II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) 2020/1245

of 2 September 2020

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

([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.

(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 types of plastics specified in the application dossier that the applicant provided to the Authority. The Authority reasoned that 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. Like polyolefins, if migration from any 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, and no further restrictions should be necessary. 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]). This Regulation requires that the four lanthanides should also be present in the dissociated ionic form. Therefore, in order to authorise their use as counter ions of already authorised acids, alcohols and phenols in all types of plastic materials and articles, and for the purpose of simplification, those four lanthanides should also be included in the scope of Article 6(3)(a). 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 chemical elements from plastic materials and articles into food or food simulants. The chemical 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 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 the Regulation. 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.

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

(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 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 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 these polar polymers are used in certain contact conditions. Significant exceedance of those limits was shown in contact conditions exceeding 4 hours at 100 °C. 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 the Regulation 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 temperature. 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

([5]) *EFSA Journal* 2019; 17(1):5552.
([6]) *EFSA Journal* 2019; 17(5):5679.
([7]) *EFSA Journal* 2019; 17(6):5737.
([8]) EFSA Journal 2004; 24 (1-13):2903.

intended to come into contact with food. It is therefore appropriate that Annex II of the Regulation 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 the Regulation 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 brought under control during the subsequent manufacturing stages of plastic materials and articles in accordance with Article 4(d) of the Regulation, these metals 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 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, and is burdensome and difficult to verify by competent authorities. Clearly defined migration limits based on opinions of the Authority would allow uniform analytical verification of compliance. It is therefore appropriate to amend Annex II of the Regulation 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 method with a limit of detection 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 of the European Parliament and of the Council ([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 the list of limits in point 1 of Annex II to the Regulation, and to redraft that list as a 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

([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.

detection of arsenic in food or food simulant has not been tested among National Reference Laboratories below the limit of detection as laid down in Article 11(4) to the Regulation. Therefore, it advised to retain the detection limit for arsenic of 0,01 mg/kg food instead. It is therefore appropriate to amend Annex II of the Regulation 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 the Regulation 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. 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 haematotoxicity. 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 the Regulation to include trivalent chromium provided that the migration 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 minimum 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,

([11]) *EFSA Journal* 2009; 980 (1-131).
([12]) *EFSA Journal* 2014;12(3):3595.

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 limit of detection as laid down in Article 11(4) to the Regulation. Therefore it advised to retain the detection limit for chromium of 0,01 mg/kg food instead.

(20) There is a large difference in toxicity between trivalent and hexavalent chromium and it is difficult to distinguish between the two chromium species without using burdensome analytical methods. Therefore, verifying compliance with the Regulation of plastic materials and articles that may contain chromium should be done on the basis of hexavalent Chromium as this is the most toxic species. Annex II of the Regulation should therefore be amended to include the detection limit 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/kg food or food simulant. However, if the business 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 the Regulation. It is therefore appropriate to amend Annex II to the Regulation.

(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 (BMDL01) 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 (SBP) annually or on average in the whole population was considered a public health issue. On this basis the Authority calculated a mean $BMDL_{01}$ for SBP of 36 µg/L, corresponding to 1,5 µg lead/kg body weight per day for effects on systolic blood pressure. It also calculated 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 therefore not be derived. The Authority also concluded that protection of children 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 to the total lead exposure. 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

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

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 limit of detection as laid down in Article 11(4) to the Regulation. Therefore, it advised to assign a detection limit for lead at 0,01 mg/kg food instead. It is therefore appropriate to amend Annex II of the Regulation 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 limit of detection as laid down in Article 11(4) to the Regulation. Therefore, it advised to retain the detection limit for mercury of 0,01 mg/kg food instead. It is therefore appropriate to amend Annex II of the Regulation 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 above 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 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 this Regulation now assigns 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 of the European Parliament and of the Council ([15]), '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 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

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

([15]) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

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 (EC) No 1935/2004, and/or complies 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 the 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 equipment or appliance for food processing and/or food production 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 whole equipment or appliance for food processing and/or food production, 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 the Regulation 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 23 March 2021 may continue to be placed on the market until 23 September 2022 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, 2 September 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

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

(1) Annex I is amended as follows:

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

(i) entry 236 on 1,3-phenylenediamine is replaced by the following:

'236	23050	00001-08-45-2	1,3-phenylenediamine	no	yes	no	ND			(28)'

(ii) entry 398 on antimony trioxide is replaced by the following:

'398	35760	00013-09-64-4	antimony trioxide	yes	no	no				(6)'

(iii) the following entries are inserted in numerical order:

'1075			Montmorillonite clay modified with hexadecyltrimethylammonium bromide	yes	no	no			Only to be used as additive at up to 4,0 % w/w in polylactic acid plastics intended for long-term storage of water at ambient temperature or below. Can form platelets in the nanoform that are in one or two dimensions thinner than 100 nm. Such platelets shall be oriented parallel to the polymer surface and shall be fully embedded in the polymer.	
1076		12279-37-46-3	Phosphorous acid, triphenyl ester, polymer with alpha-hydro-omega-hydroxypoly [oxy(methyl-1,2-ethanediyl)], C10-16 alkyl ester	yes	no	no	0,05		Only to be used as an additive at up to 0,2 % w/w in high impact polystyrene materials and articles intended contact with food at room temperature and below, including hot-fill and/or heating up to 100 °C for up to 2 hours. It shall not be used in contact with foods for which simulant C and/or D1 is assigned in Annex III.	
1077			Titanium dioxide surface-treated with fluoride-modified alumina	yes	no	no			Only to be used at up to 25,0 % w/w, including in the nanoform.	29'

(b) in point 3 of Table 3, the following entries are added:

'28	A detection limit of 0,002 mg/kg food or food simulant applies
29	In polar polymers which swell in contact with foods for which simulant B is assigned in Annex III, there is a risk that under severe contact conditions the migration limits for aluminium and fluoride are exceeded. Under contact conditions above 4 hours at 100 °C this exceedance can be high.'

(2) Annex II is replaced in its entirety by the following:

'ANNEX II

Restrictions on plastic materials and articles

The following restrictions on plastic materials and articles apply:

1. Plastic materials and articles shall not release the substances in Table 1 below in quantities exceeding the specific migration limits expressed in mg/kg food or simulant specified in column (3), and subject to the remarks in Column (4).

   Substances listed in Table 1 shall only be used in accordance with the compositional requirements set out in Chapter II. If Chapter II does not provide a basis for the authorised use of such a substance, that substance may only be present as an impurity subject to the restrictions specified in Table 1.

Table 1

General list of migration limits for substances migrating from plastic materials and articles

(1)	(2)	(3)	(4)
Name	**Salts allowed in accordance with Article 6(3)(a)**	**SML [mg/kg food or food simulant]**	**Remark**
Aluminium	yes	1	
Ammonium	yes	-	(1)
Antimony	no	0,04	(2)
Arsenic	no	ND	
Barium	yes	1	
Cadmium	no	ND (LOD 0,002)	
Calcium	yes	-	(1)
Chromium	no	ND	(3)
Cobalt	yes	0,05	
Copper	yes	5	
Europium	yes	0,05	(4)
Gadolinium	yes	0,05	(4)
Iron	yes	48	
Lanthanum	yes	0,05	(4)

Lead	no	ND	
Lithium	yes	0,6	
Magnesium	yes	-	(1)
Manganese	yes	0,6	
Mercury	no	ND	
Nickel	no	0,02	
Potassium	yes	-	(1)
Sodium	yes	-	(1)
Terbium	yes	0,05	(4)
Zinc	yes	5	

ND: Not Detectable; detection limit assigned in accordance with second subparagraph of Article 11(4); LOD: specified Limit of Detection.

Remarks

(1) The migration is subject to Article 11(3) and Article 12

(2) The note in Annex I, Table 1, FCM No 398 applies: SML might be exceeded at very high temperature

(3) To verify compliance with the Regulation, the detection limit of 0,01 mg/kg shall apply for total chromium. However if the operator that placed the material on the market can prove on the basis of pre-existing documentary evidence that the presence of hexavalent chromium in the material is excluded because it is not used or formed or during the entire production process, a limit for the total chromium of 3,6 mg/kg food shall apply.

(4) The lanthanide substances europium, gadolinium, lanthanum, and/or terbium can be used in accordance with Article 6(3)(a) provided that:

(a) The sum of all lanthanide substances migrating to the food or food simulant does not exceed the specific migration limit of 0,05 mg/kg; and

(b) analytical evidence using a well described methodology demonstrating that the lanthanide substance(s) used are present in dissociated ionic form in the food or the food simulant, forms part of the documentation referred to in Article 16.

2. Primary aromatic amines ("PAAs") listed in entry 43 to Appendix 8 of Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council (*) and for which no migration limit is specified 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. They shall not be detectable using analytical equipment with a limit of detection of 0,002 mg/kg food or food simulant applied to each individual primary aromatic amine ("PAA"), in accordance with Article 11(4).

For PAAs not listed in entry 43 to Appendix 8 of Annex XVII to Regulation (EC) No 1907/2006, but for which no specific migration limit is specified in Annex I, compliance with Article 3 of Regulation (EC) No 1935/2004 shall be verified in accordance with Article 19. The sum of those PAAs shall however not exceed 0,01 mg/kg in food or food simulant.'

(*) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).;

(3) in Annex IV, point 6 is replaced by the following:

'(6) adequate information relative to the substances used or products of degradation thereof for which restrictions and/or specifications are set out in Annex I and II to the Regulation to allow the downstream business operators to ensure compliance with the Regulation.

