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COMMISSION

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COMMISSION REGULATION (EU) …/…

of XXX

amending Annex I to Regulation (EU) No 10/2011 as regards the authorisation or the conditions of use of several substances

(Text with EEA relevance)

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amending Annex I to Regulation (EU) No 10/2011 as regards the authorisation or the conditions of use of several substances

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THE EUROPEAN COMMISSION,

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

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

Whereas:

(1) Commission Regulation (EU) No 10/2011[2] lays down specific rules as regards plastic materials and articles intended to come into contact with food. In particular, Annex I to that Regulation establishes a Union list of authorised substances that may be intentionally used in the manufacture of plastic materials and articles intended to come into contact with food.

(2) On 6 March 2024, the European Food Safety Authority ('the Authority') adopted a scientific opinion[3] on the use of the substance phosphorous acid, triphenyl ester, polymer with 1,4-cyclohexanedimethanol and polypropylene glycol, C10–16 alkyl esters. The Authority concluded that the substance is not of safety concern for the consumer if used as an additive at up to 0,15% w/w in polyolefin materials and articles intended for contact with all food types except for infant formula and human milk, for long-term storage at room temperature and below, including hot-fill and/or heating up to 100°C for up to 2 hours, if the migration of the total of phosphite and phosphate species does not exceed 5 mg/kg food, and if its low molecular weight fraction (LMWF) (<1000 Da) is not higher than 13% w/w. The Authority also indicated that the fat consumption reduction factor applies.

(3) It is therefore appropriate to authorise the substance phosphorous acid, triphenyl ester, polymer with 1,4-cyclohexanedimethanol and polypropylene glycol, C10–16 alkyl esters (CAS No 1821217-71-3, FCM No 1084).

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1 Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2024 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4, ELI: http://data.europa.eu/eli/reg/2004/1935/oj).

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, ELI: http://data.europa.eu/eli/reg/2011/10/oj).

3 EFSA CEP Panel (EFSA Panel on Food Contact Materials, Enzymes and Processing Aids) (2024). Safety assessment of the substance 'phosphorous acid, triphenyl ester, polymer with 1,4-cyclohexanedimethanol and polypropylene glycol, C10–16 alkyl esters', for use in food contact materials. *EFSA Journal*, *22*(4), e8694. https://doi.org/10.2903/j.efsa.2024.8694.

(4) On 13 March 2024, the Authority adopted a scientific opinion[4] on the use of the substance calcium *tert*-butylphosphonate. The Authority concluded that the substance is not of a safety concern for the consumer if it is used as a nucleating agent up to 0,15% w/w in polyolefin materials and articles intended for contact with all types of food for storage above 6 months at room temperature and below, including at temperatures up to 100°C for maximum 2 hours and up to 130°C for short durations, except for infant formula and human milk.

(5) It is therefore appropriate to authorise the substance calcium *tert*-butylphosphonate (CAS No 81607-35-4, FCM No 1089) accordingly.

(6) On 16 April 2024, the Authority adopted a scientific opinion[5] on the use of the substance amines, di-C14-C20-alkyl, oxidised, from hydrogenated vegetable oil. The Authority concluded that the substance is not of safety concern for the consumer if it is used as an additive at 0,1% w/w in the manufacture of polyolefin food contact materials intended to be in contact with foods simulated by food simulants A, B, C and E, except for infant formula and human milk, for storage above 6 months at room temperature and below, including hot-fill conditions and heating up to 100°C for 2 hours.

(7) It is therefore appropriate to authorise the substance amines, di-C14-C20-alkyl, oxidised, from hydrogenated vegetable oil (CAS No 1801863-42-2, FCM No 1092) accordingly.

(8) In its opinion on the substance amines, di-C14-C20-alkyl, oxidised, from hydrogenated vegetable oil, the Authority proposed renaming the substance amines, bis(hydrogenated tallow alkyl) oxidised, by including the precision 'di-C14-C20-alkyl'. This change of name was suggested as this substance contains C14- and C20-alkyl chains. Moreover, the authority recommended removing the note of verification of compliance in column 11 of Table 1 of Annex I for this substance as no substance's specific value exists to verify its compliance.

