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)

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

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2020/1245. (See end of Document for details)*

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.

(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.

(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 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 detection of arsenic in food or food simulant has not been tested among National Reference Laboratories below the limit of detection as laid down