At intermediate stages, this information shall include the identification and amount of substances in the intermediate material,

— that are subject to restrictions in Annex II, or

— for which genotoxicity has not been ruled out, and which originate from an intentional use during a manufacturing stage of that intermediate material and which could be present in an amount that foreseeably gives rise to a migration from the final material exceeding 0,00015 mg/kg food or food simulant.';

(4) Annex V is amended as follows:

(a) Chapter 2 is amended as follows:

(i) in the second paragraph of point 2.1.3, the following subparagraph is added:

'(iv) if the plastic material or article intended to come into contact with food of which the compliance must be verified becomes in its final application part of a food processing equipment or an appliance, or a part thereof, the migration tests may be carried out by determining the specific migration into the food or food simulant produced or processed by the whole equipment or appliance, or the part thereof, as appropriate, subject to the following conditions:

— the food or food simulant is processed during testing by the equipment or part thereof in accordance with the worst foreseeable conditions that can be achieved if the equipment or its part is operated in accordance with its operating instructions, and

— the migration from parts used for storage such as from reservoirs, containers, or capsules or pads which are part of the equipment during the processing of the food, is determined using conditions representative for their use, unless the applied testing conditions for the whole tested equipment or appliance are representative also of their use.

When migration testing is done under the above conditions, and the transfer of constituents from the equipment or appliance as a whole does not exceed the migration limits, the plastic parts or materials present in the equipment or appliance shall be considered to comply with Article 11(1).

The testing of the parts used for storage or supply such as reservoirs, containers, capsules or pads shall be under conditions representative of their use, and shall include the foreseeable storage conditions of the food in these parts.

The supporting documentation referred to in Article 16 shall clearly document the testing on the whole food processing and/or food producing equipment or appliance, or on parts thereof. It shall demonstrate that the testing was representative of its foreseeable use, and shall indicate for which substances migration testing was carried out and provide all testing results. The manufacturer of individual plastic parts shall ensure the absence of migration for substances for which the Regulation specifies that their migration shall not be detectable at a specified level of detection in accordance with Article 11(4).

Compliance documentation supplied in accordance with the Regulation to the producer of the final equipment or appliance, or part thereof, shall list all substances subject to migration limits that might be exceeded under the foreseeable use of the supplied part or material.

When the result is not in compliance with the Regulation it shall be determined whether the source of the non-compliance is a plastic part subject to the Regulation or a part made from another material not subject to the Regulation on the basis of documentary evidence or analytical testing. Without prejudice to Article 3 of Regulation (EU) No 1935/2004, non-compliance to the Regulation shall only be established if the migration originates from a plastic part.';

(ii) point 2.1.6, is replaced in its entirety by the following:

'2.1.6. *Repeated use materials and articles*

If the material or article is intended to come into repeated contact with foods, the migration test(s) shall be carried out three times on a single sample using another portion of food simulant on each occasion. The specific migration in the second test shall not exceed the level observed in the first test, and the specific migration in the third test shall not exceed the level observed in the second test.

Compliance of the material or article shall than be verified on the basis of the level of the migration found in the third test and on the basis of the stability of the material or article from the first to the third migration test. The stability of the material shall be considered insufficient if migration is observed above the level of detection in any of the three migration tests, and increases from the first migration test to the third migration test. In case of insufficient stability, compliance of the material shall not be established even in case the specific migration limit is not exceeded in any of the three tests.

However, if there is conclusive scientific proof that the level of the migration decreases in the second and third tests and if the migration limits are not exceeded on the first test, no further test is necessary.

Irrespective of the above rules, a material or article shall never be considered to comply with this Regulation if in the first test a substance that is prohibited from migrating or from being released in detectable quantities under Article 11(4) is detected.';

(b) Chapter 3 is amended as follows:

(i) in point 3.1, Table 3 and the four paragraphs below Table 3 are 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
OM0	30 min at 40 °C	Any food contact at cold or ambient temperatures and for a short duration (≤ 30 minutes).
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.

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
OM4	1 h at 100 °C or at reflux	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.

Test OM 7 covers also food contact conditions described for OM0, OM1, OM2, OM3, OM4, OM5. It represents the worst case conditions for fatty food simulants 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 paragraph 3.2.

Test OM 6 covers also food contact conditions described for OM0, OM1, OM2, OM3, OM4 and OM5. It represents worst case conditions for food simulants A, B and C in contact with non-polyolefins.

Test OM 5 covers also food contact conditions described for OM0, OM1, OM2, OM3, OM4. It represents the worst case conditions for all food simulants in contact with polyolefins.
Test OM 2 covers also food contact conditions described for OM0, OM1 and OM3.'

(ii) in point 3.2, the paragraphs before the table are replaced by the following:

'If it is not technically feasible to perform one or more of the tests OM0 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 overall migration shall be used to establish compliance with the Regulation.

In case it is technically not feasible to perform OM7 with food simulant D2, either test OM8 or test OM9 shall be selected as a replacement test by selecting the most appropriate of these two tests on the basis of the intended and the foreseeable use of the material or article that is being tested. Subsequently, a migration test shall be done at each of the two test conditions specified for the selected test, using a new test sample for each test condition. The test condition that results in the higher overall migration shall be used to establish compliance with the Regulation.';

(iii) point 3.3.2 is replaced in its entirety by the following:

'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 34 of Regulation (EU) 2017/625 of the European Parliament and of the Council (*). 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 vegetable 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, the difference between the second and the first test results shall be lower than the first test results and the difference between the third and the second test results shall be lower than 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 decreases 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.

(*) 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 (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).'