(9) It is therefore appropriate to change the name of the substance amines, bis(hydrogenated tallow alkyl) oxidised (FCM No 768) and remove the reference to the note on the verification of compliance accordingly. In addition, the restriction for the uses of this substance should be made consistent with the definition of 'non-fatty foods' in Regulation (EU) No 10/2011.

(10) On 3 July 2024, the Authority adopted a scientific opinion[6] on the use of the substances wax, rice bran, oxidised, and wax, rice bran, oxidised, calcium salt. The Authority concluded that these two substances are not of safety concern for the consumer if used as additives up to 0,3% w/w in polyethylene terephthalate (PET), polylactic acid (PLA) and rigid poly(vinyl chloride) (PVC) materials and articles intended for contact with all food types except for fatty foods, for long-term storage at

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4 EFSA CEP Panel (EFSA Panel on Food Contact Materials, Enzymes and Processing Aids) (2024). Safety assessment of the substance calcium *tert*-butylphosphonate for use in food contact materials. *EFSA Journal, 22*(4), e8705. https://doi.org/10.2903/j.efsa.2024.8705.

5 EFSA CEP Panel (EFSA Panel on Food Contact Materials, Enzymes and Processing Aids) (2024). Safety assessment of the substance amines, di-C14-C20-alkyl, oxidised, from hydrogenated vegetable oil, for use in food contact materials. *EFSA Journal*, *22*(5), e8769. https://doi.org/10.2903/j.efsa.2024.8769.

6 EFSA FCM Panel (EFSA Panel on Food Contact Materials) (2024). Safety assessment of the substances 'wax, rice bran, oxidised' and 'wax, rice bran, oxidised, calcium salt' for use in food contact materials. *EFSA Journal*, 2(8), e8960. https://doi.org/10.2903/j.efsa.2024.8960.

room temperature and below, including hot-fill and/or heating up to 100°C for up to 2 hours.

(11) It is therefore appropriate to authorise substances wax, rice bran, oxidised (CAS No 1883583-80-9, FCM No 1093), and wax, rice bran, oxidised, calcium salt (CAS No 1850357-57-1, FCM No 1096) accordingly.

(12) On 6 November 2024, the Authority adopted a scientific opinion[7] on the use of the substance 2,2′-oxydiethylamine . The Authority concluded that the substance is not of safety concern for the consumer at any time and temperature conditions if used as a comonomer at up to 14% w/w with adipic acid and caprolactam, or with homologues of those two substances that have longer C chains, to manufacture polyamide films with a thickness of up to 25 µm, provided that the migration of the substance does not exceed 0,05 mg/kg food, that the final films are not in contact with infant formula and human milk that the migration of oligomers with a molecular weight below 1000 Da that contain the substance does not exceed 5 mg/kg food and that, where the homologues of adipic acid and caprolactam are used as starting substances, only homologues authorised in accordance with Commission Regulation (EU) No 10/2011 are used.

(13) It is therefore appropriate to authorise the substance 2,2′-oxydiethylamine (CAS number No 2752-17-2, FCM No 1094) accordingly.

(14) In its assessment of the substance 2,2′-oxydiethylamine, the Authority also considered the available migration data and the instability of the substance in 10% ethanol (simulant A) under the applied migration test conditions, and recommended the use of water as the simulant to test compliance with the migration limit. Given the substance's high solubility in water and the possibility for testing at 60°C instead of 40°C, the Authority determined that contact with water represented the worst-case scenario for the migration of 2,2'-oxydiethylamine and recommended to indicate in a note on the verification of compliance that water is to be used for compliance verification purposes instead of food simulants.

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

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

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

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.

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[7] EFSA FCM Panel (EFSA Panel on Food Contact Materials) (2024). Safety assessment of the substance 2,2'-oxydiethylamine for use in plastic food contact materials. *EFSA Journal*, *22*(12), e9105. https://doi.org/10.2903/j.efsa.2024.9105.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN