacture a plastic material, but it can be present as an impurity. As its presence cannot be fully prevented, and it can cause health effects at any level of exposure, there should be uniform rules to ensure its presence can be controlled. It is therefore appropriate to establish a common limit for its migration from plastic materials. In absence of a health based guidance value the $BMDL_{01}$ value of 0,5 μg lead/kg body weight per day is used as basis for that limit. Lead exposure however occurs from many sources other than from articles and materials intended to come into contact with food. To derive a limit for the migration of lead from plastic materials and articles intended to come into contact with food, it is therefore appropriate to apply a conventional allocation factor of 10%, to account for the contribution of lead from materials and articles intended to come into contact with food. Taking into account conventional exposure assumptions for such materials and articles, and assuming an average body weight of 60 kg, the migration of lead from plastic materials and articles intended to come into contact with food should not exceed 0,003 mg/kg food in food or food simulant in order to reduce the probability of adverse health effects to a minimum. However, according to the EURL-FCM reliable detection of lead in food or food simulant has not been tested among National Reference Laboratories below the level of detection as laid down in Article 11(4) to the Regulation. Therefore, it advised to assign a non-detect (ND) limit for lead at 0,01 mg/kg food instead. It is therefore appropriate to amend Annex II of Regulation (EU) 10/2011 accordingly.

(23) The Authority adopted an opinion on the risks to public health related to the presence of mercury and methyl mercury in food[14] in which it identified a TWI of 4,0 μg of inorganic mercury (expressed as elemental mercury)/kg body weight for kidney toxicity. The Authority concluded that the estimated exposure to inorganic mercury in Europe from the diet alone does not exceed the TWI. Based on the TWI, on a 20% allocation factor to account for the contribution of exposure to mercury from sources other than plastic materials and articles intended to come into contact with food, and taking into account conventional exposure assumptions for food contact materials, the migration of mercury from plastic materials and articles intended to come into contact with food, should not exceed the level of 0,007 mg /kg food or food simulant. However, according to the EURL-FCM reliable detection of mercury in food or food simulant has not been tested among National Reference Laboratories below the level of detection as laid down in Article 11(4) to the Regulation. Therefore it advised to retain the non-detect (ND) limit for mercury of 0,01 mg/kg food instead. It is therefore appropriate to amend Annex II of Regulation (EU) 10/2011 accordingly.

(24) Primary aromatic amines ('PAAs') may be used in plastic food contact materials as colorants or may be present as not intentionally added substances in accordance with Article 6 of the Regulation. PAAs are a large family of compounds, some of which are carcinogens, while others are suspected carcinogens. Certain PAAs may have adverse effects at any migration level, therefore they should not migrate into the food. However, it is not possible to exclude their migration analytically, as analytical methods can only exclude migration up to their limit of detection. For the purpose of compliance verification, and to ensure legal certainty, the migration of PAAs into food has been restricted to a specified level that is not detectable in the food or food

[14] EFSA Journal 2012;10(12):2985.

simulant by means of commonly used analytical methods. However, according to the EURL-FCM advances in analytical capabilities ensure that equipment is now commonly available that allows to lower the detection limit of 0,01 mg/kg food or food simulant that the Regulation presently assigns to the detection of individual PAAs to a new detection limit of 0,002 mg/kg food or food simulant. Therefore that lower detection limit should be defined in the Regulation as the detection limit for individual PAAs.

(25) At present, the restriction on PAAs in Annex II applies to all PAAs that are not listed in Table 1 of Annex I to the Regulation. Applying the new low detection limit that is now assigned would require testing for a large number of substances, and, not all PAAs would adversely affect health above that detection limit. The most problematic PAAs are listed in entry 43 of Appendix 8 to Annex XVII to Regulation (EC) No 1907/2006, 'the Azocolourants entry'. It is therefore appropriate to apply the new detection limit only to these substances, given their established toxicity. Other PAAs for which no limit is laid down in Annex I should be assessed in accordance with Article 19 of the Regulation. However, to avoid their combined toxicity may cause adverse health problems, it is appropriate to limit their total migration to a maximum of 0.01 mg/kg in food or food simulant.

(26) Point 2 of Annex II to the Regulation requires that the sum of PAAs does not exceed 0,01 mg/kg food or food simulant, to avoid that their collective presence can cause adverse health effects. As the limit of detection is now lowered to 0,002 mg/kg food or food simulant for all PAAs listed in the Azocolourants entry, the sum would not require evaluation if such a PAA is detected because the material would not be in compliance with the Regulation anyway in this case. However, when it is known or suspected that certain PAAs not listed in Annex I or in the Azocolourants entry may be present, their presence can be assessed on the basis of migration testing and modelling considerations. Therefore, it is appropriate to maintain the provision that the sum of those PAAs does not exceed 0,01 mg/kg food or food simulant.

(27) The new or updated restrictions on substances in Annex II require clear communication in the supply chain to ensure that adequate information on the presence of these substances is available to business operators which use products from intermediate stages in the supply chain or final articles or materials in which these substances may be contained. When such information is not provided they cannot be certain on the presence and amount of these substances and they would need to test more frequently than would be needed if that information was provided. However, if the presence and amount of these substances is known to these business operators, in many cases simple calculation techniques can suffice to establish whether a limit could be exceeded, and analytical testing would not be required at all. Moreover, communication of the amounts of substances is also required to communicate on the presence of these substances to later stages of the supply chain. Therefore, it is appropriate to amend point 6 of Annex IV to the Regulation to clarify that the amount of substances subject to limits under Annex II should be included in the declaration of compliance.

(28) Before placing an intermediate or final product on the market, the manufacturer of that product needs to assess whether it complies with Article 3 of Regulation (EU) No 1935/2004, and/or to comply with Article 19 of the Regulation. Various and complementary approaches should be used in such assessment. A common and cost efficient testing approach is to determine only the safety of substances that are present above a concentration of 10 ppb by using migration testing with a food simulant.

Substances that do not exceed this limit are then considered safe. However, the migration of substances at a level of 10 ppb can only be considered safe provided that their genotoxicity can be ruled out. Therefore, the use of such a testing technique should always be complemented by an assessment of whether substances that could be genotoxic are present. Therefore, it should be communicated to downstream users of an intermediate or final material that it may contain substances of which the genotoxicity has not been ruled out. Producers of intermediate materials know that these substances can be present in their products as they use preparations that contain them, or should obtain that information from their suppliers. Therefore, point 6 of Annex IV should also be clarified to require information on substances present in a material or article, of which genotoxicity has not been ruled out.

(29) Point 2.1.6 of Annex V to the Regulation requires three subsequent tests for articles and materials that are placed in repeated contact with food. The results of the third migration test should be used to verify compliance with the migration limits. However, if the migration was to increase between the first, second and third test, the tests would not be suitable to verify compliance even in cases where the specific migration limit is not exceeded in any of the three tests, as they will not adequately predict the final migration level after continued contact with food. Thereto the migration should be strictly decreasing in subsequent tests. While this principle is already reflected in the second subparagraph of point 2.1.6 on conditions to use the results of the first test, as well as in point 3.3.2 on overall migration testing, a requirement that the migration should not increase between subsequent tests was not specified in the first paragraph of point 2.1.6. It would therefore be appropriate to amend the Regulation and add this requirement. However, in some instances, such as when migration is low relative to the measurement error, it may be difficult to establish a decreasing trend analytically and it would require complex rules. Therefore it is appropriate to only require that a the migration established in a subsequent test does not exceed that of the previous test, to clarify this principle in the Regulation, and to establish that a material that shows increasing migration over the subsequent tests should never be considered compliant.

(30) Annex V provides rules for the tests to demonstrate the compliance of migration from plastic materials and articles intended to come into contact with food with the migration limits referred to in Articles 11 and 12 of the Regulation. Certain types of plastic materials and articles are intended to come to contact with food only at cold or ambient temperatures and for a short duration (less than 30 minutes). While conditions for the specific migration testing for such intended contact are available, corresponding conditions for the overall migration testing are not assigned in table 3 of Annex V of the Regulation. The Overall Migration (OM) testing condition 2 (OM2), which requires testing at 40 °C for 10 days, and the OM3, which requires testing at 70 °C for two hours, are the two OM test conditions which come close in simulating the intended food contact conditions for these types of kitchenware but they are significantly more severe than the real life conditions which could foreseeably occur during actual use of such kitchenware. Therefore it is appropriate to amend table 3 of Annex V of this Regulation and the relevant text below that table to introduce overall migration conditions of 30 minutes at 40 °C designated as OM0 for the overall migration testing of plastic kitchenware materials and articles only at cold or ambient temperatures and for a short duration.

(31) Migration testing at 100 °C can be technically difficult in some situations because of high evaporation of water. In order to overcome this difficulty and to ensure that migration testing can be properly conducted, a reflux condition may be used as an

alternative to test for specific and overall migration at 100 °C. Such a reflux condition is provided for as an option in the OM5 and OM6 test conditions in table 3 of Annex V of the Regulation which require testing at 100 °C. A reflux alternative testing condition is not provided for the OM4 test condition which also requires testing at 100 °C. It is therefore appropriate to amend the OM4 entry in table 3 of Annex V of the Regulation to provide for the reflux condition as an option when testing at 100 °C is technically difficult.

(32) Migration testing using the whole food processing and/or food producing equipment or appliance is presently not allowed under the Regulation. However, when food processing equipment or appliances are made of multiple plastic parts, or contain plastic parts as well as other materials, it may be burdensome and in some cases impossible to verify compliance of these plastic parts with the Regulation. It should therefore be possible to verify compliance by conducting migration tests in the food or food simulant produced or processed using the whole equipment or appliance, or assemblies or modules thereof, in accordance with the operating instructions, instead of trying to establish the migration from each individual plastic part or material used in the equipment or appliance. If such a migration test is done under the worst foreseeable use conditions in the food, or when appropriate, in a food simulant, which can be achieved in accordance with the operating instructions, and the transfer of constituents from the equipment or appliance as a whole does not exceed the specific migration limits, the plastic parts of the food processing equipment should be considered to comply with the requirements of Article 11(1) of the Regulation if the plastic parts comply with the compositional provisions set out in the Regulation. It is therefore appropriate to amend Annex V of the Regulation to introduce provisions that will allow for the migration testing with the final food processing and/or food producing equipment instead of verifying the compliance of each of its individual parts.

(33) Applying the whole equipment or appliance in accordance with its operating instructions to prepare the food, or parts thereof may not be representative for all of its parts. Certain parts will be subject to different contact conditions, in particular those parts that are used for storage, in some cases long term, such as containers, reservoirs, capsules, and pads. Those parts would need to be tested also separately to ensure they are safe for those storage conditions as well.

(34) Migration testing of food processing and/or food producing equipment or appliance can only establish the compliance of the equipment with the Regulation. However, in case a non-compliant migration is observed when testing food processing and/or food producing equipment or appliances, it should be verified that this migration does not originate from materials not subject to the Regulation. Therefore, it is appropriate to require to establish whether the source of the non-compliance is a plastic part of the equipment or appliance, or whether it is another material not subject to the Regulation. The non-compliance of the equipment with the Regulation should then only be established if that non-compliance is due to a plastic part.

(35) The first paragraph of Chapter 3.2 of Annex V of the Regulation sets out conditions for the substitution of food simulant D2 with 95% ethanol and isooctane in the overall migration (OM) tests 1-6 referred to in table 3 of Annex V, when it is not technically feasible to perform one or more of the OM tests 1-6 with the simulant D2. The third sentence of that paragraph erroneously makes reference to specific migration rather than to overall migration. It is therefore necessary to correct that sentence.

(36) The second paragraph of Chapter 3.2 of Annex V of Regulation (EU) No 10/2011 sets out conditions for the substitution of the overall migration (OM) test 7 with the OM tests 8 or 9 when it is not technically feasible to perform the OM test 7 with simulant D2. The wording of that paragraph does not clearly specify by which test OM 7 should be substituted, and makes reference to the highest overall migration in the last sentence, which could be erroneously interpreted in such a way that more than two OM tests should be conducted. It is therefore appropriate to clarify the paragraph by laying down that one test should be selected and by referring to the higher overall migration obtained under the two testing conditions required in that test.

(37) Regulation (EU) No 10/2011 should therefore be amended and corrected accordingly.

(38) Plastic materials and articles complying with Regulation (EU) No 10/2011, as applicable before the date of the entry into force of this Regulation, and which were also placed on the market before that date should be allowed to be placed on the market for two more years and remain on the market until the exhaustion of stocks. However, this long period should not be used to develop new materials and articles which had not yet been placed on the market at the time of entry into force of this Regulation, and are not yet compliant with it. Business operators may not be able to fully anticipate the entry into force of this Regulation when they would have been already planning to place such new materials on the market before the entry into force of this Regulation. Therefore it is appropriate to allow such placing on the market of new materials and articles based on the old rules for six months after the entry into force of this Regulation.

(39) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed.

HAS ADOPTED THIS REGULATION:

Article 1

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

(1) In Article 6(3), point (a) is replaced by the following:

"(a) all salts of substances for which 'yes' is indicated in column 2 in table 1 of Annex II of authorised acids, phenols or alcohols, and subject to the restrictions set out in column 3 and 4 of that table".

(2) Annexes I, II, 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, and which were first placed on the market before *[enter date 6 months after the date of entry into force of this Regulation]* may continue to be placed on the market until [*enter date 24 months after the date of entry into force of this Regulation*] and remain on the market until the 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
Ursula VON DER LEYEN